Dossier zur Nutzenbewertung gemäß § 35a SGB V

Zolbetuximab (VYLOY™)

Astellas Pharma GmbH

Modul 4 A, Anhang 4-G5

Erstlinienbehandlung von erwachsenen Patienten mit lokal fortgeschrittenem inoperablem oder metastasiertem HER2-negativem Adenokarzinom des Magens oder des GEJ, deren Tumore Claudin18.2 positiv sind

Ergänzende Analysen zu Übelkeit und Erbrechen

Stand: 30.10.2024

Inhaltsverzeichnis

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen

Anhang 4-G5 Studie GLOW, Finaler Datenschnitt vom 12.01.2024

1. Time-to-Event-Analysen

Table 302.3.2003.1: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	31 (12.2%)	9 (3.6%)	
Number of patients censored	223 (87.8%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.613 [1.720, 7.591]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.2: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	254 (100.0%)	249 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			NC

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.3: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	16 (6.3%)	9 (3.6%)	
Number of patients censored	238 (93.7%)	240 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.792 [0.792, 4.057]
Log-rank test			
Two-sided stratified log-rank p-value			0.1560

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.4: Summary and Results of Vomiting (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	9 (3.5%)	4 (1.6%)	
Number of patients censored	245 (96.5%)	245 (98.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.181 [0.671, 7.087]
Log-rank test			
Two-sided stratified log-rank p-value			0.1845

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.5: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	Placebo + CAPOX (N= 249)	Zolbetuximab + CAPOX vs. Placebo + CAPOX
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	22 (8.7%)	6 (2.4%)	
Number of patients censored	232 (91.3%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.779 [1.532, 9.323]
Log-rank test			
Two-sided stratified log-rank p-value			0.0019

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.6: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	254 (100.0%)	249 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			NC

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.7: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	15 (5.9%)	6 (2.4%)	
Number of patients censored	239 (94.1%)	243 (97.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.545 [0.987, 6.564]
Log-rank test			
Two-sided stratified log-rank p-value			0.0450

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.8: Summary and Results of Nausea (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	6 (2.4%)	3 (1.2%)	
Number of patients censored	248 (97.6%)	246 (98.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.900 [0.475, 7.604]
Log-rank test			
Two-sided stratified log-rank p-value			0.3574

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.9: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	174 (68.5%)	175 (70.3%)	
Number of patients censored	80 (31.5%)	74 (29.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.5 [2.8, 3.9]	3.6 [3.0, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.040 [0.840, 1.286]
Log-rank test			
Two-sided stratified log-rank p-value			0.7282

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.10: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	179 (70.5%)	175 (70.3%)	
Number of patients censored	75 (29.5%)	74 (29.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.1 [2.1, 3.6]	3.6 [3.0, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.122 [0.908, 1.386]
Log-rank test			
Two-sided stratified log-rank p-value			0.2905

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.11: Summary and Results of TEAEs (CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	177 (69.7%)	164 (65.9%)	
Number of patients censored	77 (30.3%)	85 (34.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [1.9, 3.5]	4.1 [3.2, 4.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.249 [1.007, 1.548]
Log-rank test			
Two-sided stratified log-rank p-value			0.0467

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.12: Summary and Results of Severe TEAEs (CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	45 (17.7%)	52 (20.9%)	
Number of patients censored	209 (82.3%)	197 (79.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.882 [0.589, 1.322]
Log-rank test			
Two-sided stratified log-rank p-value			0.5437

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.13: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	71 (28.0%)	60 (24.1%)	
Number of patients censored	183 (72.0%)	189 (75.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [16.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.240 [0.878, 1.751]
Log-rank test			
Two-sided stratified log-rank p-value			0.2322

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; SOC= system organ class; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2003.14: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade >= 4) - Safety Analysis Set

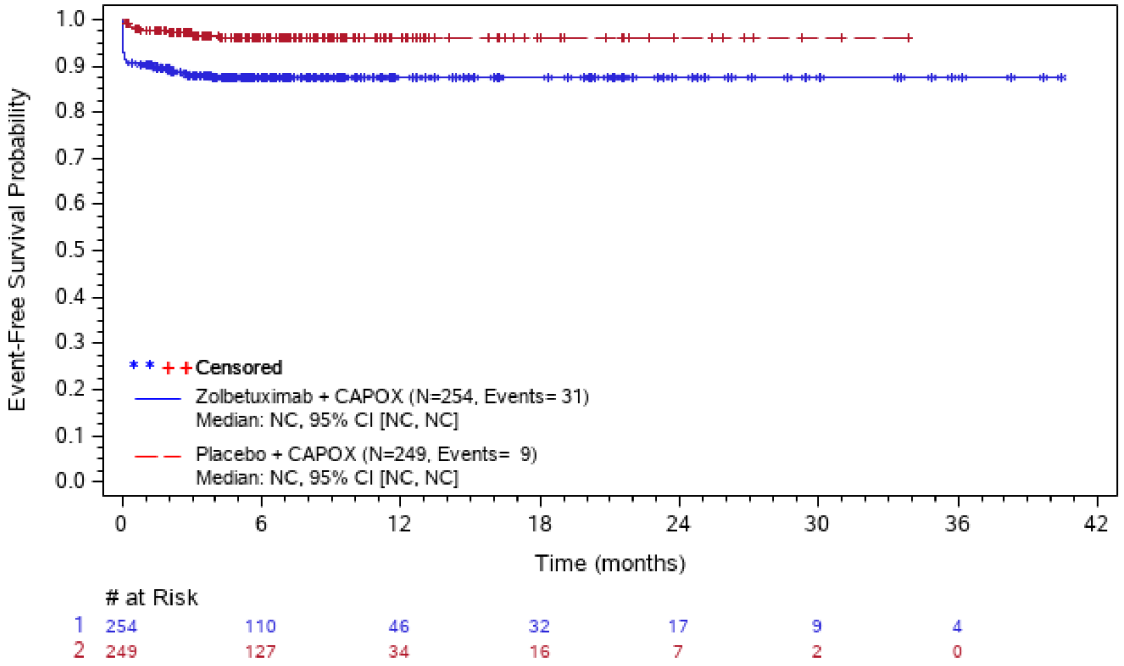
	Zolbetuximab + CAPOX (N= 254)	**Placebo + CAPOX (N= 249)**	**Zolbetuximab + CAPOX vs. Placebo + CAPOX**
Number of patients at risk	254 (100.0%)	249 (100.0%)	
Number of patients with events	8 (3.1%)	8 (3.2%)	
Number of patients censored	246 (96.9%)	241 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.081 [0.405, 2.882]
Log-rank test			
Two-sided stratified log-rank p-value			0.8770

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; SOC= system organ class; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Studie GLOW, Finaler Datenschnitt vom 12.01.2024

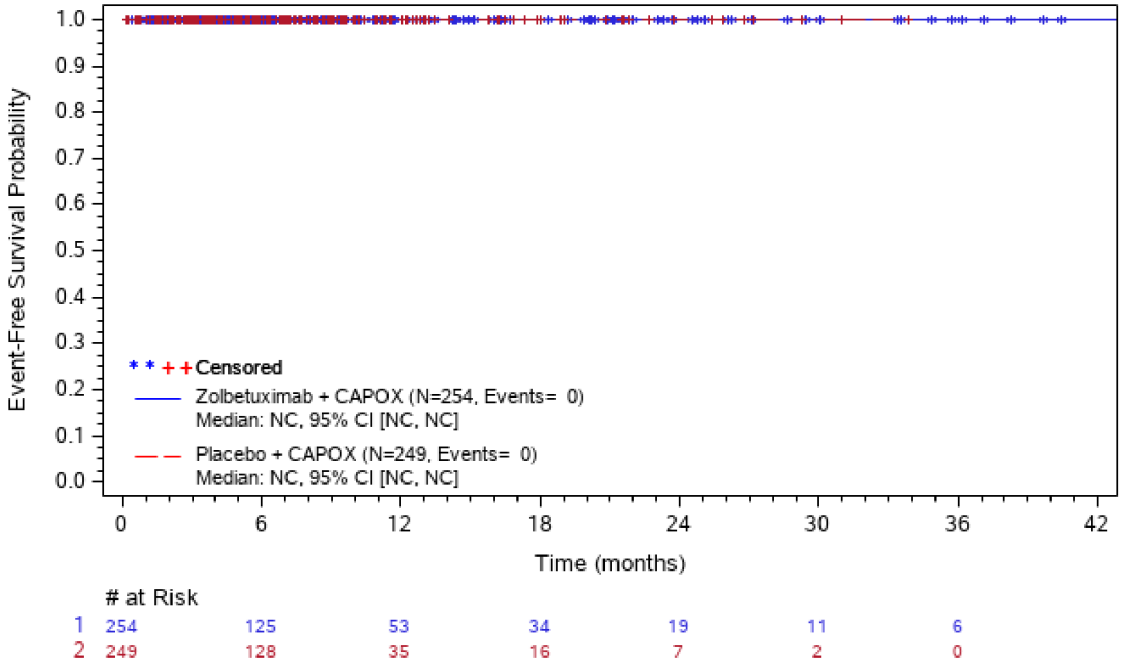
2. Kaplan-Meier-Plots

Figure 302.3.2003.1: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade 3) - Safety Analysis Set



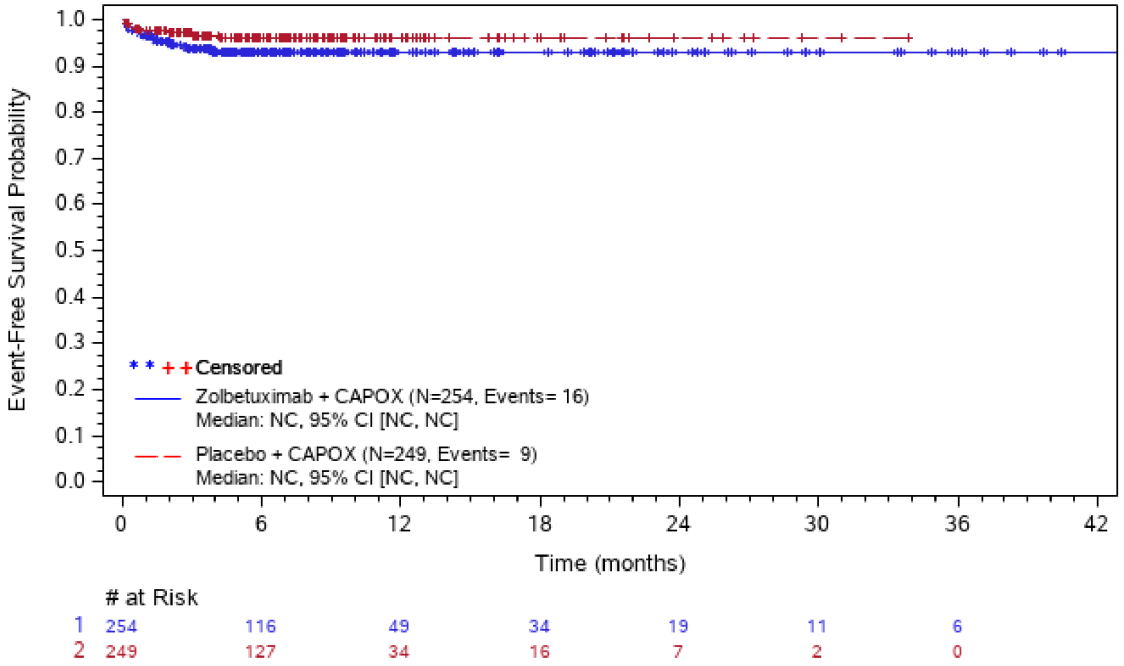
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.2: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade >= 4) - Safety Analysis Set



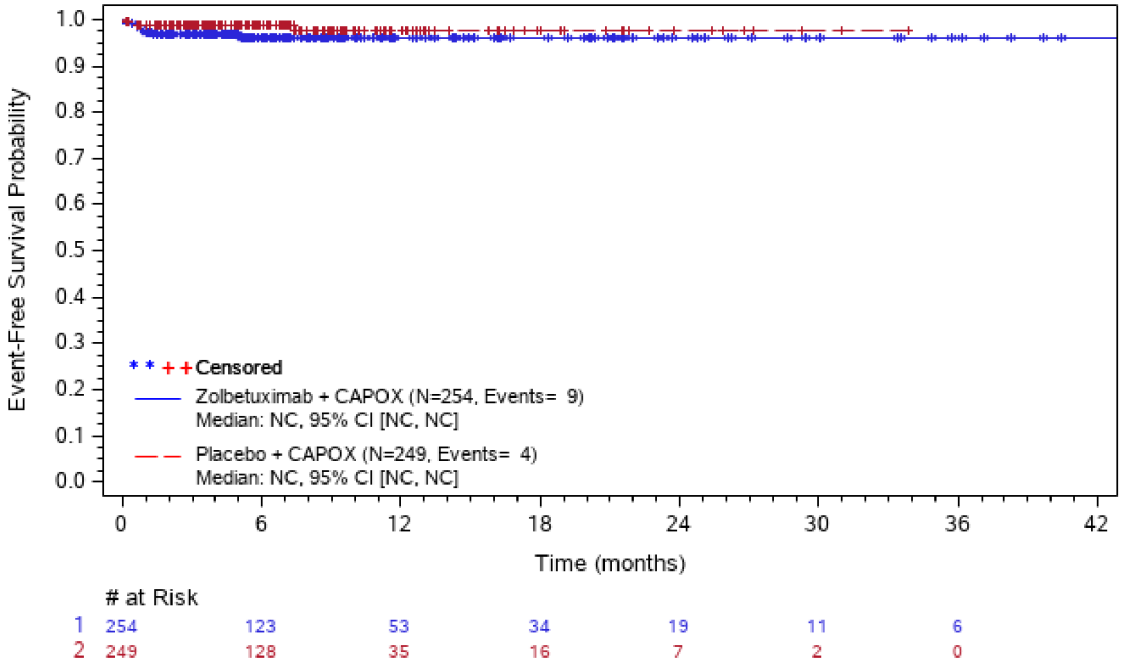
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.3: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade >= 3) - excluding events occuring at visit 1 - Safety Analysis Set



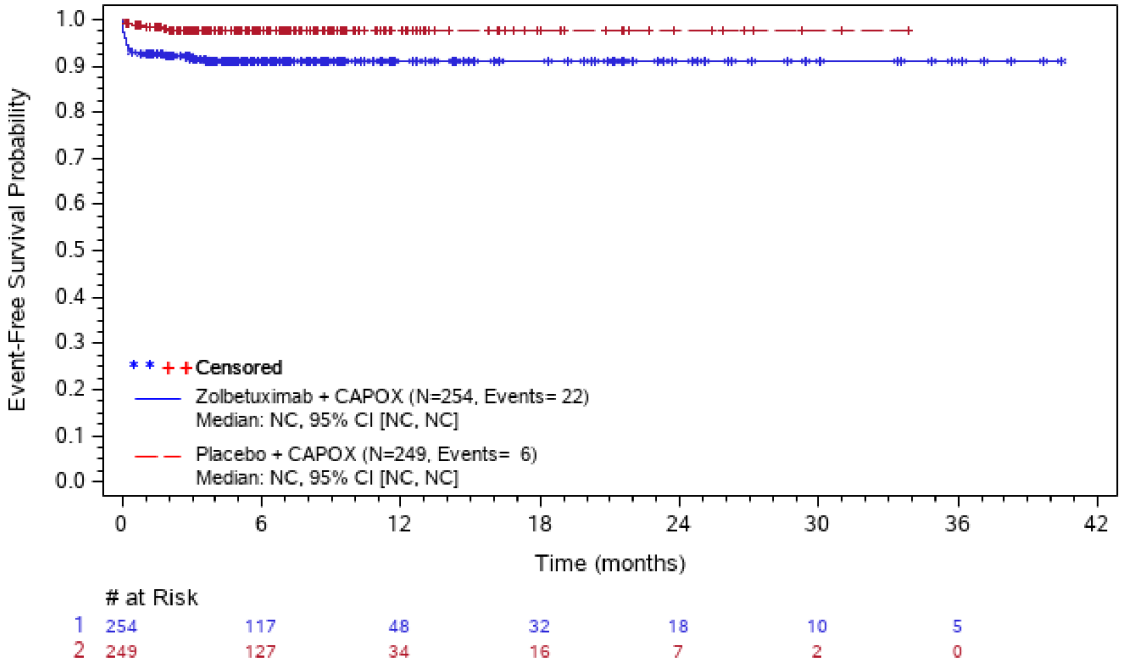
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.4: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAESI) - Leading to Permanent Treatment Discontinuation - Safety Analysis Set



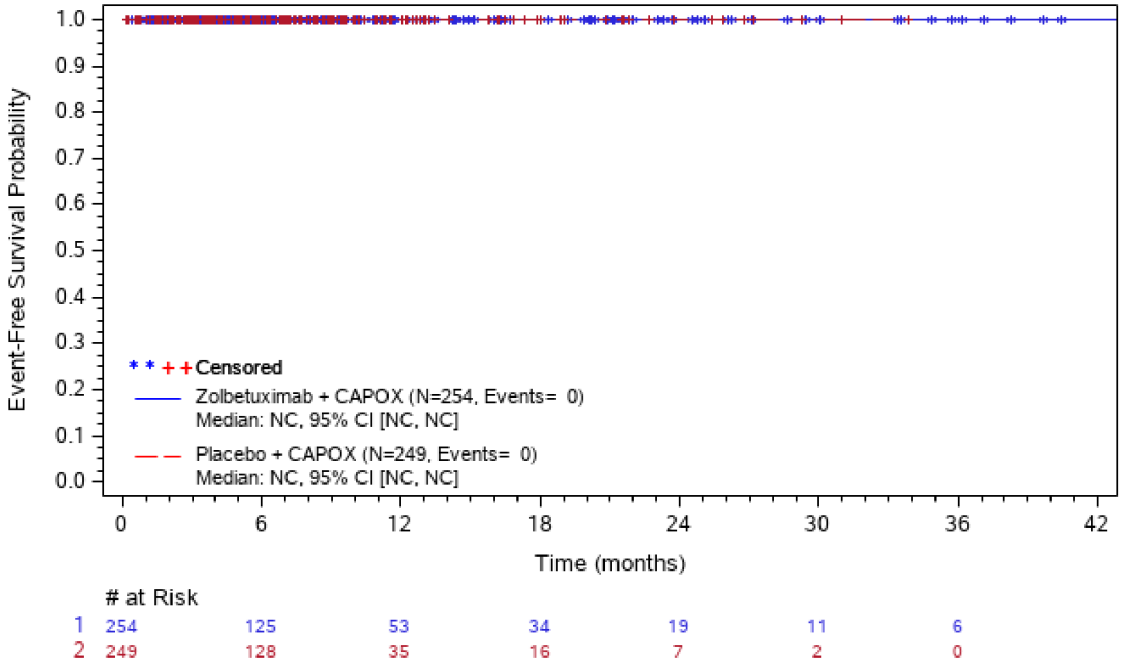
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.5: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade 3) - Safety Analysis Set



