Dossier zur Nutzenbewertung gemäß § 35a SGB V

Zolbetuximab (VYLOY™)

Astellas Pharma GmbH

Modul 4 A, Anhang 4-G2

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

Studie FAST

Finaler Datenschnitt vom 31.01.2019

Stand: 30.10.2024

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Anhang 4-G2 Post hoc Analysen für die Studie FAST, Datenschnitt 31.01.2019

Anhang 4-G2 Baseline Charakteristika

Table GM03.1.1001.1: Summary of Baseline Demographics - mITT Analysis Set

Parameter and Category/Statistic	Zolbetuximab + EOX (N= 56)	EOX (N= 58)
Sex		
Male	32 (57.1%)	37 (63.8%)
Female	24 (42.9%)	21 (36.2%)
Age (years)		
n	56	58
Mean (SD)	57.34 (10.36)	55.66 (10.63)
Median	58.5	57.0
Range	32.0 - 77.0	24.0 - 73.0
Age (years)		
>=18 to <=64	43 (76.8%)	47 (81.0%)
>=65 to <85	13 (23.2%)	11 (19.0%)
>=85	0	0
Age Group 1 (years)		
<=65	44 (78.6%)	48 (82.8%)
>65	12 (21.4%)	10 (17.2%)
Age Group 2 (years)		
<=75	55 (98.2%)	58 (100.0%)
>75	1 (1.8%)	0
Race		
White	52 (92.9%)	55 (94.8%)
Black or African American	0	0
Asian	0	0
American Indian or Alaska Native	0	0
Native Hawaiian or Other Pacific Islander	0	0
Other	4 (7.1%)	3 (5.2%)

Abbreviations: BMI=body mass index; BSA=body surface area; ECOG=eastern cooperative oncology group; mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.1: Summary of Baseline Demographics - mITT Analysis Set

Parameter and Category/Statistic	Zolbetuximab + EOX (N= 56)	EOX (N= 58)
Height (cm)		
n	56	58
Mean (SD)	169.61 (10.45)	168.17 (8.30)
Median	170.0	168.0
Range	150.0 - 196.0	146.0 - 185.0
Weight (kg)		
n	56	58
Mean (SD)	69.75 (15.41)	64.02 (11.87)
Median	68.0	63.0
Range	46.0 - 113.0	41.0 - 102.0
BMI (kg/m^2)		
<18.5	3 (5.4%)	4 (6.9%)
>=18.5 to <25	30 (53.6%)	42 (72.4%)
>=25 to <30	14 (25.0%)	11 (19.0%)
>=30	9 (16.1%)	1 (1.7%)
BSA (m^2)		
n	56	58
Mean (SD)	1.80 (0.22)	1.72 (0.18)
Median	1.8	1.7
Range	1.4 - 2.5	1.4 - 2.2
BSA (m^2)		
<1.7	13 (23.2%)	20 (34.5%)
>=1.7	43 (76.8%)	38 (65.5%)
Baseline ECOG Status		
0	20 (35.7%)	16 (27.6%)

Abbreviations: BMI=body mass index; BSA=body surface area; ECOG=eastern cooperative oncology group; mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.1: Summary of Baseline Demographics - mITT Analysis Set

Parameter and Category/Statistic	Zolbetuximab + EOX (N= 56)	EOX (N= 58)
>=1	36 (64.3%)	42 (72.4%)
Number of Organs with Metastatic Sites		
0-2	18 (32.1%)	18 (31.0%)
>=3	38 (67.9%)	40 (69.0%)
Prior Gastrectomy		
Yes	13 (23.2%)	16 (27.6%)
No	43 (76.8%)	42 (72.4%)

Abbreviations: BMI=body mass index; BSA=body surface area; ECOG=eastern cooperative oncology group; mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.3: Summary of Primary Diagnosis - mITT Analysis Set