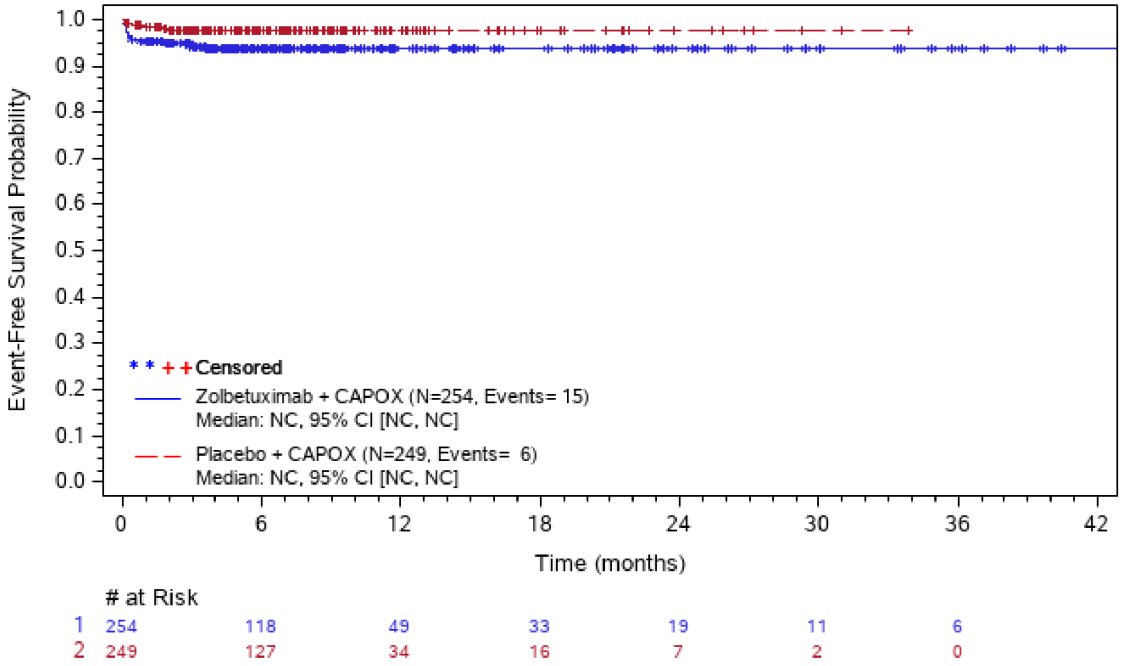
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.6: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade >= 4) - Safety Analysis Set



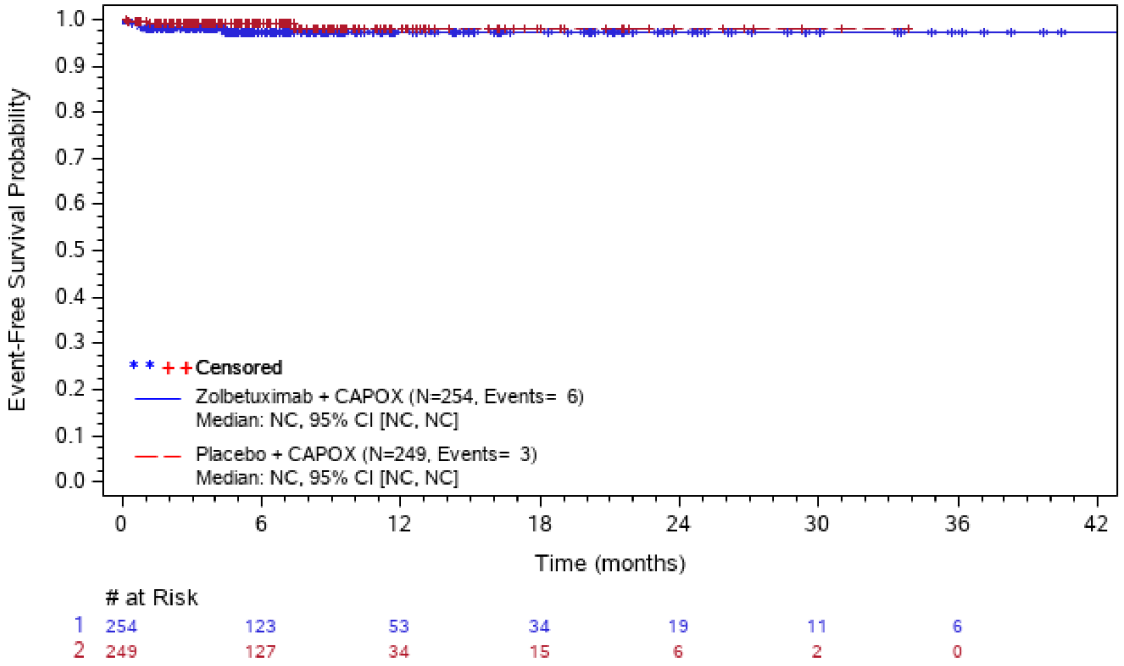
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.7: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set



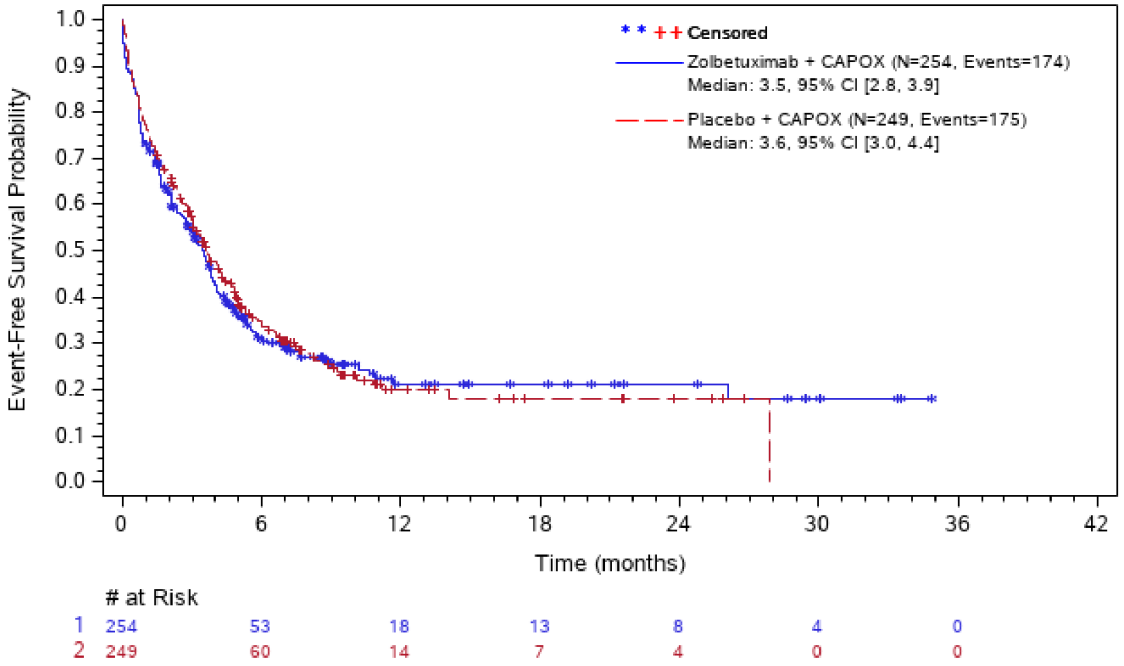
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.8: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAESI) - Leading to Permanent Treatment Discontinuation - Safety Analysis Set



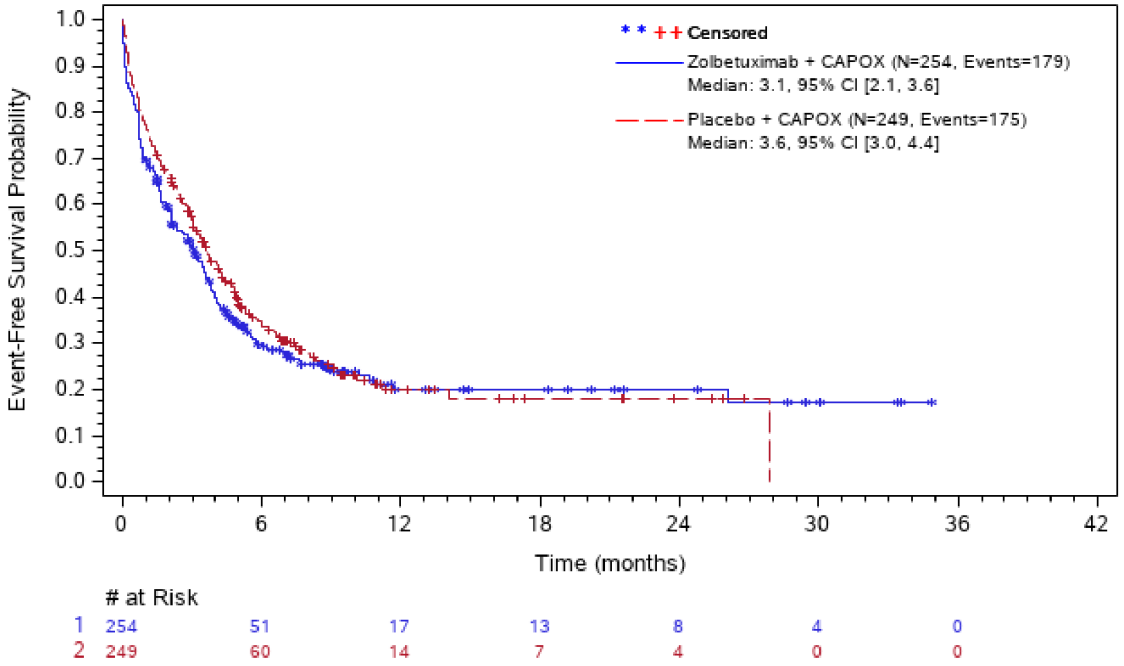
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.9: Kaplan-Meier Plot of Time to Severe TEAEs (CTCAE Grade >= 3) - excluding any Nausea and Vomiting events - Safety Analysis Set



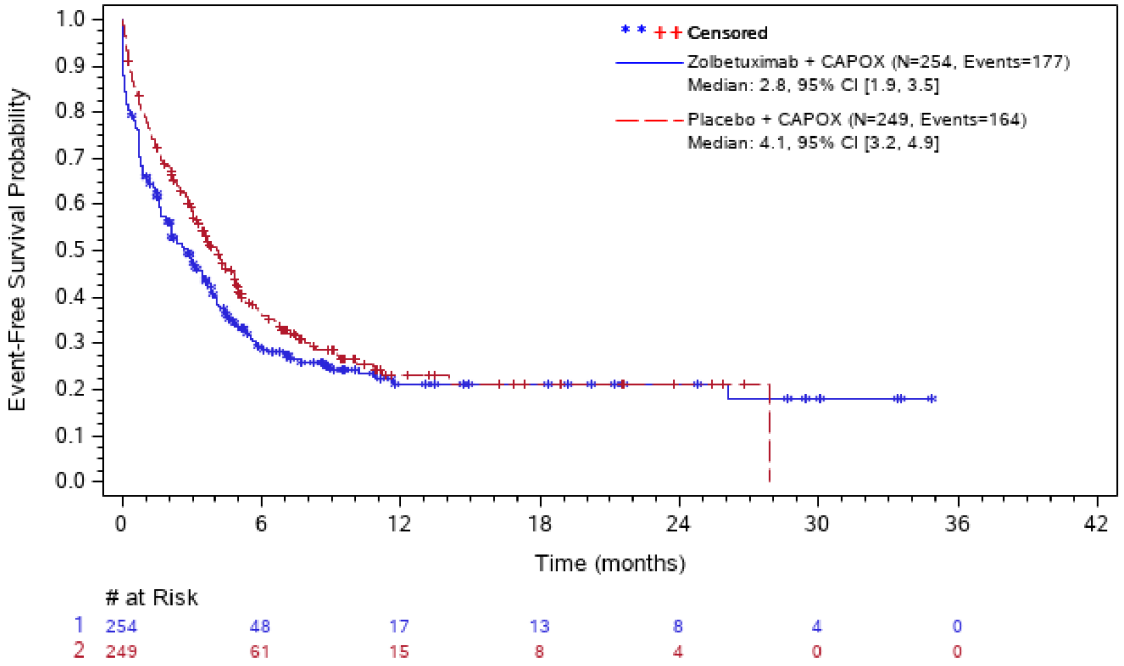
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; PT=preferred term; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.10: Kaplan-Meier Plot of Time to Severe TEAEs (CTCAE Grade >= 3) - excluding any Nausea and Vomiting events occuring at visit 1 - Safety Analysis Set



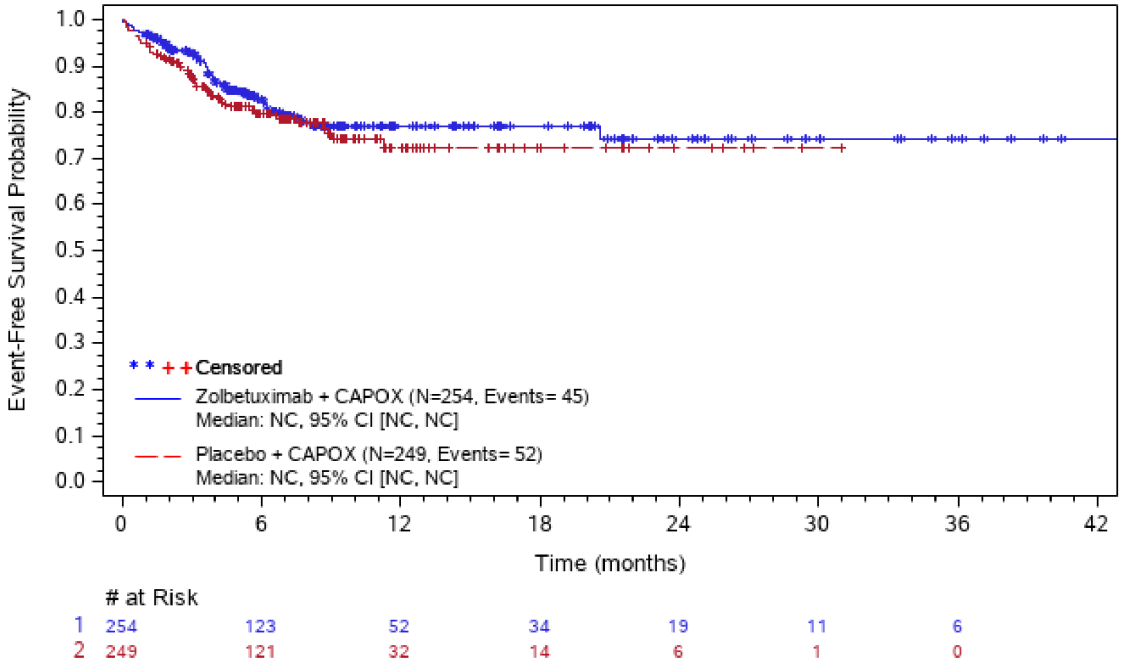
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; PT=preferred term; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.11: Kaplan-Meier Plot of Time to TEAEs - CTCAE Grade 3 - Safety Analysis Set



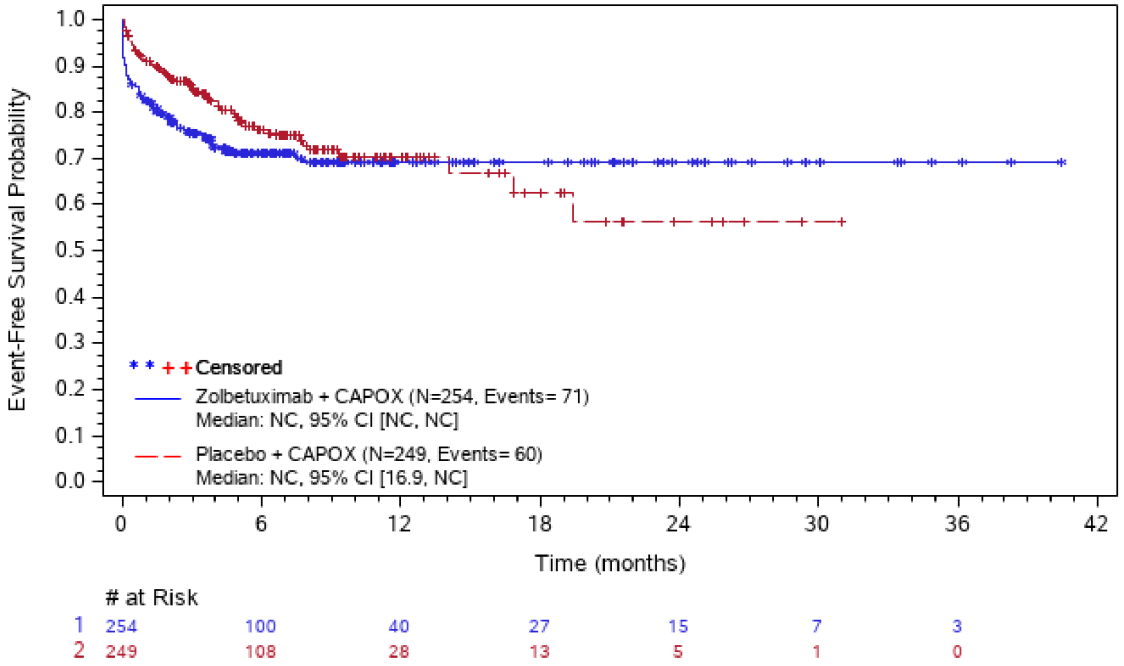
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.12: Kaplan-Meier Plot of Time to Severe TEAE - CTCAE Grade >= 4 - Safety Analysis Set



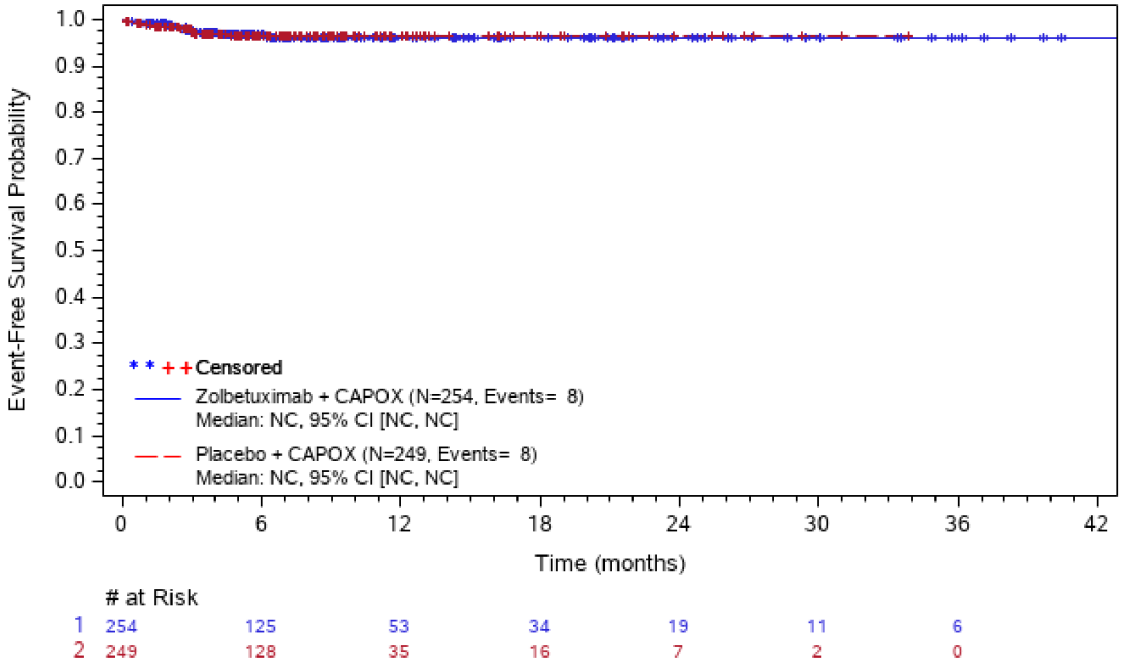
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.13: Kaplan-Meier Plot of Time to TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade 3) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; SOC=system organ class; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Figure 302.3.2003.14: Kaplan-Meier Plot of Time to Severe TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade >= 4) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; SOC=system organ class; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Studie GLOW, Finaler Datenschnitt vom 12.01.2024