Parameter	Category/Statistic	Zolbetuximab + EOX (N=56)	EOX (N=58)
Time since First Diagnosis of Gastroesophageal Cancer (months)	n	56	58
	Mean (SD)	4.93 (13.30)	4.07 (5.70)
	Median	1.6	1.5
	Range	0.4 - 96.0	0.4 - 24.1
Time since Histology (months)	n	56	58
	Mean (SD)	3.11 (4.81)	6.08 (19.08)
	Median	1.4	1.5
	Range	0.4 - 26.3	0.4 - 143.9
Location of Tumor at First Diagnosis	Gastroesophageal Junction	7 (12.5%)	9 (15.5%)
	Cardia Carcinoma	5 (8.9%)	5 (8.6%)
	Distal Esophageal Carcinoma	1 (1.8%)	3 (5.2%)
	Subcardia Carcinoma	1 (1.8%)	1 (1.7%)
	Missing	1	1
	Stomach	49 (87.5%)	49 (84.5%)
	Antrum	6 (10.7%)	12 (20.7%)
	Corpus	39 (69.6%)	34 (58.6%)
	Fundus	7 (12.5%)	6 (10.3%)
	Pylorus	4 (7.1%)	8 (13.8%)
T-Classification at First Diagnosis	1	1 (1.8%)	1 (1.7%)
	2	0	3 (5.2%)
	3	15 (26.8%)	15 (25.9%)
	4	32 (57.1%)	32 (55.2%)
	4A	1 (1.8%)	1 (1.7%)
	X	7 (12.5%)	6 (10.3%)
N-Classification at First Diagnosis	0	9 (16.1%)	4 (7.0%)

Abbreviations: CTC=common terminology criteria; mITT=modified intention-to-treat; N=number of patients in treatment arm; n=number of patients; NCI=national cancer institute; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.3: Summary of Primary Diagnosis - mITT Analysis Set

Parameter	Category/Statistic	Zolbetuximab + EOX (N=56)	EOX (N=58)
	1	15 (26.8%)	17 (29.8%)
	2	16 (28.6%)	19 (33.3%)
	3	4 (7.1%)	2 (3.5%)
	3A	1 (1.8%)	0
	X	11 (19.6%)	15 (26.3%)
	Missing	0	1
M-Classification at First Diagnosis	0	8 (14.3%)	13 (22.4%)
	1	46 (82.1%)	43 (74.1%)
	2	1 (1.8%)	1 (1.7%)
	X	1 (1.8%)	1 (1.7%)
Type of Tumor at Histological Diagnosis	Diffuse	30 (53.6%)	27 (46.6%)
	Intestinal	13 (23.2%)	15 (25.9%)
	Mixed	8 (14.3%)	9 (15.5%)
	Signet Ring Cell Carcinoma	0	1 (1.7%)
	Unknown	5 (8.9%)	6 (10.3%)
Extent at Study Entry	Locally Advanced	1 (1.8%)	3 (5.2%)
	Metastatic	55 (98.2%)	55 (94.8%)
NCI CTC Grade for Pain/Tumor Pain at Study Entry	1	35 (85.4%)	30 (81.1%)
	2	5 (12.2%)	7 (18.9%)
	3	1 (2.4%)	0
	Missing	15	21
HER2 Test at Study Entry	Negative	6 (10.7%)	7 (12.1%)
	Not Assessed	50 (89.3%)	50 (86.2%)
	Unknown	0	1 (1.7%)
HER2 Test (Categorized) at Study Entry	0	4 (66.7%)	7 (87.5%)

Abbreviations: CTC=common terminology criteria; mITT=modified intention-to-treat; N=number of patients in treatment arm; n=number of patients; NCI=national cancer institute; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.3: Summary of Primary Diagnosis - mITT Analysis Set