3. Anzahl und Dauer dokumentierter unerwünschter Ereignisse: Übelkeit

Table 302.3.2000.9.1: Summary of Duration of Nausea (TEAE) - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Number of Nausea events per patient		
Total number of patients with Nausea events	175	125
Mean (SD)	2.9 (2.66)	2.3 (1.98)
Median	2.0	1.0
Q1-Q3	1.0 - 4.0	1.0 - 3.0
Range	1 - 14	1 - 9
Duration of any Nausea events (days)		
Total number of Nausea events	515	289
Number of Nausea events with missing duration	37	28
Number of Nausea events with non missing duration	478	261
Mean (SD)	12.1 (39.67)	18.2 (47.28)
Median	3.0	7.0
Q1-Q3	1.0 - 10.0	3.0 - 12.0
Range	1 - 525	1 - 435
Cumulative duration of Nausea events per patient (days)		
Total number of patients with Nausea events	175	125
Number of patients with at least one Nausea event with missing duration	37	28
Number of patients with non missing cumulative duration	160	106
Mean (SD)	36.1 (72.54)	44.7 (73.07)
Median	14.0	18.0
Q1-Q3	5.0 - 33.0	8.0 - 45.0
Range	1 - 580	1 - 435
Duration of any components treatment for patients with any Nausea event (days)		
Number of patients with non missing duration	174	125
Mean (SD)	207.0 (193.77)	195.2 (168.79)
Median	148.0	159.0
Q1-Q3	76.0 - 259.0	79.0 - 261.0
Range	1 - 1177	1 - 798

Abbreviations: N=number of patients; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Duration of nausea is defined as the time from end date - start date + 1 of the respective nausea event. Episodes with missing start or end date were excluded for calculation of duration respectively.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.9.2: Summary of Duration of Severe Nausea (TEAE, CTCAE Grade >=3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Number of Nausea events per patient		
Total number of patients with Nausea events	22	6
Mean (SD)	1.1 (0.29)	1.2 (0.41)
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0
Range	1 - 2	1 - 2
Duration of any Nausea events (days)		
Total number of Nausea events	24	7
Number of Nausea events with missing duration	4	0
Number of Nausea events with non missing duration	20	7
Mean (SD)	10.7 (8.52)	10.7 (12.80)
Median	8.0	6.0
Q1-Q3	6.0 - 12.5	4.0 - 15.0
Range	1 - 31	1 - 38
Cumulative duration of Nausea events per patient (days)		
Total number of patients with Nausea events	22	6
Number of patients with at least one Nausea event with missing duration	4	0
Number of patients with non missing cumulative duration	19	6
Mean (SD)	11.2 (8.76)	12.5 (13.10)
Median	8.0	6.5
Q1-Q3	6.0 - 16.0	5.0 - 15.0
Range	1 - 31	4 - 38
Duration of any components treatment for patients with any Nausea event (days)		
Number of patients with non missing duration	21	6
Mean (SD)	170.0 (180.24)	125.2 (118.41)
Median	120.0	93.5
Q1-Q3	28.0 - 212.0	61.0 - 106.0
Range	3 - 582	36 - 361

Abbreviations: N=number of patients; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Duration of nausea is defined as the time from end date - start date + 1 of the respective nausea event. Episodes with missing start or end date were excluded for calculation of duration respectively.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.9.3: Summary of Duration of Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Number of Nausea events per patient		
Total number of patients with Nausea events	175	125
Mean (SD)	2.9 (2.66)	2.3 (1.98)
Median	2.0	1.0
Q1-Q3	1.0 - 4.0	1.0 - 3.0
Range	1 - 14	1 - 9
Duration of any Nausea events (days)		
Total number of Nausea events	515	289
Number of Nausea events with missing duration	37	28
Number of Nausea events with non missing duration	478	261
Mean (SD)	12.1 (39.67)	18.2 (47.28)
Median	3.0	7.0
Q1-Q3	1.0 - 10.0	3.0 - 12.0
Range	1 - 525	1 - 435
Cumulative duration of Nausea events per patient (days)		
Total number of patients with Nausea events	175	125
Number of patients with at least one Nausea event with missing duration	37	28
Number of patients with non missing cumulative duration	160	106
Mean (SD)	36.1 (72.54)	44.7 (73.07)
Median	14.0	18.0
Q1-Q3	5.0 - 33.0	8.0 - 45.0
Range	1 - 580	1 - 435
Duration of any components treatment for patients with any Nausea event (days)		
Number of patients with non missing duration	174	125
Mean (SD)	207.0 (193.77)	195.2 (168.79)
Median	148.0	159.0
Q1-Q3	76.0 - 259.0	79.0 - 261.0
Range	1 - 1177	1 - 798

Abbreviations: N=number of patients; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Duration of nausea is defined as the time from end date - start date + 1 of the respective nausea event. Episodes with missing start or end date were excluded for calculation of duration respectively.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.9.4: Summary of Duration of Severe Nausea (AESI, CTCAE Grade >=3) - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Number of Nausea events per patient		
Total number of patients with Nausea events	22	6
Mean (SD)	1.1 (0.29)	1.2 (0.41)
Median	1.0	1.0
Q1-Q3	1.0 - 1.0	1.0 - 1.0
Range	1 - 2	1 - 2
Duration of any Nausea events (days)		
Total number of Nausea events	24	7
Number of Nausea events with missing duration	4	0
Number of Nausea events with non missing duration	20	7
Mean (SD)	10.7 (8.52)	10.7 (12.80)
Median	8.0	6.0
Q1-Q3	6.0 - 12.5	4.0 - 15.0
Range	1 - 31	1 - 38
Cumulative duration of Nausea events per patient (days)		
Total number of patients with Nausea events	22	6
Number of patients with at least one Nausea event with missing duration	4	0
Number of patients with non missing cumulative duration	19	6
Mean (SD)	11.2 (8.76)	12.5 (13.10)
Median	8.0	6.5
Q1-Q3	6.0 - 16.0	5.0 - 15.0
Range	1 - 31	4 - 38
Duration of any components treatment for patients with any Nausea event (days)		
Number of patients with non missing duration	21	6
Mean (SD)	170.0 (180.24)	125.2 (118.41)
Median	120.0	93.5
Q1-Q3	28.0 - 212.0	61.0 - 106.0
Range	3 - 582	36 - 361

Abbreviations: N=number of patients; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Duration of nausea is defined as the time from end date - start date + 1 of the respective nausea event. Episodes with missing start or end date were excluded for calculation of duration respectively.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Studie GLOW, Finaler Datenschnitt vom 12.01.2024