Parameter	Category/Statistic	Zolbetuximab + EOX (N=56)	EOX (N=58)
	1+	2 (33.3%)	0
	Unknown	0	1 (12.5%)
	Missing	50	50
Metastatic Sites at Study Entry	n	56	58
	Mean (SD)	3.29 (1.42)	3.14 (1.36)
	Median	3.0	3.0
	Range	1.0 - 7.0	1.0 - 7.0
Location of Metastatic Sites at Study Entry	Liver	17 (30.4%)	20 (34.5%)
	Lung	12 (21.4%)	8 (13.8%)
	Lymph	45 (80.4%)	45 (77.6%)
	Primary Tumor	37 (66.1%)	38 (65.5%)
	Other	38 (67.9%)	36 (62.1%)
	Peritoneal Carcinomatosis	16 (28.6%)	18 (31.0%)
Tumor Grade at Histological Diagnosis	1	1 (1.9%)	1 (2.0%)
	2	12 (22.6%)	8 (16.0%)
	3	15 (28.3%)	18 (36.0%)
	4	25 (47.2%)	23 (46.0%)
	Missing	3	8
CLDN18.2 at Study Entry	2+	14 (25.0%)	18 (31.0%)
	3+	42 (75.0%)	40 (69.0%)
Number of CLDN18.2 Stained Cells at Study Entry	n	56	58
	Mean (SD)	83.75 (8.11)	82.88 (8.10)
	Median	82.5	80.0
	Range	70.0 - 100.0	70.0 - 100.0
Measurable Disease at Study Entry	Measurable	43 (76.8%)	44 (75.9%)

Abbreviations: CTC=common terminology criteria; mITT=modified intention-to-treat; N=number of patients in treatment arm; n=number of patients; NCI=national cancer institute; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.3: Summary of Primary Diagnosis - mITT Analysis Set

Parameter	Category/Statistic	Zolbetuximab + EOX (N=56)	EOX (N=58)
	Non-Measurable	13 (23.2%)	14 (24.1%)

Abbreviations: CTC=common terminology criteria; mITT=modified intention-to-treat; N=number of patients in treatment arm; n=number of patients; NCI=national cancer institute; SD=standard deviation.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.4: Summary of Pre-Existing Conditions by SOC/PT - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Overall	6 (10.9%)	6 (10.5%)	12 (10.7%)
Blood And Lymphatic System Disorders	3 (5.5%)	0	3 (2.7%)
Anaemia	3 (5.5%)	0	3 (2.7%)
Gastrointestinal Disorders	0	2 (3.5%)	2 (1.8%)
Constipation	0	2 (3.5%)	2 (1.8%)
Vomiting	0	1 (1.8%)	1 (0.9%)
General Disorders And Administration Site Conditions	0	2 (3.5%)	2 (1.8%)
Asthenia	0	2 (3.5%)	2 (1.8%)
Investigations	3 (5.5%)	1 (1.8%)	4 (3.6%)
Alanine Aminotransferase Increased	1 (1.8%)	1 (1.8%)	2 (1.8%)
Aspartate Aminotransferase Increased	1 (1.8%)	1 (1.8%)	2 (1.8%)
C-Reactive Protein Increased	1 (1.8%)	1 (1.8%)	2 (1.8%)
Blood Lactate Dehydrogenase Increased	1 (1.8%)	0	1 (0.9%)
Platelet Count Increased	0	1 (1.8%)	1 (0.9%)
Metabolism And Nutrition Disorders	0	1 (1.8%)	1 (0.9%)
Hypoalbuminaemia	0	1 (1.8%)	1 (0.9%)
Musculoskeletal And Connective Tissue Disorders	0	1 (1.8%)	1 (0.9%)
Muscle Haemorrhage	0	1 (1.8%)	1 (0.9%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	1 (1.8%)	0	1 (0.9%)
Uterine Leiomyoma	1 (1.8%)	0	1 (0.9%)
Psychiatric Disorders	0	1 (1.8%)	1 (0.9%)
Insomnia	0	1 (1.8%)	1 (0.9%)
Reproductive System And Breast Disorders	0	1 (1.8%)	1 (0.9%)

Abbreviations: MedDRA=medical dictionary for regulatory activities; N=number of patients in treatment arm; PT=preferred term; SOC=system organ class.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.4: Summary of Pre-Existing Conditions by SOC/PT - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Benign Prostatic Hyperplasia	0	1 (1.8%)	1 (0.9%)
Vascular Disorders	0	1 (1.8%)	1 (0.9%)
Arteriosclerosis	0	1 (1.8%)	1 (0.9%)
Vasculitis	0	1 (1.8%)	1 (0.9%)

Abbreviations: MedDRA=medical dictionary for regulatory activities; N=number of patients in treatment arm; PT=preferred term; SOC=system organ class.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G2 Gesamtüberleben