4. Neu- und Wiederauftreten von Übelkeit und Erbrechen nach Zeitintervallen in Zyklen ab Randomisierung

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	99 (39.0%)	35 (14.1%)
2 events	35 (13.8%)	7 (2.8%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
1 incident event	60 (23.6%)	33 (13.3%)
2 events	49 (19.3%)	8 (3.2%)
3 events	17 (6.7%)	3 (1.2%)
>= 4 events	8 (3.1%)	3 (1.2%)
Cycle 3		
1 incident event	49 (19.3%)	26 (10.4%)
2 events	38 (15.0%)	8 (3.2%)
3 events	26 (10.2%)	5 (2.0%)
>= 4 events	15 (5.9%)	4 (1.6%)
Cycle 4		
1 incident event	39 (15.4%)	24 (9.6%)
2 events	35 (13.8%)	7 (2.8%)
3 events	22 (8.7%)	5 (2.0%)
>= 4 events	24 (9.4%)	5 (2.0%)
Cycle 5		
1 incident event	34 (13.4%)	21 (8.4%)
2 events	35 (13.8%)	8 (3.2%)
3 events	19 (7.5%)	4 (1.6%)
>= 4 events	26 (10.2%)	7 (2.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 6		
1 incident event	30 (11.8%)	22 (8.8%)
2 events	27 (10.6%)	8 (3.2%)
3 events	23 (9.1%)	2 (0.8%)
>= 4 events	21 (8.3%)	6 (2.4%)
Cycle 7		
1 incident event	26 (10.2%)	19 (7.6%)
2 events	23 (9.1%)	7 (2.8%)
3 events	17 (6.7%)	3 (1.2%)
>= 4 events	17 (6.7%)	5 (2.0%)
Cycle 8		
1 incident event	25 (9.8%)	16 (6.4%)
2 events	17 (6.7%)	8 (3.2%)
3 events	17 (6.7%)	2 (0.8%)
>= 4 events	19 (7.5%)	6 (2.4%)
Cycle 9		
1 incident event	20 (7.9%)	13 (5.2%)
2 events	13 (5.1%)	9 (3.6%)
3 events	18 (7.1%)	2 (0.8%)
>= 4 events	18 (7.1%)	4 (1.6%)
Cycle 10		
1 incident event	17 (6.7%)	11 (4.4%)
2 events	11 (4.3%)	6 (2.4%)
3 events	15 (5.9%)	2 (0.8%)
>= 4 events	15 (5.9%)	4 (1.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	16 (6.3%)	8 (3.2%)
2 events	10 (3.9%)	5 (2.0%)
3 events	14 (5.5%)	1 (0.4%)
>= 4 events	16 (6.3%)	4 (1.6%)
Cycle 12		
1 incident event	16 (6.3%)	7 (2.8%)
2 events	9 (3.5%)	5 (2.0%)
3 events	12 (4.7%)	1 (0.4%)
>= 4 events	15 (5.9%)	2 (0.8%)
Cycle 13		
1 incident event	14 (5.5%)	6 (2.4%)
2 events	7 (2.8%)	5 (2.0%)
3 events	9 (3.5%)	0
>= 4 events	15 (5.9%)	1 (0.4%)
Cycle 14		
1 incident event	14 (5.5%)	6 (2.4%)
2 events	7 (2.8%)	5 (2.0%)
3 events	8 (3.1%)	0
>= 4 events	13 (5.1%)	1 (0.4%)
Cycle 15		
1 incident event	12 (4.7%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	8 (3.1%)	1 (0.4%)
>= 4 events	11 (4.3%)	1 (0.4%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 16		
1 incident event	10 (3.9%)	4 (1.6%)
2 events	6 (2.4%)	4 (1.6%)
3 events	7 (2.8%)	1 (0.4%)
>= 4 events	11 (4.3%)	1 (0.4%)
Cycle 17		
1 incident event	7 (2.8%)	3 (1.2%)
2 events	5 (2.0%)	3 (1.2%)
3 events	7 (2.8%)	0
>= 4 events	11 (4.3%)	1 (0.4%)
Cycle 18		
1 incident event	7 (2.8%)	3 (1.2%)
2 events	4 (1.6%)	2 (0.8%)
3 events	5 (2.0%)	0
>= 4 events	12 (4.7%)	0
Cycle 19		
1 incident event	7 (2.8%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	5 (2.0%)	1 (0.4%)
>= 4 events	11 (4.3%)	0
Cycle 20		
1 incident event	6 (2.4%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	5 (2.0%)	1 (0.4%)
>= 4 events	10 (3.9%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	5 (2.0%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	9 (3.5%)	0
Cycle 22		
1 incident event	5 (2.0%)	3 (1.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 23		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 24		
1 incident event	4 (1.6%)	1 (0.4%)
2 events	1 (0.4%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 25		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	7 (2.8%)	0
Cycle 27		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	5 (2.0%)	0
Cycle 28		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	4 (1.6%)	0
Cycle 29		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	4 (1.6%)	0
Cycle 30		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	3 (1.2%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	2 (0.8%)	1 (0.4%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 32		
1 incident event	2 (0.8%)	1 (0.4%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 33		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 34		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 35		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 37		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 38		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 39		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 40		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 42		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 43		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 44		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 45		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 47		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 48		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 49		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 50		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 52		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 53		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 54		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 55		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.1: Summary of Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 57		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 58		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 59		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 60		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 1		
1 incident event	24 (9.4%)	5 (2.0%)
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 2		
1 incident event	16 (6.3%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	0	0
>= 4 events	0	0
Cycle 3		
1 incident event	14 (5.5%)	4 (1.6%)
2 events	3 (1.2%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 4		
1 incident event	13 (5.1%)	3 (1.2%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 5		
1 incident event	14 (5.5%)	3 (1.2%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	13 (5.1%)	3 (1.2%)
2 events	3 (1.2%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 7		
1 incident event	12 (4.7%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 8		
1 incident event	12 (4.7%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 9		
1 incident event	10 (3.9%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 10		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 12		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 13		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 14		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 15		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 17		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 18		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 19		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 20		
1 incident event	3 (1.2%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	3 (1.2%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 22		
1 incident event	2 (0.8%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 23		
1 incident event	2 (0.8%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 24		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 25		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 27		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 28		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 29		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 30		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 32		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 33		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 34		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 35		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 37		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 38		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 39		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 40		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 42		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 43		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 44		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 45		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 46		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 47		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 48		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 49		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 50		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 51		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 52		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 53		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 54		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 55		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.2: Summary of Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 56		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 57		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 58		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 59		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 60		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	100 (39.4%)	35 (14.1%)
2 events	35 (13.8%)	7 (2.8%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
1 incident event	61 (24.0%)	33 (13.3%)
2 events	49 (19.3%)	8 (3.2%)
3 events	17 (6.7%)	3 (1.2%)
>= 4 events	8 (3.1%)	3 (1.2%)
Cycle 3		
1 incident event	50 (19.7%)	26 (10.4%)
2 events	38 (15.0%)	8 (3.2%)
3 events	26 (10.2%)	5 (2.0%)
>= 4 events	15 (5.9%)	4 (1.6%)
Cycle 4		
1 incident event	40 (15.7%)	24 (9.6%)
2 events	35 (13.8%)	7 (2.8%)
3 events	22 (8.7%)	5 (2.0%)
>= 4 events	24 (9.4%)	5 (2.0%)
Cycle 5		
1 incident event	35 (13.8%)	21 (8.4%)
2 events	35 (13.8%)	8 (3.2%)
3 events	19 (7.5%)	4 (1.6%)
>= 4 events	26 (10.2%)	7 (2.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	31 (12.2%)	22 (8.8%)
2 events	27 (10.6%)	8 (3.2%)
3 events	23 (9.1%)	2 (0.8%)
>= 4 events	21 (8.3%)	6 (2.4%)
Cycle 7		
1 incident event	27 (10.6%)	19 (7.6%)
2 events	23 (9.1%)	7 (2.8%)
3 events	17 (6.7%)	3 (1.2%)
>= 4 events	17 (6.7%)	5 (2.0%)
Cycle 8		
1 incident event	26 (10.2%)	16 (6.4%)
2 events	17 (6.7%)	8 (3.2%)
3 events	17 (6.7%)	2 (0.8%)
>= 4 events	19 (7.5%)	6 (2.4%)
Cycle 9		
1 incident event	21 (8.3%)	13 (5.2%)
2 events	13 (5.1%)	9 (3.6%)
3 events	18 (7.1%)	2 (0.8%)
>= 4 events	18 (7.1%)	4 (1.6%)
Cycle 10		
1 incident event	18 (7.1%)	11 (4.4%)
2 events	11 (4.3%)	6 (2.4%)
3 events	15 (5.9%)	2 (0.8%)
>= 4 events	15 (5.9%)	4 (1.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	17 (6.7%)	8 (3.2%)
2 events	10 (3.9%)	5 (2.0%)
3 events	14 (5.5%)	1 (0.4%)
>= 4 events	16 (6.3%)	4 (1.6%)
Cycle 12		
1 incident event	17 (6.7%)	7 (2.8%)
2 events	9 (3.5%)	5 (2.0%)
3 events	12 (4.7%)	1 (0.4%)
>= 4 events	15 (5.9%)	2 (0.8%)
Cycle 13		
1 incident event	15 (5.9%)	6 (2.4%)
2 events	7 (2.8%)	5 (2.0%)
3 events	9 (3.5%)	0
>= 4 events	15 (5.9%)	1 (0.4%)
Cycle 14		
1 incident event	15 (5.9%)	6 (2.4%)
2 events	7 (2.8%)	5 (2.0%)
3 events	8 (3.1%)	0
>= 4 events	13 (5.1%)	1 (0.4%)
Cycle 15		
1 incident event	13 (5.1%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	8 (3.1%)	1 (0.4%)
>= 4 events	11 (4.3%)	1 (0.4%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 16		
1 incident event	11 (4.3%)	4 (1.6%)
2 events	6 (2.4%)	4 (1.6%)
3 events	7 (2.8%)	1 (0.4%)
>= 4 events	11 (4.3%)	1 (0.4%)
Cycle 17		
1 incident event	8 (3.1%)	3 (1.2%)
2 events	5 (2.0%)	3 (1.2%)
3 events	7 (2.8%)	0
>= 4 events	11 (4.3%)	1 (0.4%)
Cycle 18		
1 incident event	8 (3.1%)	3 (1.2%)
2 events	4 (1.6%)	2 (0.8%)
3 events	5 (2.0%)	0
>= 4 events	12 (4.7%)	0
Cycle 19		
1 incident event	8 (3.1%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	5 (2.0%)	1 (0.4%)
>= 4 events	11 (4.3%)	0
Cycle 20		
1 incident event	7 (2.8%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	5 (2.0%)	1 (0.4%)
>= 4 events	10 (3.9%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	6 (2.4%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	9 (3.5%)	0
Cycle 22		
1 incident event	6 (2.4%)	3 (1.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 23		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 24		
1 incident event	4 (1.6%)	1 (0.4%)
2 events	1 (0.4%)	1 (0.4%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0
Cycle 25		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	8 (3.1%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	7 (2.8%)	0
Cycle 27		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	5 (2.0%)	0
Cycle 28		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	1 (0.4%)	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	4 (1.6%)	0
Cycle 29		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	4 (1.6%)	0
Cycle 30		
1 incident event	2 (0.8%)	2 (0.8%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	3 (1.2%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	2 (0.8%)	1 (0.4%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 32		
1 incident event	2 (0.8%)	1 (0.4%)
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 33		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 34		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 35		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 37		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 38		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	2 (0.8%)	0
Cycle 39		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 40		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 42		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 43		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 44		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 45		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 47		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 48		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 49		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	2 (0.8%)	0
Cycle 50		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 52		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 53		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 54		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 55		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.3: Summary of Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 56		
1 incident event	0	0
2 events	0	0
3 events	2 (0.8%)	0
>= 4 events	0	0
Cycle 57		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 58		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 59		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 60		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	24 (9.4%)	5 (2.0%)
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 2		
1 incident event	16 (6.3%)	3 (1.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	0	0
>= 4 events	0	0
Cycle 3		
1 incident event	14 (5.5%)	4 (1.6%)
2 events	3 (1.2%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 4		
1 incident event	13 (5.1%)	3 (1.2%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 5		
1 incident event	14 (5.5%)	3 (1.2%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	13 (5.1%)	3 (1.2%)
2 events	3 (1.2%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 7		
1 incident event	12 (4.7%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 8		
1 incident event	12 (4.7%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 9		
1 incident event	10 (3.9%)	1 (0.4%)
2 events	2 (0.8%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 10		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 12		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 13		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 14		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 15		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 16		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 17		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 18		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	1 (0.4%)	0
Cycle 19		
1 incident event	4 (1.6%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 20		
1 incident event	3 (1.2%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	3 (1.2%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 22		
1 incident event	2 (0.8%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 23		
1 incident event	2 (0.8%)	0
2 events	1 (0.4%)	0
3 events	0	0
>= 4 events	0	0
Cycle 24		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 25		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 27		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 28		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 29		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 30		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 32		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 33		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 34		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 35		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 37		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 38		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 39		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 40		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 42		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 43		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 44		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 45		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 46		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 47		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 48		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 49		
1 incident event	2 (0.8%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 50		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 51		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 52		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 53		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 54		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 55		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.1.4: Summary of Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 56		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 57		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 58		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 59		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 60		
1 incident event	1 (0.4%)	0
2 events	0	0
3 events	0	0
>= 4 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	99 (39.0%)	35 (14.1%)
2 events	35 (13.8%)	7 (2.8%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
1 incident event	73 (28.7%)	40 (16.1%)
2 events	54 (21.3%)	11 (4.4%)
3 events	19 (7.5%)	3 (1.2%)
>= 4 events	8 (3.1%)	3 (1.2%)
Cycle 3		
1 incident event	67 (26.4%)	37 (14.9%)
2 events	48 (18.9%)	12 (4.8%)
3 events	30 (11.8%)	5 (2.0%)
>= 4 events	16 (6.3%)	5 (2.0%)
Cycle 4		
1 incident event	61 (24.0%)	39 (15.7%)
2 events	46 (18.1%)	13 (5.2%)
3 events	28 (11.0%)	5 (2.0%)
>= 4 events	28 (11.0%)	7 (2.8%)
Cycle 5		
1 incident event	58 (22.8%)	40 (16.1%)
2 events	48 (18.9%)	14 (5.6%)
3 events	27 (10.6%)	4 (1.6%)
>= 4 events	31 (12.2%)	9 (3.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 6		
1 incident event	57 (22.4%)	44 (17.7%)
2 events	43 (16.9%)	14 (5.6%)
3 events	33 (13.0%)	3 (1.2%)
>= 4 events	31 (12.2%)	10 (4.0%)
Cycle 7		
1 incident event	57 (22.4%)	44 (17.7%)
2 events	41 (16.1%)	14 (5.6%)
3 events	34 (13.4%)	4 (1.6%)
>= 4 events	32 (12.6%)	10 (4.0%)
Cycle 8		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	39 (15.4%)	15 (6.0%)
3 events	34 (13.4%)	4 (1.6%)
>= 4 events	34 (13.4%)	12 (4.8%)
Cycle 9		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	16 (6.4%)
3 events	37 (14.6%)	5 (2.0%)
>= 4 events	35 (13.8%)	12 (4.8%)
Cycle 10		
1 incident event	60 (23.6%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	5 (2.0%)
>= 4 events	36 (14.2%)	12 (4.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	4 (1.6%)
>= 4 events	37 (14.6%)	13 (5.2%)
Cycle 12		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	4 (1.6%)
>= 4 events	37 (14.6%)	13 (5.2%)
Cycle 13		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	35 (13.8%)	4 (1.6%)
>= 4 events	38 (15.0%)	13 (5.2%)
Cycle 14		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	35 (13.8%)	4 (1.6%)
>= 4 events	38 (15.0%)	13 (5.2%)
Cycle 15		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	37 (14.6%)	15 (6.0%)
3 events	35 (13.8%)	5 (2.0%)
>= 4 events	38 (15.0%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 16		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	37 (14.6%)	15 (6.0%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	39 (15.4%)	13 (5.2%)
Cycle 17		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	37 (14.6%)	16 (6.4%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	39 (15.4%)	13 (5.2%)
Cycle 18		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	16 (6.4%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 19		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 20		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 22		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 23		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 24		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 25		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 27		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 28		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 29		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 30		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 32		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 33		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 34		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 35		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 37		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 38		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 39		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 40		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 42		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 43		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 44		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 45		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 47		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 48		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 49		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 50		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 52		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 53		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 54		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 55		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.1: Summary of Cumulative Recurrence of Vomiting (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 57		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 58		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 59		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 60		
1 incident event	58 (22.8%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 1		
1 incident event	24 (9.4%)	5 (2.0%)
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 2		
1 incident event	23 (9.1%)	5 (2.0%)
2 events	3 (1.2%)	1 (0.4%)
3 events	0	0
>= 4 events	0	0
Cycle 3		
1 incident event	24 (9.4%)	6 (2.4%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 4		
1 incident event	24 (9.4%)	6 (2.4%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 5		
1 incident event	26 (10.2%)	7 (2.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 7		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 8		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 9		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 10		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 12		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 13		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 14		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 15		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 17		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 18		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 19		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 20		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 22		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 23		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 24		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 25		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 27		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 28		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 29		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 30		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 32		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 33		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 34		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 35		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 37		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 38		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 39		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 40		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 42		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 43		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 44		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 45		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 47		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 48		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 49		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 50		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 52		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 53		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 54		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 55		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.2: Summary of Cumulative Recurrence of Vomiting (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 57		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 58		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 59		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 60		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	100 (39.4%)	35 (14.1%)
2 events	35 (13.8%)	7 (2.8%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
1 incident event	74 (29.1%)	40 (16.1%)
2 events	54 (21.3%)	11 (4.4%)
3 events	19 (7.5%)	3 (1.2%)
>= 4 events	8 (3.1%)	3 (1.2%)
Cycle 3		
1 incident event	68 (26.8%)	37 (14.9%)
2 events	48 (18.9%)	12 (4.8%)
3 events	30 (11.8%)	5 (2.0%)
>= 4 events	16 (6.3%)	5 (2.0%)
Cycle 4		
1 incident event	62 (24.4%)	39 (15.7%)
2 events	46 (18.1%)	13 (5.2%)
3 events	28 (11.0%)	5 (2.0%)
>= 4 events	28 (11.0%)	7 (2.8%)
Cycle 5		
1 incident event	59 (23.2%)	40 (16.1%)
2 events	48 (18.9%)	14 (5.6%)
3 events	27 (10.6%)	4 (1.6%)
>= 4 events	31 (12.2%)	9 (3.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	43 (16.9%)	14 (5.6%)
3 events	33 (13.0%)	3 (1.2%)
>= 4 events	31 (12.2%)	10 (4.0%)
Cycle 7		
1 incident event	58 (22.8%)	44 (17.7%)
2 events	41 (16.1%)	14 (5.6%)
3 events	34 (13.4%)	4 (1.6%)
>= 4 events	32 (12.6%)	10 (4.0%)
Cycle 8		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	39 (15.4%)	15 (6.0%)
3 events	34 (13.4%)	4 (1.6%)
>= 4 events	34 (13.4%)	12 (4.8%)
Cycle 9		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	16 (6.4%)
3 events	37 (14.6%)	5 (2.0%)
>= 4 events	35 (13.8%)	12 (4.8%)
Cycle 10		
1 incident event	61 (24.0%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	5 (2.0%)
>= 4 events	36 (14.2%)	12 (4.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
1 incident event	60 (23.6%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	4 (1.6%)
>= 4 events	37 (14.6%)	13 (5.2%)
Cycle 12		
1 incident event	60 (23.6%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	36 (14.2%)	4 (1.6%)
>= 4 events	37 (14.6%)	13 (5.2%)
Cycle 13		
1 incident event	60 (23.6%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	35 (13.8%)	4 (1.6%)
>= 4 events	38 (15.0%)	13 (5.2%)
Cycle 14		
1 incident event	60 (23.6%)	45 (18.1%)
2 events	36 (14.2%)	16 (6.4%)
3 events	35 (13.8%)	4 (1.6%)
>= 4 events	38 (15.0%)	13 (5.2%)
Cycle 15		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	37 (14.6%)	15 (6.0%)
3 events	35 (13.8%)	5 (2.0%)
>= 4 events	38 (15.0%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	37 (14.6%)	15 (6.0%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	39 (15.4%)	13 (5.2%)
Cycle 17		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	37 (14.6%)	16 (6.4%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	39 (15.4%)	13 (5.2%)
Cycle 18		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	16 (6.4%)
3 events	34 (13.4%)	5 (2.0%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 19		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 20		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 22		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 23		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 24		
1 incident event	59 (23.2%)	44 (17.7%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 25		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 27		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 28		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 29		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 30		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 32		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 33		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 34		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 35		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 37		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 38		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 39		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 40		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 42		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 43		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 44		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 45		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 47		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 48		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 49		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 50		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 52		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 53		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 54		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 55		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.3: Summary of Cumulative Recurrence of Vomiting (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 57		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 58		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 59		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)
Cycle 60		
1 incident event	59 (23.2%)	45 (18.1%)
2 events	36 (14.2%)	15 (6.0%)
3 events	34 (13.4%)	6 (2.4%)
>= 4 events	40 (15.7%)	13 (5.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	24 (9.4%)	5 (2.0%)
2 events	0	0
3 events	0	0
>= 4 events	0	0
Cycle 2		
1 incident event	23 (9.1%)	5 (2.0%)
2 events	3 (1.2%)	1 (0.4%)
3 events	0	0
>= 4 events	0	0
Cycle 3		
1 incident event	24 (9.4%)	6 (2.4%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 4		
1 incident event	24 (9.4%)	6 (2.4%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 5		
1 incident event	26 (10.2%)	7 (2.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 6		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 7		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0
Cycle 8		
1 incident event	26 (10.2%)	8 (3.2%)
2 events	2 (0.8%)	1 (0.4%)
3 events	2 (0.8%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 9		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 10		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 11		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 12		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 13		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 14		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 15		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 16		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 17		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 18		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 19		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 20		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 22		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 23		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 24		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 25		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 26		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 27		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 28		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 29		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 30		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 31		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 32		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 33		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 34		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 35		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 36		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 37		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 38		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 39		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 40		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 42		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 43		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 44		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 45		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 46		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 47		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 48		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 49		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 50		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 51		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 52		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 53		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 54		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 55		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 56		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.2.4: Summary of Cumulative Recurrence of Vomiting (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 57		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 58		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 59		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 60		
1 incident event	25 (9.8%)	8 (3.2%)
2 events	3 (1.2%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of vomiting is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	99 (39.0%)	35 (14.1%)
+2 events	35 (13.8%)	7 (2.8%)
+3 events	4 (1.6%)	1 (0.4%)
>= +4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
+1 event	63 (24.8%)	21 (8.4%)
+2 events	10 (3.9%)	2 (0.8%)
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 3		
+1 event	45 (17.7%)	15 (6.0%)
+2 events	5 (2.0%)	0
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 4		
+1 event	30 (11.8%)	13 (5.2%)
+2 events	6 (2.4%)	1 (0.4%)
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 5		
+1 event	15 (5.9%)	11 (4.4%)
+2 events	3 (1.2%)	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
+1 event	13 (5.1%)	8 (3.2%)
+2 events	2 (0.8%)	0
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 7		
+1 event	5 (2.0%)	4 (1.6%)
+2 events	3 (1.2%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 8		
+1 event	10 (3.9%)	10 (4.0%)
+2 events	1 (0.4%)	0
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 9		
+1 event	7 (2.8%)	6 (2.4%)
+2 events	2 (0.8%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 10		
+1 event	4 (1.6%)	2 (0.8%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
+1 event	6 (2.4%)	2 (0.8%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 12		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 13		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 14		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 15		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 17		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 18		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 19		
+1 event	0	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 20		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 22		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 23		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 24		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 25		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 27		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 28		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 29		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 30		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 32		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 33		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 34		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 35		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 37		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 38		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 39		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 40		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 42		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 43		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 44		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 45		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.1: Summary of Newly Occuring Vomiting Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.2: Summary of Newly Occuring Vomiting Events (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	24 (9.4%)	5 (2.0%)
+2 events	0	0
Cycle 2		
+1 event	5 (2.0%)	2 (0.8%)
+2 events	0	0
Cycle 3		
+1 event	4 (1.6%)	1 (0.4%)
+2 events	0	0
Cycle 4		
+1 event	0	0
+2 events	1 (0.4%)	0
Cycle 5		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 6		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 7		
+1 event	1 (0.4%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.2: Summary of Newly Occuring Vomiting Events (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
+1 event	0	0
+2 events	0	0
Cycle 9		
+1 event	2 (0.8%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	100 (39.4%)	35 (14.1%)
+2 events	35 (13.8%)	7 (2.8%)
+3 events	4 (1.6%)	1 (0.4%)
>= +4 events	2 (0.8%)	1 (0.4%)
Cycle 2		
+1 event	63 (24.8%)	21 (8.4%)
+2 events	10 (3.9%)	2 (0.8%)
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 3		
+1 event	45 (17.7%)	15 (6.0%)
+2 events	5 (2.0%)	0
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 4		
+1 event	30 (11.8%)	13 (5.2%)
+2 events	6 (2.4%)	1 (0.4%)
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 5		
+1 event	15 (5.9%)	11 (4.4%)
+2 events	3 (1.2%)	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
+1 event	13 (5.1%)	8 (3.2%)
+2 events	2 (0.8%)	0
+3 events	1 (0.4%)	0
>= +4 events	0	0
Cycle 7		
+1 event	5 (2.0%)	4 (1.6%)
+2 events	3 (1.2%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 8		
+1 event	10 (3.9%)	10 (4.0%)
+2 events	1 (0.4%)	0
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 9		
+1 event	7 (2.8%)	6 (2.4%)
+2 events	2 (0.8%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 10		
+1 event	4 (1.6%)	2 (0.8%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
+1 event	6 (2.4%)	2 (0.8%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 12		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 13		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 14		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 15		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 16		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 17		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 18		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 19		
+1 event	0	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 20		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 22		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 23		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 24		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 25		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 27		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 28		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 29		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 30		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 32		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 33		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 34		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 35		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 37		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 38		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 39		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 40		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 42		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 43		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 44		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 45		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.3: Summary of Newly Occuring Vomiting Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.4: Summary of Newly Occuring Vomiting Events (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	24 (9.4%)	5 (2.0%)
+2 events	0	0
Cycle 2		
+1 event	5 (2.0%)	2 (0.8%)
+2 events	0	0
Cycle 3		
+1 event	4 (1.6%)	1 (0.4%)
+2 events	0	0
Cycle 4		
+1 event	0	0
+2 events	1 (0.4%)	0
Cycle 5		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 6		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 7		
+1 event	1 (0.4%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.11.3.4: Summary of Newly Occuring Vomiting Events (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
+1 event	0	0
+2 events	0	0
Cycle 9		
+1 event	2 (0.8%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring vomiting events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	102 (40.2%)	80 (32.1%)
2 events	41 (16.1%)	1 (0.4%)
3 events	3 (1.2%)	3 (1.2%)
>= 4 events	1 (0.4%)	0
Cycle 2		
1 incident event	70 (27.6%)	59 (23.7%)
2 events	49 (19.3%)	32 (12.9%)
3 events	18 (7.1%)	4 (1.6%)
>= 4 events	7 (2.8%)	2 (0.8%)
Cycle 3		
1 incident event	54 (21.3%)	46 (18.5%)
2 events	38 (15.0%)	23 (9.2%)
3 events	31 (12.2%)	17 (6.8%)
>= 4 events	15 (5.9%)	5 (2.0%)
Cycle 4		
1 incident event	44 (17.3%)	41 (16.5%)
2 events	30 (11.8%)	22 (8.8%)
3 events	25 (9.8%)	8 (3.2%)
>= 4 events	27 (10.6%)	15 (6.0%)
Cycle 5		
1 incident event	40 (15.7%)	34 (13.7%)
2 events	32 (12.6%)	21 (8.4%)
3 events	20 (7.9%)	8 (3.2%)
>= 4 events	31 (12.2%)	17 (6.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	35 (13.8%)	32 (12.9%)
2 events	28 (11.0%)	17 (6.8%)
3 events	18 (7.1%)	6 (2.4%)
>= 4 events	30 (11.8%)	18 (7.2%)
Cycle 7		
1 incident event	33 (13.0%)	28 (11.2%)
2 events	22 (8.7%)	14 (5.6%)
3 events	12 (4.7%)	3 (1.2%)
>= 4 events	26 (10.2%)	18 (7.2%)
Cycle 8		
1 incident event	26 (10.2%)	28 (11.2%)
2 events	19 (7.5%)	12 (4.8%)
3 events	14 (5.5%)	4 (1.6%)
>= 4 events	26 (10.2%)	15 (6.0%)
Cycle 9		
1 incident event	24 (9.4%)	25 (10.0%)
2 events	20 (7.9%)	10 (4.0%)
3 events	10 (3.9%)	4 (1.6%)
>= 4 events	24 (9.4%)	14 (5.6%)
Cycle 10		
1 incident event	18 (7.1%)	20 (8.0%)
2 events	19 (7.5%)	8 (3.2%)
3 events	9 (3.5%)	3 (1.2%)
>= 4 events	21 (8.3%)	12 (4.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 11		
1 incident event	17 (6.7%)	19 (7.6%)
2 events	18 (7.1%)	7 (2.8%)
3 events	6 (2.4%)	2 (0.8%)
>= 4 events	21 (8.3%)	11 (4.4%)
Cycle 12		
1 incident event	16 (6.3%)	18 (7.2%)
2 events	16 (6.3%)	6 (2.4%)
3 events	5 (2.0%)	2 (0.8%)
>= 4 events	19 (7.5%)	9 (3.6%)
Cycle 13		
1 incident event	14 (5.5%)	17 (6.8%)
2 events	13 (5.1%)	6 (2.4%)
3 events	6 (2.4%)	2 (0.8%)
>= 4 events	16 (6.3%)	6 (2.4%)
Cycle 14		
1 incident event	13 (5.1%)	14 (5.6%)
2 events	14 (5.5%)	7 (2.8%)
3 events	4 (1.6%)	2 (0.8%)
>= 4 events	15 (5.9%)	6 (2.4%)
Cycle 15		
1 incident event	13 (5.1%)	11 (4.4%)
2 events	12 (4.7%)	7 (2.8%)
3 events	4 (1.6%)	2 (0.8%)
>= 4 events	14 (5.5%)	6 (2.4%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	12 (4.7%)	8 (3.2%)
2 events	11 (4.3%)	5 (2.0%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	12 (4.7%)	5 (2.0%)
Cycle 17		
1 incident event	11 (4.3%)	5 (2.0%)
2 events	10 (3.9%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	5 (2.0%)
Cycle 18		
1 incident event	11 (4.3%)	4 (1.6%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	3 (1.2%)
Cycle 19		
1 incident event	9 (3.5%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	3 (1.2%)
Cycle 20		
1 incident event	9 (3.5%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	10 (3.9%)	2 (0.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 21		
1 incident event	6 (2.4%)	5 (2.0%)
2 events	7 (2.8%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	2 (0.8%)
Cycle 22		
1 incident event	5 (2.0%)	5 (2.0%)
2 events	6 (2.4%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 23		
1 incident event	5 (2.0%)	4 (1.6%)
2 events	5 (2.0%)	5 (2.0%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 24		
1 incident event	5 (2.0%)	4 (1.6%)
2 events	4 (1.6%)	5 (2.0%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 25		
1 incident event	5 (2.0%)	3 (1.2%)
2 events	4 (1.6%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	9 (3.5%)	1 (0.4%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	4 (1.6%)	4 (1.6%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	8 (3.1%)	1 (0.4%)
Cycle 27		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	4 (1.6%)	4 (1.6%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 28		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	3 (1.2%)	4 (1.6%)
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 29		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	3 (1.2%)	3 (1.2%)
3 events	1 (0.4%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 30		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	2 (0.8%)
>= 4 events	6 (2.4%)	1 (0.4%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	1 (0.4%)
>= 4 events	5 (2.0%)	1 (0.4%)
Cycle 32		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	0
>= 4 events	5 (2.0%)	2 (0.8%)
Cycle 33		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 34		
1 incident event	1 (0.4%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 35		
1 incident event	1 (0.4%)	1 (0.4%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 37		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 38		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	1 (0.4%)
Cycle 39		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 40		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 42		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 43		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 44		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 45		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 46		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 47		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 48		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 49		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	3 (1.2%)	0
Cycle 50		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 51		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 52		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 53		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 54		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 55		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.1: Summary of Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 56		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 57		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 58		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 59		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 60		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	17 (6.7%)	3 (1.2%)
2 events	1 (0.4%)	0
Cycle 2		
1 incident event	14 (5.5%)	4 (1.6%)
2 events	1 (0.4%)	0
Cycle 3		
1 incident event	11 (4.3%)	4 (1.6%)
2 events	0	1 (0.4%)
Cycle 4		
1 incident event	10 (3.9%)	3 (1.2%)
2 events	0	1 (0.4%)
Cycle 5		
1 incident event	11 (4.3%)	2 (0.8%)
2 events	0	1 (0.4%)
Cycle 6		
1 incident event	12 (4.7%)	2 (0.8%)
2 events	0	1 (0.4%)
Cycle 7		
1 incident event	9 (3.5%)	1 (0.4%)
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
1 incident event	8 (3.1%)	1 (0.4%)
2 events	0	0
Cycle 9		
1 incident event	8 (3.1%)	1 (0.4%)
2 events	0	0
Cycle 10		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 11		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 12		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 13		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 14		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 15		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	0	0
Cycle 16		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	0	0
Cycle 17		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 18		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 19		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 20		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 21		
1 incident event	5 (2.0%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 22		
1 incident event	4 (1.6%)	0
2 events	0	0
Cycle 23		
1 incident event	3 (1.2%)	0
2 events	0	0
Cycle 24		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 25		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 26		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 27		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 28		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 29		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 30		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 31		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 32		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 33		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 34		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 35		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 37		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 38		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 39		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 40		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 41		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 42		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 43		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 44		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 45		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 46		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 47		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 48		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 49		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 50		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 51		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 52		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 53		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 54		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 55		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 56		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.2: Summary of Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 57		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 58		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 59		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 60		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	102 (40.2%)	80 (32.1%)
2 events	41 (16.1%)	1 (0.4%)
3 events	3 (1.2%)	3 (1.2%)
>= 4 events	1 (0.4%)	0
Cycle 2		
1 incident event	70 (27.6%)	59 (23.7%)
2 events	49 (19.3%)	32 (12.9%)
3 events	18 (7.1%)	4 (1.6%)
>= 4 events	7 (2.8%)	2 (0.8%)
Cycle 3		
1 incident event	54 (21.3%)	46 (18.5%)
2 events	38 (15.0%)	23 (9.2%)
3 events	31 (12.2%)	17 (6.8%)
>= 4 events	15 (5.9%)	5 (2.0%)
Cycle 4		
1 incident event	44 (17.3%)	41 (16.5%)
2 events	30 (11.8%)	22 (8.8%)
3 events	25 (9.8%)	8 (3.2%)
>= 4 events	27 (10.6%)	15 (6.0%)
Cycle 5		
1 incident event	40 (15.7%)	34 (13.7%)
2 events	32 (12.6%)	21 (8.4%)
3 events	20 (7.9%)	8 (3.2%)
>= 4 events	31 (12.2%)	17 (6.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	35 (13.8%)	32 (12.9%)
2 events	28 (11.0%)	17 (6.8%)
3 events	18 (7.1%)	6 (2.4%)
>= 4 events	30 (11.8%)	18 (7.2%)
Cycle 7		
1 incident event	33 (13.0%)	28 (11.2%)
2 events	22 (8.7%)	14 (5.6%)
3 events	12 (4.7%)	3 (1.2%)
>= 4 events	26 (10.2%)	18 (7.2%)
Cycle 8		
1 incident event	26 (10.2%)	28 (11.2%)
2 events	19 (7.5%)	12 (4.8%)
3 events	14 (5.5%)	4 (1.6%)
>= 4 events	26 (10.2%)	15 (6.0%)
Cycle 9		
1 incident event	24 (9.4%)	25 (10.0%)
2 events	20 (7.9%)	10 (4.0%)
3 events	10 (3.9%)	4 (1.6%)
>= 4 events	24 (9.4%)	14 (5.6%)
Cycle 10		
1 incident event	18 (7.1%)	20 (8.0%)
2 events	19 (7.5%)	8 (3.2%)
3 events	9 (3.5%)	3 (1.2%)
>= 4 events	21 (8.3%)	12 (4.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
1 incident event	17 (6.7%)	19 (7.6%)
2 events	18 (7.1%)	7 (2.8%)
3 events	6 (2.4%)	2 (0.8%)
>= 4 events	21 (8.3%)	11 (4.4%)
Cycle 12		
1 incident event	16 (6.3%)	18 (7.2%)
2 events	16 (6.3%)	6 (2.4%)
3 events	5 (2.0%)	2 (0.8%)
>= 4 events	19 (7.5%)	9 (3.6%)
Cycle 13		
1 incident event	14 (5.5%)	17 (6.8%)
2 events	13 (5.1%)	6 (2.4%)
3 events	6 (2.4%)	2 (0.8%)
>= 4 events	16 (6.3%)	6 (2.4%)
Cycle 14		
1 incident event	13 (5.1%)	14 (5.6%)
2 events	14 (5.5%)	7 (2.8%)
3 events	4 (1.6%)	2 (0.8%)
>= 4 events	15 (5.9%)	6 (2.4%)
Cycle 15		
1 incident event	13 (5.1%)	11 (4.4%)
2 events	12 (4.7%)	7 (2.8%)
3 events	4 (1.6%)	2 (0.8%)
>= 4 events	14 (5.5%)	6 (2.4%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	12 (4.7%)	8 (3.2%)
2 events	11 (4.3%)	5 (2.0%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	12 (4.7%)	5 (2.0%)
Cycle 17		
1 incident event	11 (4.3%)	5 (2.0%)
2 events	10 (3.9%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	5 (2.0%)
Cycle 18		
1 incident event	11 (4.3%)	4 (1.6%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	3 (1.2%)
Cycle 19		
1 incident event	9 (3.5%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	3 (1.2%)
Cycle 20		
1 incident event	9 (3.5%)	5 (2.0%)
2 events	8 (3.1%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	10 (3.9%)	2 (0.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
1 incident event	6 (2.4%)	5 (2.0%)
2 events	7 (2.8%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	11 (4.3%)	2 (0.8%)
Cycle 22		
1 incident event	5 (2.0%)	5 (2.0%)
2 events	6 (2.4%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 23		
1 incident event	5 (2.0%)	4 (1.6%)
2 events	5 (2.0%)	5 (2.0%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 24		
1 incident event	5 (2.0%)	4 (1.6%)
2 events	4 (1.6%)	5 (2.0%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	10 (3.9%)	1 (0.4%)
Cycle 25		
1 incident event	5 (2.0%)	3 (1.2%)
2 events	4 (1.6%)	4 (1.6%)
3 events	4 (1.6%)	1 (0.4%)
>= 4 events	9 (3.5%)	1 (0.4%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	4 (1.6%)	4 (1.6%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	8 (3.1%)	1 (0.4%)
Cycle 27		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	4 (1.6%)	4 (1.6%)
3 events	3 (1.2%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 28		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	3 (1.2%)	4 (1.6%)
3 events	2 (0.8%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 29		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	3 (1.2%)	3 (1.2%)
3 events	1 (0.4%)	1 (0.4%)
>= 4 events	6 (2.4%)	1 (0.4%)
Cycle 30		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	2 (0.8%)
>= 4 events	6 (2.4%)	1 (0.4%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 31		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	1 (0.4%)
>= 4 events	5 (2.0%)	1 (0.4%)
Cycle 32		
1 incident event	5 (2.0%)	2 (0.8%)
2 events	2 (0.8%)	2 (0.8%)
3 events	1 (0.4%)	0
>= 4 events	5 (2.0%)	2 (0.8%)
Cycle 33		
1 incident event	4 (1.6%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 34		
1 incident event	1 (0.4%)	2 (0.8%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 35		
1 incident event	1 (0.4%)	1 (0.4%)
2 events	2 (0.8%)	1 (0.4%)
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 37		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	2 (0.8%)
Cycle 38		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	1 (0.4%)
Cycle 39		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 40		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 42		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 43		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 44		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 45		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 46		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 47		
1 incident event	0	0
2 events	2 (0.8%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 48		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	4 (1.6%)	0
Cycle 49		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	3 (1.2%)	0
Cycle 50		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 52		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	2 (0.8%)	0
Cycle 53		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 54		
1 incident event	0	0
2 events	1 (0.4%)	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 55		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.3: Summary of Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	1 (0.4%)	0
Cycle 57		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 58		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 59		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0
Cycle 60		
1 incident event	0	0
2 events	0	0
3 events	1 (0.4%)	0
>= 4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	17 (6.7%)	3 (1.2%)
2 events	1 (0.4%)	0
Cycle 2		
1 incident event	14 (5.5%)	4 (1.6%)
2 events	1 (0.4%)	0
Cycle 3		
1 incident event	11 (4.3%)	4 (1.6%)
2 events	0	1 (0.4%)
Cycle 4		
1 incident event	10 (3.9%)	3 (1.2%)
2 events	0	1 (0.4%)
Cycle 5		
1 incident event	11 (4.3%)	2 (0.8%)
2 events	0	1 (0.4%)
Cycle 6		
1 incident event	12 (4.7%)	2 (0.8%)
2 events	0	1 (0.4%)
Cycle 7		
1 incident event	9 (3.5%)	1 (0.4%)
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
1 incident event	8 (3.1%)	1 (0.4%)
2 events	0	0
Cycle 9		
1 incident event	8 (3.1%)	1 (0.4%)
2 events	0	0
Cycle 10		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 11		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 12		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 13		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0
Cycle 14		
1 incident event	6 (2.4%)	1 (0.4%)
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 15		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	0	0
Cycle 16		
1 incident event	5 (2.0%)	1 (0.4%)
2 events	0	0
Cycle 17		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 18		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 19		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 20		
1 incident event	5 (2.0%)	0
2 events	0	0
Cycle 21		
1 incident event	5 (2.0%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 22		
1 incident event	4 (1.6%)	0
2 events	0	0
Cycle 23		
1 incident event	3 (1.2%)	0
2 events	0	0
Cycle 24		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 25		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 26		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 27		
1 incident event	2 (0.8%)	0
2 events	0	0
Cycle 28		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 29		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 30		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 31		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 32		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 33		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 34		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 35		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 37		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 38		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 39		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 40		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 41		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 42		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 43		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 44		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 45		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 46		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 47		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 48		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 49		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 50		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 51		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 52		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 53		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 54		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 55		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 56		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.1.4: Summary of Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 57		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 58		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 59		
1 incident event	1 (0.4%)	0
2 events	0	0
Cycle 60		
1 incident event	1 (0.4%)	0
2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	102 (40.2%)	80 (32.1%)
2 events	41 (16.1%)	1 (0.4%)
3 events	3 (1.2%)	3 (1.2%)
>= 4 events	1 (0.4%)	0
Cycle 2		
1 incident event	79 (31.1%)	66 (26.5%)
2 events	56 (22.0%)	32 (12.9%)
3 events	19 (7.5%)	4 (1.6%)
>= 4 events	8 (3.1%)	2 (0.8%)
Cycle 3		
1 incident event	70 (27.6%)	59 (23.7%)
2 events	46 (18.1%)	24 (9.6%)
3 events	35 (13.8%)	19 (7.6%)
>= 4 events	16 (6.3%)	5 (2.0%)
Cycle 4		
1 incident event	65 (25.6%)	62 (24.9%)
2 events	40 (15.7%)	24 (9.6%)
3 events	34 (13.4%)	11 (4.4%)
>= 4 events	29 (11.4%)	16 (6.4%)
Cycle 5		
1 incident event	63 (24.8%)	60 (24.1%)
2 events	43 (16.9%)	27 (10.8%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	35 (13.8%)	18 (7.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	62 (24.4%)	61 (24.5%)
2 events	42 (16.5%)	25 (10.0%)
3 events	30 (11.8%)	11 (4.4%)
>= 4 events	37 (14.6%)	20 (8.0%)
Cycle 7		
1 incident event	64 (25.2%)	62 (24.9%)
2 events	42 (16.5%)	25 (10.0%)
3 events	27 (10.6%)	9 (3.6%)
>= 4 events	40 (15.7%)	22 (8.8%)
Cycle 8		
1 incident event	64 (25.2%)	64 (25.7%)
2 events	39 (15.4%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	41 (16.1%)	22 (8.8%)
Cycle 9		
1 incident event	63 (24.8%)	64 (25.7%)
2 events	41 (16.1%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	42 (16.5%)	23 (9.2%)
Cycle 10		
1 incident event	63 (24.8%)	64 (25.7%)
2 events	41 (16.1%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
1 incident event	63 (24.8%)	66 (26.5%)
2 events	41 (16.1%)	24 (9.6%)
3 events	27 (10.6%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 12		
1 incident event	63 (24.8%)	66 (26.5%)
2 events	41 (16.1%)	24 (9.6%)
3 events	27 (10.6%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 13		
1 incident event	63 (24.8%)	67 (26.9%)
2 events	40 (15.7%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 14		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 15		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 17		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 18		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	40 (15.7%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 19		
1 incident event	62 (24.4%)	67 (26.9%)
2 events	40 (15.7%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 20		
1 incident event	62 (24.4%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
1 incident event	61 (24.0%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 22		
1 incident event	61 (24.0%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 23		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 24		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 25		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)
Cycle 27		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)
Cycle 28		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 29		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 30		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	44 (17.3%)	23 (9.2%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 32		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 33		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 34		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 35		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 37		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 38		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 39		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 40		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 42		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 43		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 44		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 45		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 47		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 48		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 49		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 50		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 52		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 53		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 54		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 55		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.1: Summary of Cumulative Recurrence of Nausea (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 57		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 58		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 59		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 60		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	17 (6.7%)	3 (1.2%)
2 events	1 (0.4%)	0
Cycle 2		
1 incident event	17 (6.7%)	4 (1.6%)
2 events	2 (0.8%)	0
Cycle 3		
1 incident event	18 (7.1%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 4		
1 incident event	18 (7.1%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 5		
1 incident event	19 (7.5%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 6		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 7		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 9		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 10		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 11		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 12		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 13		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 14		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 15		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 16		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 17		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 18		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 19		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 20		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 21		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 22		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 23		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 24		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 25		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 26		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 27		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 28		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 29		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 30		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 31		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 32		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 33		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 34		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 35		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 37		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 38		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 39		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 40		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 41		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 42		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 43		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 44		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 45		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 46		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 47		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 48		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 49		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 50		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 51		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 52		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 53		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 54		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 55		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 56		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.2: Summary of Cumulative Recurrence of Nausea (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 57		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 58		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 59		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 60		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	102 (40.2%)	80 (32.1%)
2 events	41 (16.1%)	1 (0.4%)
3 events	3 (1.2%)	3 (1.2%)
>= 4 events	1 (0.4%)	0
Cycle 2		
1 incident event	79 (31.1%)	66 (26.5%)
2 events	56 (22.0%)	32 (12.9%)
3 events	19 (7.5%)	4 (1.6%)
>= 4 events	8 (3.1%)	2 (0.8%)
Cycle 3		
1 incident event	70 (27.6%)	59 (23.7%)
2 events	46 (18.1%)	24 (9.6%)
3 events	35 (13.8%)	19 (7.6%)
>= 4 events	16 (6.3%)	5 (2.0%)
Cycle 4		
1 incident event	65 (25.6%)	62 (24.9%)
2 events	40 (15.7%)	24 (9.6%)
3 events	34 (13.4%)	11 (4.4%)
>= 4 events	29 (11.4%)	16 (6.4%)
Cycle 5		
1 incident event	63 (24.8%)	60 (24.1%)
2 events	43 (16.9%)	27 (10.8%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	35 (13.8%)	18 (7.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
1 incident event	62 (24.4%)	61 (24.5%)
2 events	42 (16.5%)	25 (10.0%)
3 events	30 (11.8%)	11 (4.4%)
>= 4 events	37 (14.6%)	20 (8.0%)
Cycle 7		
1 incident event	64 (25.2%)	62 (24.9%)
2 events	42 (16.5%)	25 (10.0%)
3 events	27 (10.6%)	9 (3.6%)
>= 4 events	40 (15.7%)	22 (8.8%)
Cycle 8		
1 incident event	64 (25.2%)	64 (25.7%)
2 events	39 (15.4%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	41 (16.1%)	22 (8.8%)
Cycle 9		
1 incident event	63 (24.8%)	64 (25.7%)
2 events	41 (16.1%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	42 (16.5%)	23 (9.2%)
Cycle 10		
1 incident event	63 (24.8%)	64 (25.7%)
2 events	41 (16.1%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
1 incident event	63 (24.8%)	66 (26.5%)
2 events	41 (16.1%)	24 (9.6%)
3 events	27 (10.6%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 12		
1 incident event	63 (24.8%)	66 (26.5%)
2 events	41 (16.1%)	24 (9.6%)
3 events	27 (10.6%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 13		
1 incident event	63 (24.8%)	67 (26.9%)
2 events	40 (15.7%)	24 (9.6%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 14		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 15		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 17		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	28 (11.0%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 18		
1 incident event	62 (24.4%)	66 (26.5%)
2 events	40 (15.7%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 19		
1 incident event	62 (24.4%)	67 (26.9%)
2 events	40 (15.7%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 20		
1 incident event	62 (24.4%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
1 incident event	61 (24.0%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 22		
1 incident event	61 (24.0%)	67 (26.9%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 23		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 24		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 25		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 26		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)
Cycle 27		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	30 (11.8%)	10 (4.0%)
>= 4 events	43 (16.9%)	23 (9.2%)
Cycle 28		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 29		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	26 (10.4%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 30		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	44 (17.3%)	23 (9.2%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	11 (4.4%)
>= 4 events	44 (17.3%)	23 (9.2%)
Cycle 32		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 33		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 34		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 35		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 37		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 38		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 39		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 40		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 42		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 43		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 44		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 45		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 46		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 47		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 48		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 49		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 50		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 51		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 52		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 53		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 54		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 55		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.3: Summary of Cumulative Recurrence of Nausea (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 56		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 57		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 58		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 59		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)
Cycle 60		
1 incident event	61 (24.0%)	66 (26.5%)
2 events	41 (16.1%)	25 (10.0%)
3 events	29 (11.4%)	10 (4.0%)
>= 4 events	44 (17.3%)	24 (9.6%)