1. Time-to-Event-Analyse

Table GM03.1.1002.1.1: Summary of Overall Survival - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	45 (80.4%)	54 (93.1%)	
Number of patients censored	11 (19.6%)	4 (6.9%)	
Probability of being event-free (a) [95% CI] (b) at			
Month 6	85.1 [72.4, 92.3]	75.0 [61.5, 84.4]	10.0 [-4.8, 24.8], p=0.1840
Month 12	62.4 [48.0, 73.9]	31.1 [19.5, 43.5]	31.3 [13.4, 49.2], p=0.0006
Month 18	47.3 [33.4, 59.9]	9.2 [3.4, 18.5]	38.1 [22.7, 53.6], p=<.0001
Month 24	35.4 [22.7, 48.2]	7.3 [2.4, 16.2]	28.1 [13.3, 42.8], p=0.0002
Month 30	27.1 [15.7, 39.7]	7.3 [2.4, 16.2]	19.7 [5.7, 33.8], p=0.0060
Month 36	16.6 [7.9, 28.2]	7.3 [2.4, 16.2]	9.3 [-3.2, 21.8], p=0.1430
Month 42	14.6 [6.5, 25.8]	5.5 [1.4, 13.7]	9.1 [-2.5, 20.6], p=0.1240
Month 48	12.5 [5.1, 23.3]	5.5 [1.4, 13.7]	7.0 [-4.1, 18.0], p=0.2149
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI (c)			
50%	16.5 [10.3, 22.6]	8.9 [7.1, 11.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.493 [0.328, 0.742]
Log-rank test			
Two-sided stratified log-rank p-value			0.0006

Abbreviations: CI=confidence interval; HR=hazard ratio; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
Note: The stratification factor is presence of disease at baseline (non-measurable vs. measurable).
(a) Estimated from the Kaplan-Meier Method; (b) Calculated using the log-log transformation according to Kalbfleisch and Prentice and Greenwood's formula for computing the standard error of the survival estimate; (c) Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.1.2: Type of Events and Censoring of Overall Survival - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Number of patients at risk	56 (100.0%)	58 (100.0%)
Number of patients with events	45 (80.4%)	54 (93.1%)
Death	45 (80.4%)	54 (93.1%)
Number of patients censored	11 (19.6%)	4 (6.9%)
Censored at End of Study	11 (19.6%)	4 (6.9%)

Abbreviations: mITT=modified intention-to-treat; N=number of patients.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.1.3: Summary of Overall Survival by Subgroups - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	35 (79.5)	20.1 [12.1, 22.6]	48	46 (95.8)	8.9 [7.1, 11.0]	0.336 [0.207, 0.544]	<.0001	0.0312
>65 years	12	10 (83.3)	10.3 [6.0, 30.3]	10	8 (80.0)	9.6 [1.2, 66.3]	1.152 [0.449, 2.957]	0.7687	
Sex									
Male	32	25 (78.1)	16.6 [9.7, 29.3]	37	34 (91.9)	8.6 [6.8, 10.9]	0.349 [0.200, 0.608]	0.0001	0.0523
Female	24	20 (83.3)	13.7 [7.8, 24.8]	21	20 (95.2)	10.7 [6.9, 16.3]	0.759 [0.405, 1.424]	0.3988	
Number of Organs with Metastatic Sites									
0-2	18	15 (83.3)	16.5 [10.3, 27.2]	18	15 (83.3)	13.0 [9.9, 17.4]	0.709 [0.343, 1.466]	0.3591	0.0615
>=3	38	30 (78.9)	16.6 [8.3, 26.5]	40	39 (97.5)	7.1 [5.3, 8.6]	0.408 [0.248, 0.672]	0.0003	
Prior Gastrectomy (total or partial)									
Yes	13	10 (76.9)	12.8 [6.7, 21.3]	16	14 (87.5)	11.4 [8.6, 17.5]	0.930 [0.411, 2.101]	0.8611	0.0316
No	43	35 (81.4)	20.2 [9.7, 27.2]	42	40 (95.2)	8.3 [6.4, 9.6]	0.327 [0.198, 0.539]	<.0001	
Histology (Tumor Type)									
Diffuse	30	25 (83.3)	16.6 [9.7, 27.2]	27	25 (92.6)	8.6 [6.8, 11.1]	0.318 [0.166, 0.612]	0.0003	0.0740
Intestinal	13	11 (84.6)	20.2 [4.9, 26.5]	15	14 (93.3)	12.3 [3.9, 17.5]	0.946 [0.413, 2.171]	0.8966	
Mixed/Other	8	5 (62.5)	21.7 [6.1, NC]	10	9 (90.0)	8.3 [1.3, 16.3]	0.240 [0.063, 0.924]	0.0259	
Tumor Location 1									
Gastric	49	39 (79.6)	16.6 [9.7, 22.6]	49	45 (91.8)	9.6 [7.9, 11.1]	0.514 [0.331, 0.798]	0.0026	0.5663
GEJ	7	6 (85.7)	13.0 [6.7, 43.0]	9	9 (100.0)	8.3 [1.7, 13.8]	0.344 [0.104, 1.140]	0.0685	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients; n=number of patients with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.1.3: Summary of Overall Survival by Subgroups - mITT Analysis Set