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
1 incident event	17 (6.7%)	3 (1.2%)
2 events	1 (0.4%)	0
Cycle 2		
1 incident event	17 (6.7%)	4 (1.6%)
2 events	2 (0.8%)	0
Cycle 3		
1 incident event	18 (7.1%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 4		
1 incident event	18 (7.1%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 5		
1 incident event	19 (7.5%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 6		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 7		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 8		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 9		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 10		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 11		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 12		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 13		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 14		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 15		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 16		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 17		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 18		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 19		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 20		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 21		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 22		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 23		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 24		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 25		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 26		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 27		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 28		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 29		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 30		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 31		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 32		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 33		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 34		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 35		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 36		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 37		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 38		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 39		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 40		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 41		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 42		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 43		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 44		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 45		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 46		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 47		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 48		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 49		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 50		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 51		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 52		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 53		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 54		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 55		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 56		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.2.4: Summary of Cumulative Recurrence of Nausea (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 57		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 58		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 59		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)
Cycle 60		
1 incident event	20 (7.9%)	5 (2.0%)
2 events	2 (0.8%)	1 (0.4%)

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Cumulative recurrence of nausea is defined as the number of events per patient up to each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle. For patients who ended the study, events at their last available cycle will be carried forward until the last observed cycle of the study.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	102 (40.2%)	80 (32.1%)
+2 events	41 (16.1%)	1 (0.4%)
+3 events	3 (1.2%)	3 (1.2%)
>= +4 events	1 (0.4%)	0
Cycle 2		
+1 event	63 (24.8%)	50 (20.1%)
+2 events	10 (3.9%)	4 (1.6%)
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 3		
+1 event	50 (19.7%)	26 (10.4%)
+2 events	4 (1.6%)	4 (1.6%)
+3 events	0	0
>= +4 events	0	0
Cycle 4		
+1 event	41 (16.1%)	23 (9.2%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 5		
+1 event	26 (10.2%)	21 (8.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
+1 event	22 (8.7%)	15 (6.0%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 7		
+1 event	12 (4.7%)	11 (4.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 8		
+1 event	11 (4.3%)	13 (5.2%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 9		
+1 event	9 (3.5%)	3 (1.2%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 10		
+1 event	7 (2.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
+1 event	4 (1.6%)	3 (1.2%)
+2 events	0	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 12		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 13		
+1 event	3 (1.2%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 14		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 15		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 17		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 18		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 19		
+1 event	0	1 (0.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 20		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 22		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 23		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 24		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 25		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 27		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 28		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 29		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 30		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 32		
+1 event	0	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 33		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 34		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 35		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 37		
+1 event	0	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 38		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 39		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 40		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 41		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 42		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 43		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 44		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 45		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.1: Summary of Newly Occuring Nausea Events (TEAE) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 47		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.2: Summary of Newly Occuring Nausea Events (TEAE, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	17 (6.7%)	3 (1.2%)
+2 events	1 (0.4%)	0
Cycle 2		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 3		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	1 (0.4%)
Cycle 4		
+1 event	0	0
+2 events	0	0
Cycle 5		
+1 event	1 (0.4%)	0
+2 events	0	0
Cycle 6		
+1 event	1 (0.4%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAE=treatment-emergent adverse event.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	102 (40.2%)	80 (32.1%)
+2 events	41 (16.1%)	1 (0.4%)
+3 events	3 (1.2%)	3 (1.2%)
>= +4 events	1 (0.4%)	0
Cycle 2		
+1 event	63 (24.8%)	50 (20.1%)
+2 events	10 (3.9%)	4 (1.6%)
+3 events	0	1 (0.4%)
>= +4 events	0	0
Cycle 3		
+1 event	50 (19.7%)	26 (10.4%)
+2 events	4 (1.6%)	4 (1.6%)
+3 events	0	0
>= +4 events	0	0
Cycle 4		
+1 event	41 (16.1%)	23 (9.2%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 5		
+1 event	26 (10.2%)	21 (8.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 6		
+1 event	22 (8.7%)	15 (6.0%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 7		
+1 event	12 (4.7%)	11 (4.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 8		
+1 event	11 (4.3%)	13 (5.2%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 9		
+1 event	9 (3.5%)	3 (1.2%)
+2 events	1 (0.4%)	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 10		
+1 event	7 (2.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 11		
+1 event	4 (1.6%)	3 (1.2%)
+2 events	0	1 (0.4%)
+3 events	0	0
>= +4 events	0	0
Cycle 12		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 13		
+1 event	3 (1.2%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 14		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 15		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 16		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 17		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 18		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 19		
+1 event	0	1 (0.4%)
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 20		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 21		
+1 event	1 (0.4%)	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 22		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 23		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 24		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 25		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 26		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 27		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 28		
+1 event	2 (0.8%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 29		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 30		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 31		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 32		
+1 event	0	1 (0.4%)
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 33		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 34		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 35		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 36		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 37		
+1 event	0	0
+2 events	1 (0.4%)	0
+3 events	0	0
>= +4 events	0	0
Cycle 38		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 39		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 40		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	Placebo + CAPOX (N=249)
Cycle 41		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 42		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 43		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 44		
+1 event	0	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 45		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.3: Summary of Newly Occuring Nausea Events (TEAESI) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 46		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0
Cycle 47		
+1 event	1 (0.4%)	0
+2 events	0	0
+3 events	0	0
>= +4 events	0	0

Abbreviations: N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Table 302.3.2000.12.3.4: Summary of Newly Occuring Nausea Events (TEAESI, CTCAE Grade >=3) by Cycle within Overall Population - Safety Analysis Set

	Zolbetuximab + CAPOX (N=254)	**Placebo + CAPOX (N=249)**
Cycle 1		
+1 event	17 (6.7%)	3 (1.2%)
+2 events	1 (0.4%)	0
Cycle 2		
+1 event	2 (0.8%)	1 (0.4%)
+2 events	0	0
Cycle 3		
+1 event	1 (0.4%)	1 (0.4%)
+2 events	0	1 (0.4%)
Cycle 4		
+1 event	0	0
+2 events	0	0
Cycle 5		
+1 event	1 (0.4%)	0
+2 events	0	0
Cycle 6		
+1 event	1 (0.4%)	0
+2 events	0	0

Abbreviations: CTCAE=common terminology criteria of adverse events; N=number of patients; TEAESI=treatment-emergent adverse event of special interest.
Note: Newly occuring nausea events are defined as the number of events per patient that were observed within each cycle. Events are assigned to a cycle if they occurred after the start of the respective cycle and before the start of the next cycle.
Percentages are calculated based on the total population for each treatment group.
As only treatment-emergent adverse events are considered, baseline cannot occur and is not presented.
ASTELLAS Data Cutoff Date: 12JAN24

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Studie FAST, Finaler Datenschnitt vom 31.01.2019

1. Time-to-Event-Analysen

Table GM03.1.2003.1: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	4 (7.3%)	2 (3.5%)	
Number of patients censored	51 (92.7%)	55 (96.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.941 [0.355, 10.606]
Log-rank test			
Two-sided stratified log-rank p-value			0.4378

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.2: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	EOX (N= 57)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	55 (100.0%)	57 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			NC

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.3: Summary and Results of first occurence of Vomiting (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	EOX (N= 57)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	2 (3.6%)	2 (3.5%)	
Number of patients censored	53 (96.4%)	55 (96.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.948 [0.133, 6.735]
Log-rank test			
Two-sided stratified log-rank p-value			0.9574

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.4: Summary and Results of Vomiting (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	2 (3.6%)	2 (3.5%)	
Number of patients censored	53 (96.4%)	55 (96.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.909 [0.128, 6.468]
Log-rank test			
Two-sided stratified log-rank p-value			0.9238

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.5: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	4 (7.3%)	3 (5.3%)	
Number of patients censored	51 (92.7%)	54 (94.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.478 [0.327, 6.681]
Log-rank test			
Two-sided stratified log-rank p-value			0.6098

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.6: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	EOX (N= 57)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	55 (100.0%)	57 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			NC

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.7: Summary and Results of first occurence of Nausea (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	3 (5.5%)	3 (5.3%)	
Number of patients censored	52 (94.5%)	54 (94.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.122 [0.223, 5.636]
Log-rank test			
Two-sided stratified log-rank p-value			0.8890

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.8: Summary and Results of Nausea (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	1 (1.8%)	0 (0.0%)	
Number of patients censored	54 (98.2%)	57 (100.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.3243

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.9: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	36 (65.5%)	30 (52.6%)	
Number of patients censored	19 (34.5%)	27 (47.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.0, 4.9]	4.1 [2.0, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.180 [0.720, 1.936]
Log-rank test			
Two-sided stratified log-rank p-value			0.5021

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.10: Summary and Results of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events occuring at visit 1 - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	EOX (N= 57)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	38 (69.1%)	30 (52.6%)	
Number of patients censored	17 (30.9%)	27 (47.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.0 [1.4, 4.9]	4.1 [2.0, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.278 [0.784, 2.083]
Log-rank test			
Two-sided stratified log-rank p-value			0.3179

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.11: Summary and Results of TEAEs (CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	35 (63.6%)	24 (42.1%)	
Number of patients censored	20 (36.4%)	33 (57.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.4 [1.4, 5.7]	7.7 [2.8, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.549 [0.913, 2.629]
Log-rank test			
Two-sided stratified log-rank p-value			0.1011

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.12: Summary and Results of Severe TEAEs (CTCAE Grade >= 4) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	10 (18.2%)	13 (22.8%)	
Number of patients censored	45 (81.8%)	44 (77.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.741 [0.324, 1.696]
Log-rank test			
Two-sided stratified log-rank p-value			0.4762

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.13: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade 3) - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	9 (16.4%)	10 (17.5%)	
Number of patients censored	46 (83.6%)	47 (82.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	11.5 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.838 [0.333, 2.105]
Log-rank test			
Two-sided stratified log-rank p-value			0.6995

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; SOC= system organ class; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2003.14: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade >= 4) - Safety Analysis Set

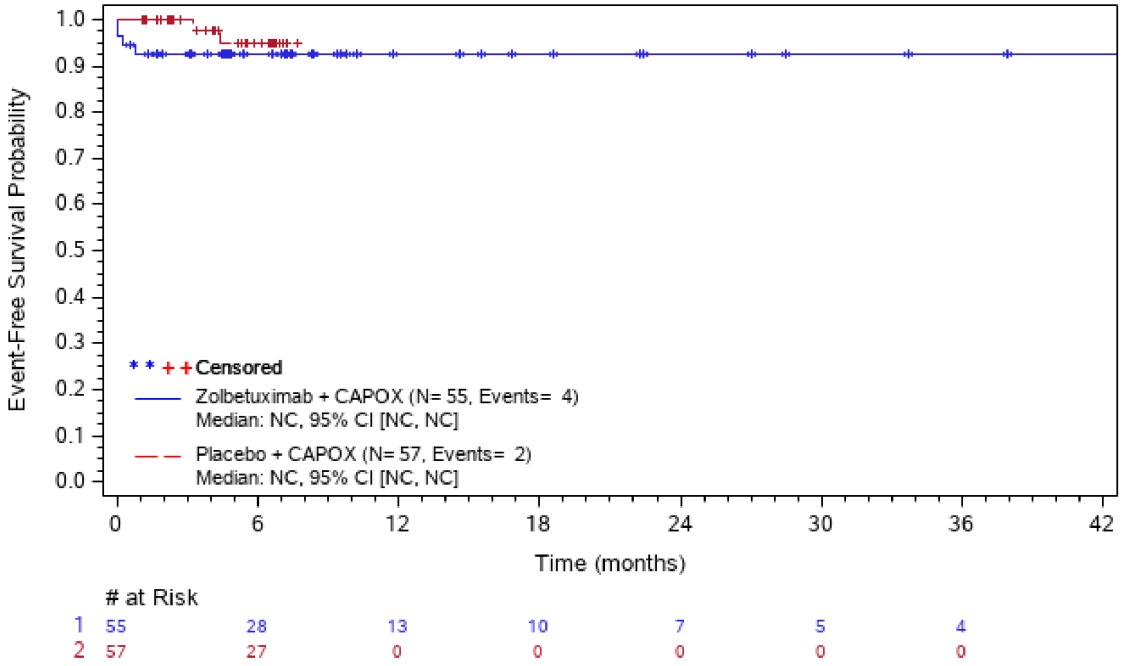
	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	55 (100.0%)	57 (100.0%)	
Number of patients with events	1 (1.8%)	2 (3.5%)	
Number of patients censored	54 (98.2%)	55 (96.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.000 [0.000, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.1711

Abbreviations: CI=confidence interval; CTCAE=common terminology criteria of adverse events; HR=hazard ratio; N=number of patients; NC=not calculated; SOC= system organ class; TEAE=treatment-emergent adverse event.
Note: Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of study treatment + 30 days, death date).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Studie FAST, Finaler Datenschnitt vom 31.01.2019

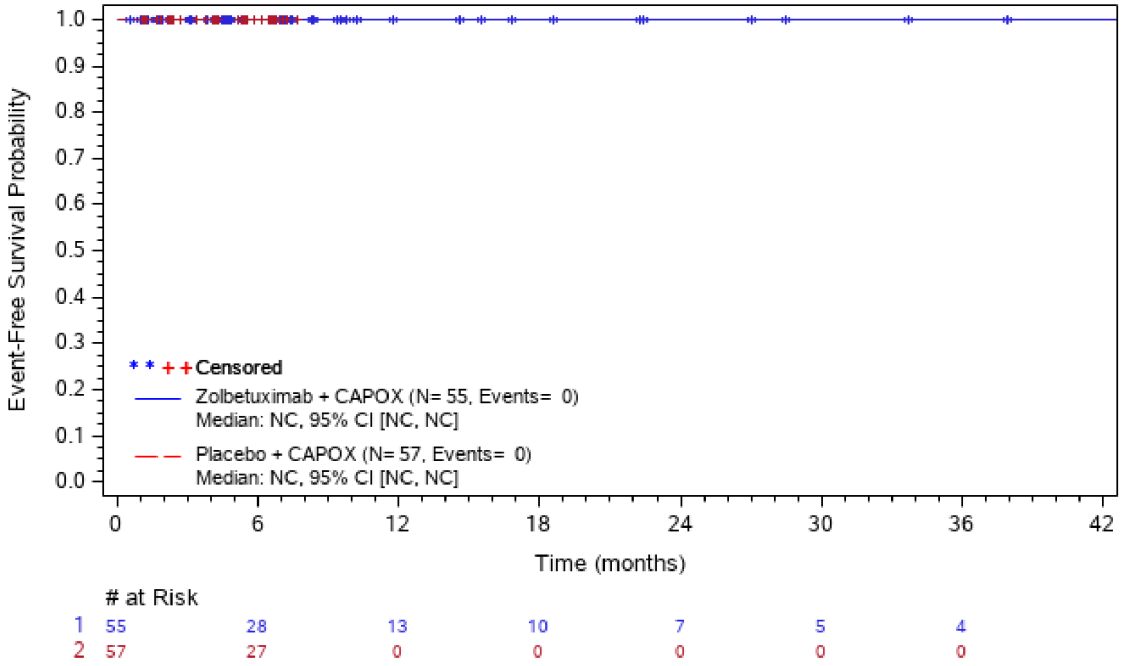
2. Kaplan-Meier-Plots

Figure GM03.1.2003.1: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade 3) - Safety Analysis Set



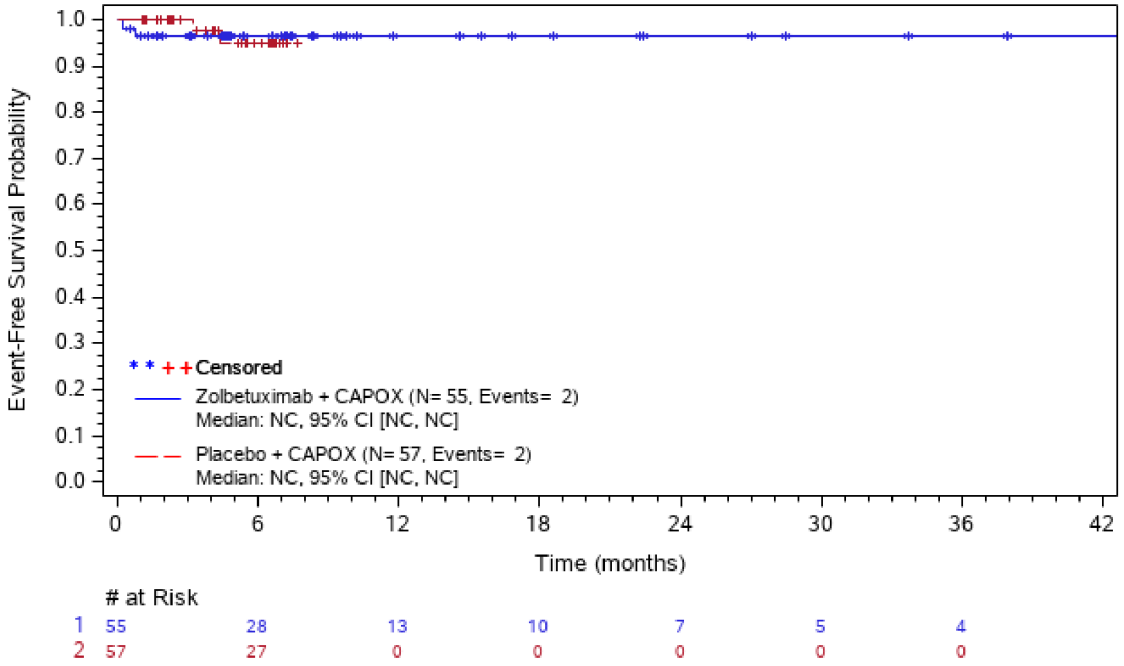
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.2: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade >= 4) - Safety Analysis Set



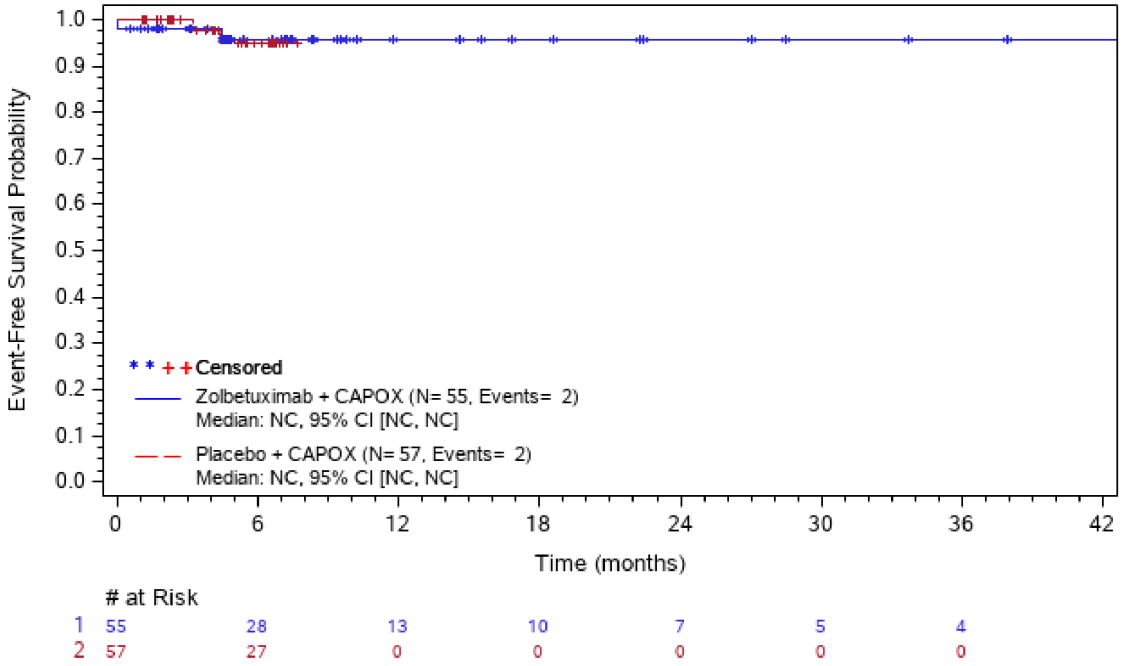
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.3: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAE, CTCAE Grade >= 3) - excluding events occuring at visit 1 - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

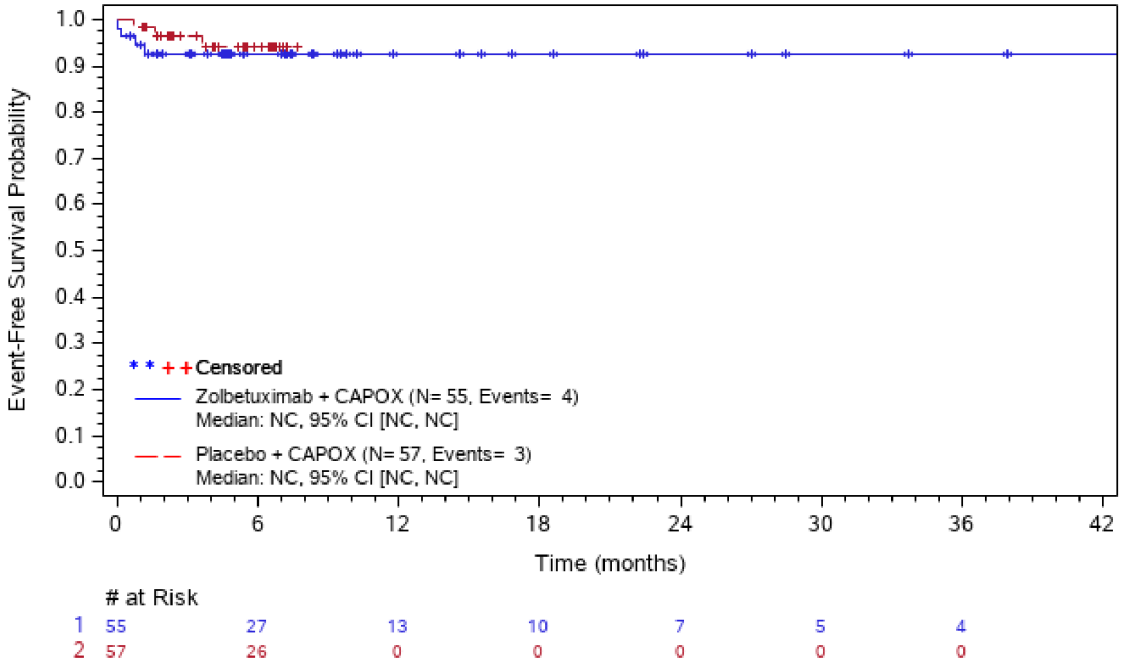
Figure GM03.1.2003.4: Kaplan-Meier Plot of Time to first occurence of Vomiting (TEAESI) - Leading to Permanent Treatment Discontinuation - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.

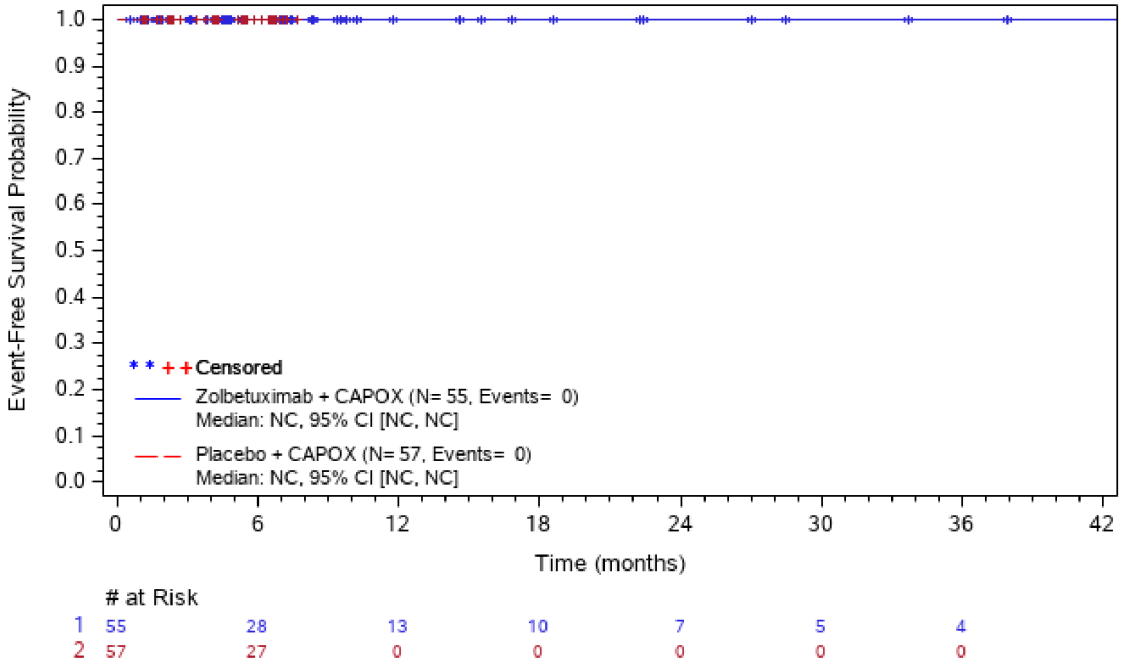
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.5: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade 3) - Safety Analysis Set



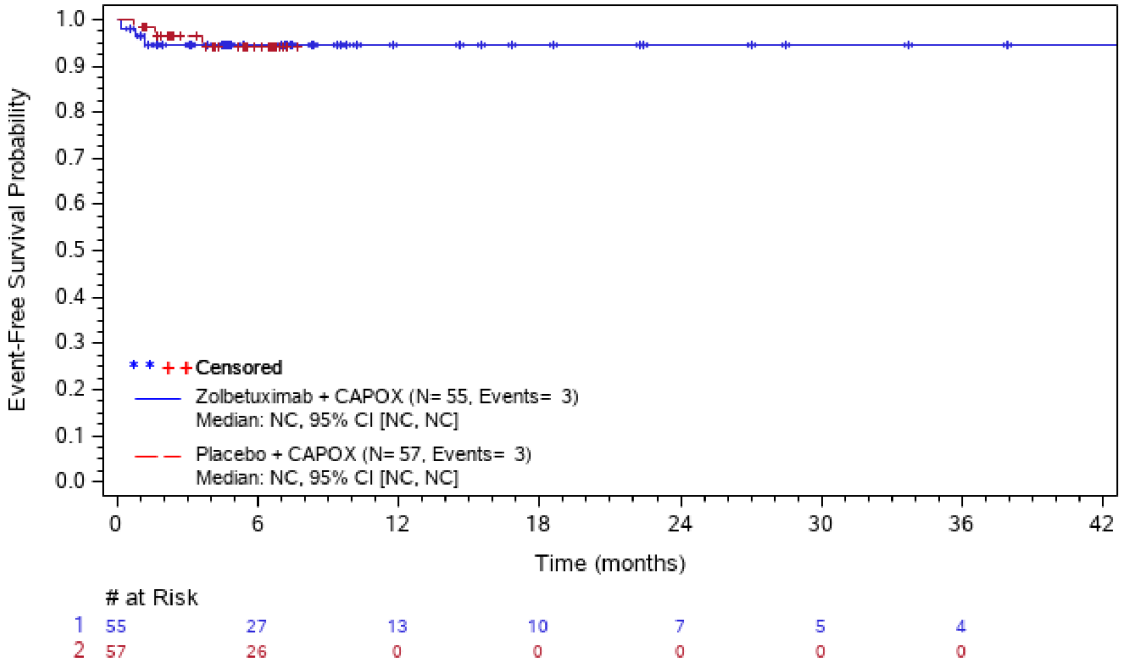
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.6: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade >= 4) - Safety Analysis Set



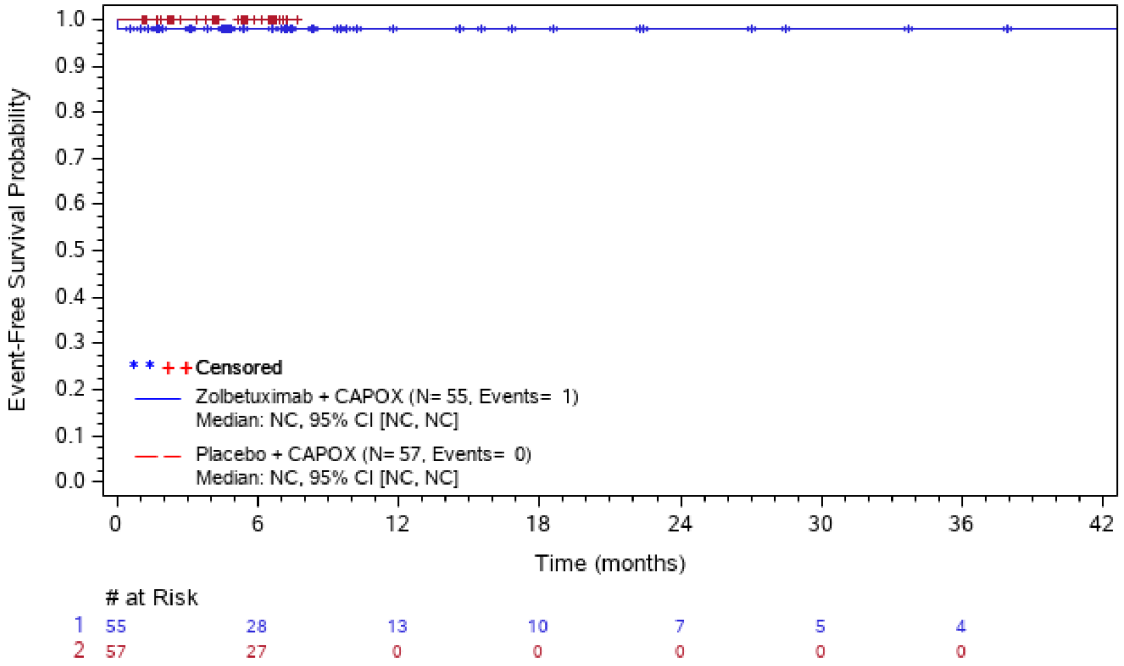
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.7: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set



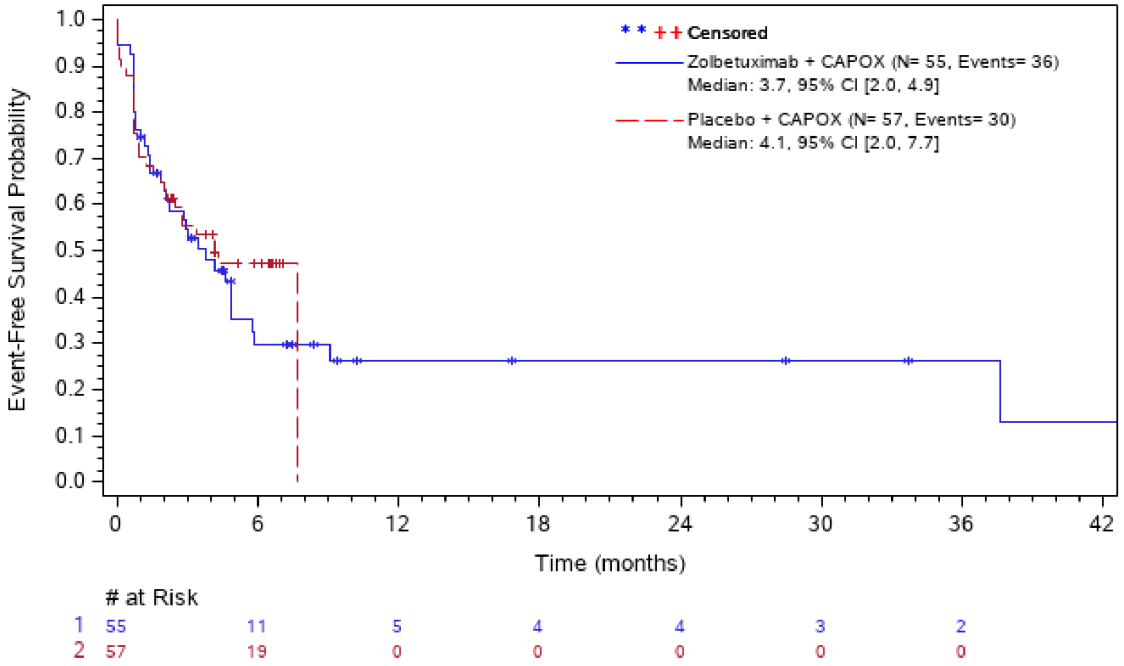
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.8: Kaplan-Meier Plot of Time to first occurence of Nausea (TEAESI) - Leading to Permanent Treatment Discontinuation - Safety Analysis Set



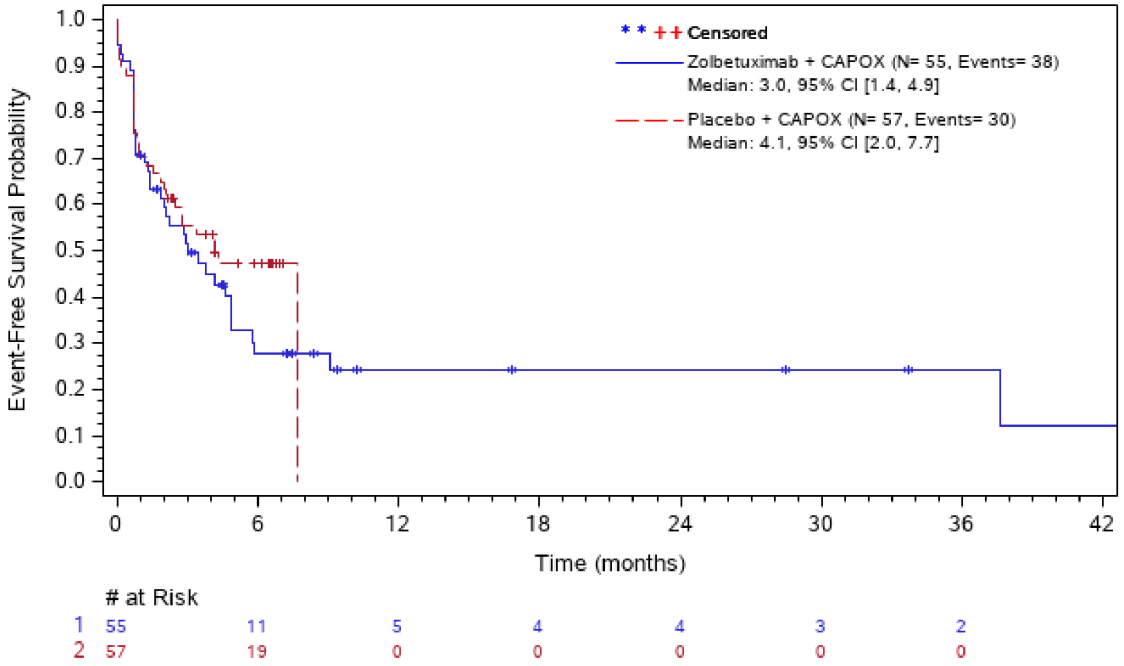
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TEAESI=treatment-emergent adverse event of special interest.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.9: Kaplan-Meier Plot of Time to Severe TEAEs (CTCAE Grade >= 3) - excluding any Nausea and Vomiting events - Safety Analysis Set



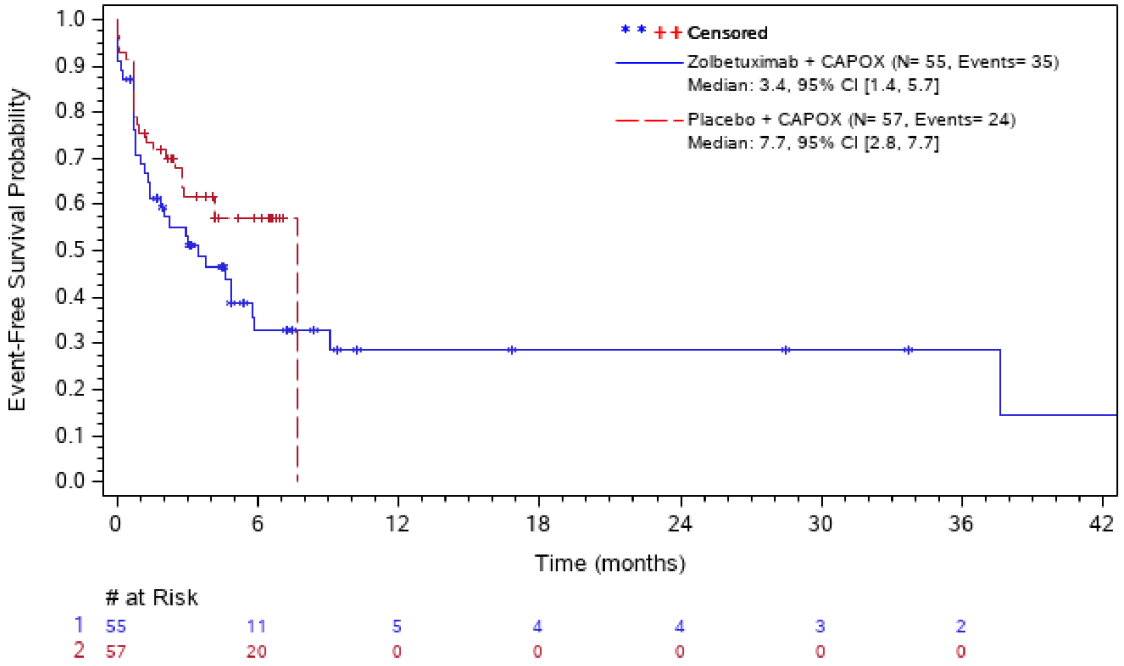
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; PT=preferred term; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.10: Kaplan-Meier Plot of Time to Severe TEAEs (CTCAE Grade >= 3) - excluding any Nausea and Vomiting events occuring at visit 1 - Safety Analysis Set



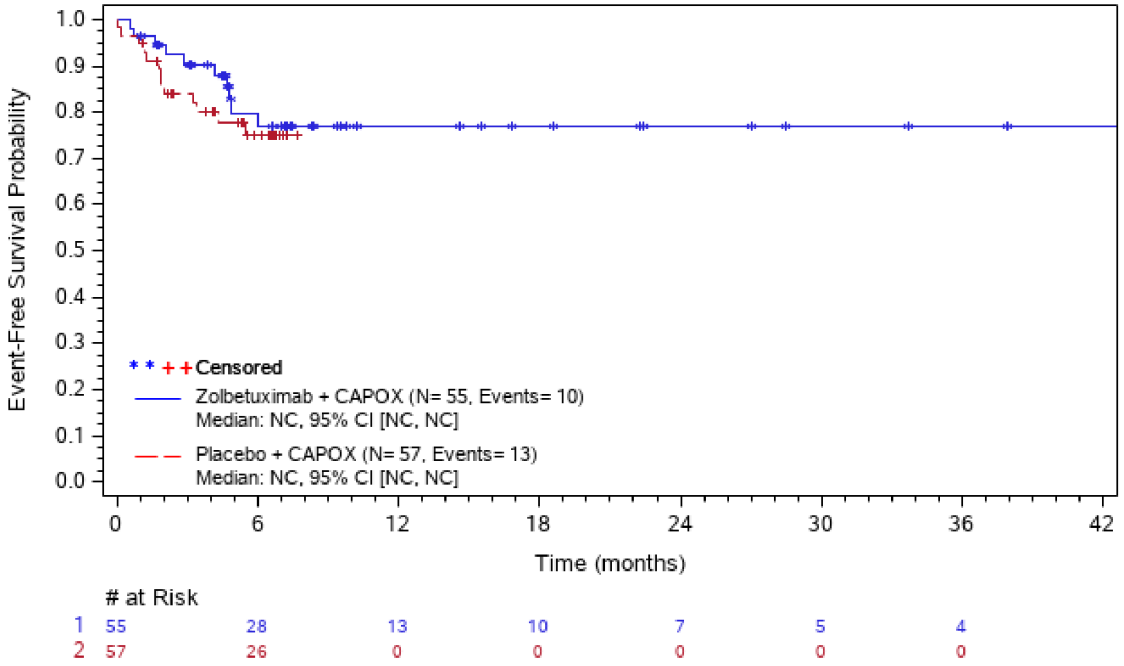
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; PT=preferred term; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.11: Kaplan-Meier Plot of Time to TEAEs - CTCAE Grade 3 - Safety Analysis Set



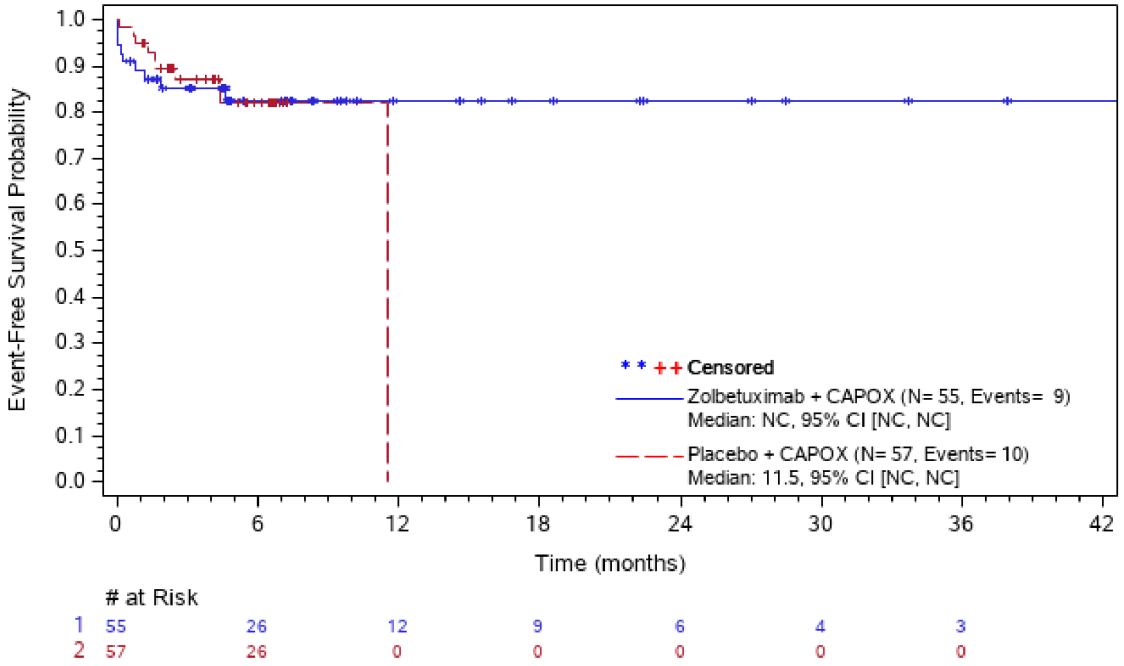
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.12: Kaplan-Meier Plot of Time to Severe TEAE - CTCAE Grade >= 4 - Safety Analysis Set



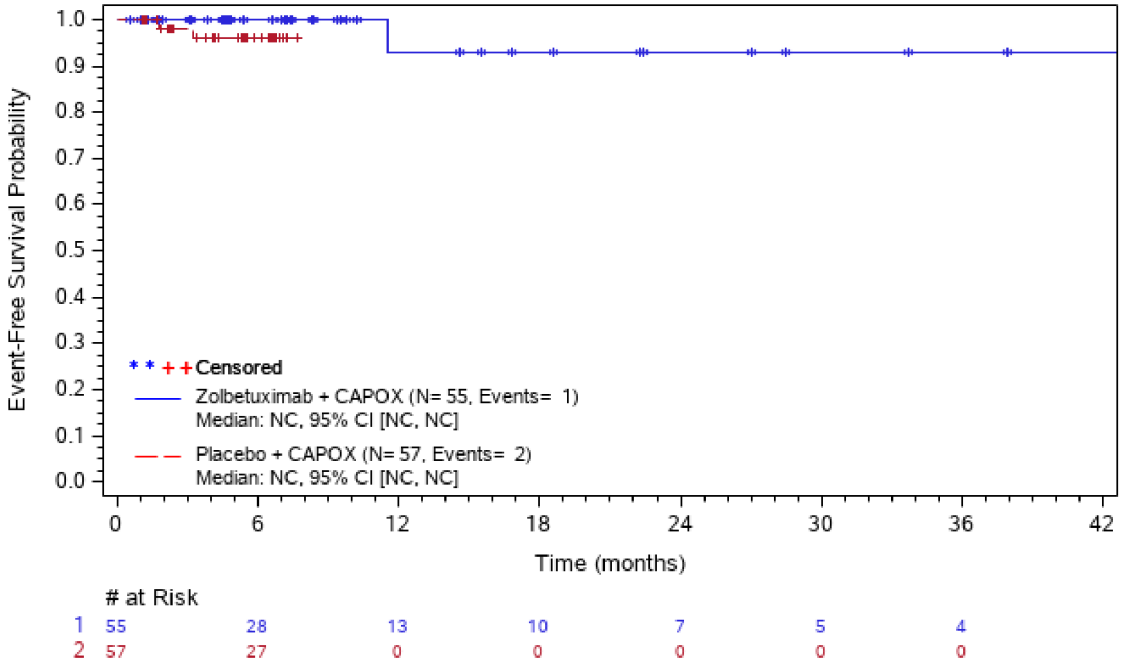
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.13: Kaplan-Meier Plot of Time to TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade 3) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; SOC=system organ class; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2003.14: Kaplan-Meier Plot of Time to Severe TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade >= 4) - Safety Analysis Set



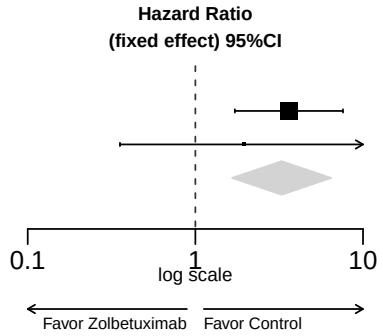
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; CTCAE=common terminology criteria of adverse events; N=number of patients; NC=not calculated; SOC=system organ class; TEAE=treatment-emergent adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G5 Ergänzende Analysen zu Übelkeit und Erbrechen
Anhang 4-G5 Metaanalyse aus den beiden Studien GLOW und FAST

Contents

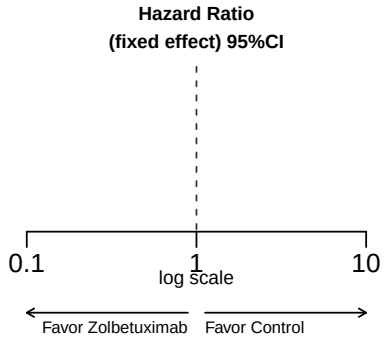
A-MA.3.2003.1: Forest Plot for Hazard Ratio of first occurence of Vomiting (TEAE, CTCAE Grade 3) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	31 / 254	9 / 249	84.0	3.613 [1.720, 7.591]
GM03 − FAST	4 / 55	2 / 57	16.0	1.941 [0.355, 10.606]
Total	**35 / 309**	**11 / 306**	**100**	**3.270 [1.656, 6.457]**
Heterogeneity	Q = 0.43 (df = 1)	p = 0.5112	I² = 0.0%	p(Effect) = 0.0006



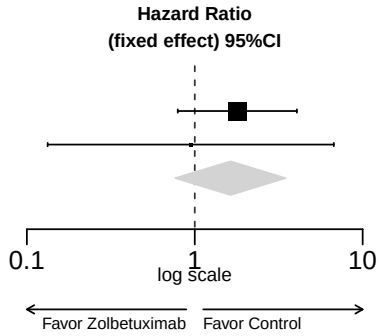
A-MA.3.2003.2: Forest Plot for Hazard Ratio of first occurence of Vomiting (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	0 / 254	0 / 249	NC	NC [NC, NC]
GM03 − FAST	0 / 55	0 / 57	NC	NC [NC, NC]
Total	**0 / 309**	**0 / 306**	**NC**	**NC [NC, NC]**
Heterogeneity	Q = NC	p = NC	I^2 = NC	p(Effect) = NC



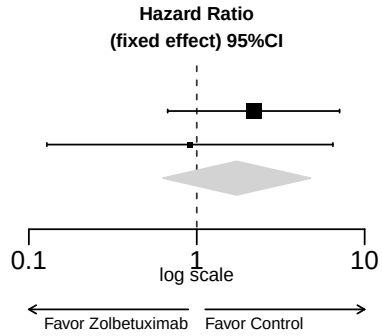
A-MA.3.2003.3: Forest Plot for Hazard Ratio of first occurence of Vomiting (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	16 / 254	9 / 249	85.2	1.792 [0.792, 4.057]
GM03 − FAST	2 / 55	2 / 57	14.8	0.948 [0.133, 6.735]
Total	**18 / 309**	**11 / 306**	**100**	**1.631 [0.767, 3.467]**
Heterogeneity	Q = 0.34 (df = 1)	p = 0.5571	I^2 = 0.0%	p(Effect) = 0.2035



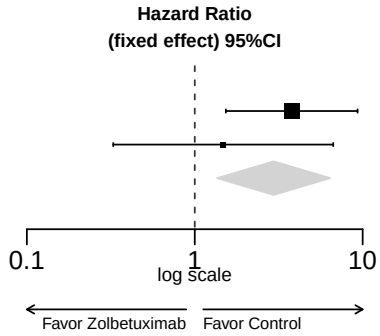
A-MA.3.2003.4: Forest Plot for Hazard Ratio of Vomiting (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	9 / 254	4 / 249	73.5	2.181 [0.671, 7.087]
GM03 − FAST	2 / 55	2 / 57	26.5	0.909 [0.128, 6.468]
Total	**11 / 309**	**6 / 306**	**100**	**1.729 [0.630, 4.748]**
Heterogeneity	Q = 0.56 (df = 1)	p = 0.4535	I² = 0.0%	p(Effect) = 0.2881



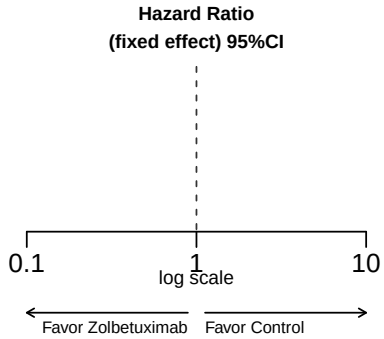
A-MA.3.2003.5: Forest Plot for Hazard Ratio of first occurence of Nausea (TEAE, CTCAE Grade 3) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	22 / 254	6 / 249	73.6	3.779 [1.532, 9.323]
GM03 − FAST	4 / 55	3 / 57	26.4	1.478 [0.327, 6.681]
Total	**26 / 309**	**9 / 306**	**100**	**2.950 [1.359, 6.402]**
Heterogeneity	Q = 1.10 (df = 1)	p = 0.2953	I^2 = 8.7%	p(Effect) = 0.0062



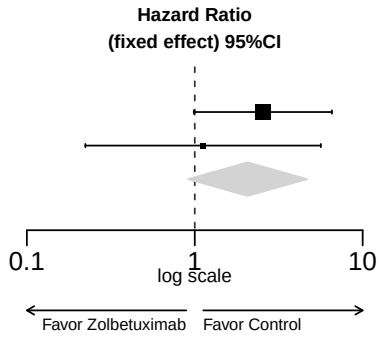
A-MA.3.2003.6: Forest Plot for Hazard Ratio of first occurence of Nausea (TEAE, CTCAE Grade >= 4) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	0 / 254	0 / 249	NC	NC [NC, NC]
GM03 − FAST	0 / 55	0 / 57	NC	NC [NC, NC]
Total	**0 / 309**	**0 / 306**	**NC**	**NC [NC, NC]**
Heterogeneity	Q = NC	p = NC	I² = NC	p(Effect) = NC



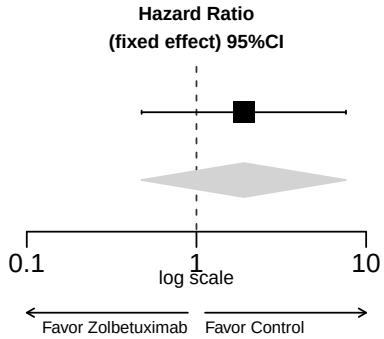
A-MA.3.2003.7: Forest Plot for Hazard Ratio of first occurence of Nausea (TEAE, CTCAE Grade >= 3) excluding events occuring at visit 1 - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	15 / 254	6 / 249	74.4	2.545 [0.987, 6.564]
GM03 − FAST	3 / 55	3 / 57	25.6	1.122 [0.223, 5.636]
Total	**18 / 309**	**9 / 306**	**100**	**2.064 [0.911, 4.672]**
Heterogeneity	Q = 0.74 (df = 1)	p = 0.3912	I² = 0.0%	p(Effect) = 0.0823



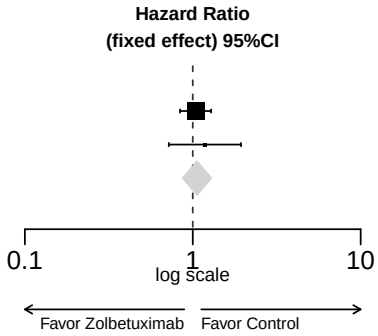
A-MA.3.2003.8: Forest Plot for Hazard Ratio of Nausea (TEAESI) leading to Permanent Treatment Discontinuation - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	6 / 254	3 / 249	100	1.900 [0.475, 7.604]
GM03 − FAST	1 / 55	0 / 57	NC	NC [NC, NC]
Total	**7 / 309**	**3 / 306**	**100**	**1.900 [0.475, 7.602]**
Heterogeneity	Q = NC	p = NC	I² = NC	p(Effect) = 0.3643



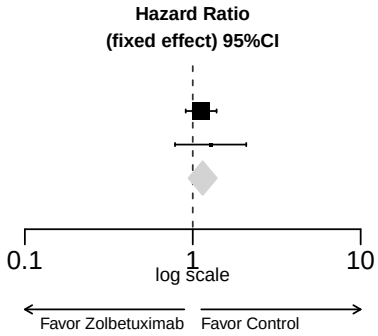
A-MA.3.2003.9: Forest Plot for Hazard Ratio of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	174 / 254	175 / 249	84.4	1.040 [0.840, 1.286]
GM03 − FAST	36 / 55	30 / 57	15.6	1.180 [0.720, 1.936]
Total	**210 / 309**	**205 / 306**	**100**	**1.061 [0.872, 1.290]**
Heterogeneity	Q = 0.21 (df = 1)	p = 0.6457	I^2 = 0.0%	p(Effect) = 0.5545



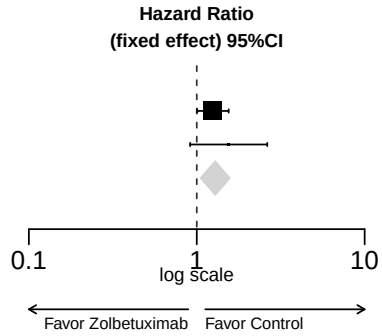
A-MA.3.2003.10: Forest Plot for Hazard Ratio of Severe TEAEs (CTCAE Grade >= 3) excluding any Nausea and Vomiting events occuring at visit 1 - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	179 / 254	175 / 249	84.2	1.122 [0.908, 1.386]
GM03 − FAST	38 / 55	30 / 57	15.8	1.278 [0.784, 2.083]
Total	**217 / 309**	**205 / 306**	**100**	**1.145 [0.943, 1.391]**
Heterogeneity	Q = 0.23 (df = 1)	p = 0.6317	I^2 = 0.0%	p(Effect) = 0.1707



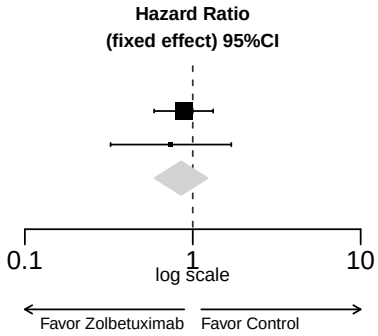
A-MA.3.2003.11: Forest Plot for Hazard Ratio of TEAEs (CTCAE Grade 3) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	177 / 254	164 / 249	85.8	1.249 [1.007, 1.548]
GM03 − FAST	35 / 55	24 / 57	14.2	1.549 [0.913, 2.629]
Total	**212 / 309**	**188 / 306**	**100**	**1.288 [1.055, 1.572]**
Heterogeneity	Q = 0.55 (df = 1)	p = 0.4598	I^2 = 0.0%	p(Effect) = 0.0128



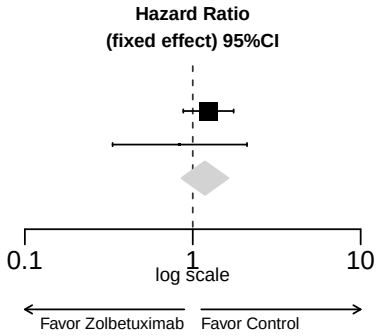
A-MA.3.2003.12: Forest Plot for Hazard Ratio of Severe TEAEs (CTCAE Grade >= 4) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	45 / 254	52 / 249	80.7	0.882 [0.589, 1.322]
GM03 − FAST	10 / 55	13 / 57	19.3	0.741 [0.324, 1.696]
Total	**55 / 309**	**65 / 306**	**100**	**0.853 [0.593, 1.226]**
Heterogeneity	Q = 0.14 (df = 1)	p = 0.7109	I^2 = 0.0%	p(Effect) = 0.3906



A-MA.3.2003.13: Forest Plot for Hazard Ratio of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade 3) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	71 / 254	60 / 249	87.7	1.240 [0.878, 1.751]
GM03 − FAST	9 / 55	10 / 57	12.3	0.838 [0.333, 2.105]
Total	**80 / 309**	**70 / 306**	**100**	**1.182 [0.855, 1.633]**
Heterogeneity	Q = 0.61 (df = 1)	p = 0.4353	I^2 = 0.0%	p(Effect) = 0.3114



A-MA.3.2003.14: Forest Plot for Hazard Ratio of TEAEs - Gastrointestinal Disorders (SOC, CTCAE Grade >= 4) - Safety Analysis Set

Study	Zolbetuximab Events / Total	Placebo Events / Total	Weights (%)	Hazard Ratio (fixed effect) 95%CI
302 − GLOW	8 / 254	8 / 249	100	1.081 [0.405, 2.882]
GM03 − FAST	1 / 55	2 / 57	NC	0.000 [0.000, NC]
Total	**9 / 309**	**10 / 306**	**100**	**1.081 [0.405, 2.884]**
Heterogeneity	Q = NC	p = NC	I² = NC	p(Effect) = 0.8764