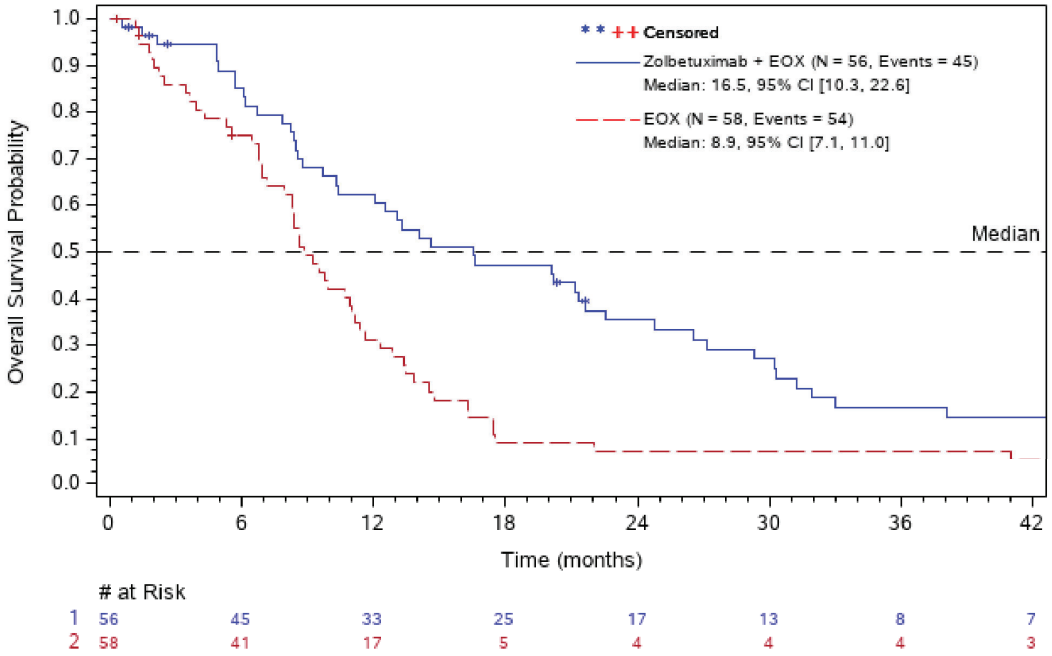
	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Tumor Location 2									
Gastric Proximal	41	33 (80.5)	20.2 [9.7, 24.8]	33	30 (90.9)	8.6 [5.6, 11.0]	0.444 [0.265, 0.745]	0.0018	0.3534
Gastric Distal	6	5 (83.3)	11.4 [8.2, NC]	12	12 (100.0)	9.7 [5.3, 22.0]	0.725 [0.253, 2.080]	0.5487	
Tumor Location 3									
GEJ Proximal	1	1 (100.0)	6.7 [NC, NC]	2	2 (100.0)	9.6 [6.9, 12.3]	5.64E8 [0.000, NC]	0.1573	0.9952
GEJ Distal	5	4 (80.0)	29.3 [12.1, 43.0]	5	5 (100.0)	8.3 [6.7, 13.8]	0.165 [0.030, 0.892]	0.0198	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients; n=number of patients with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G2 Gesamtüberleben

2. Kaplan-Meier-Plots

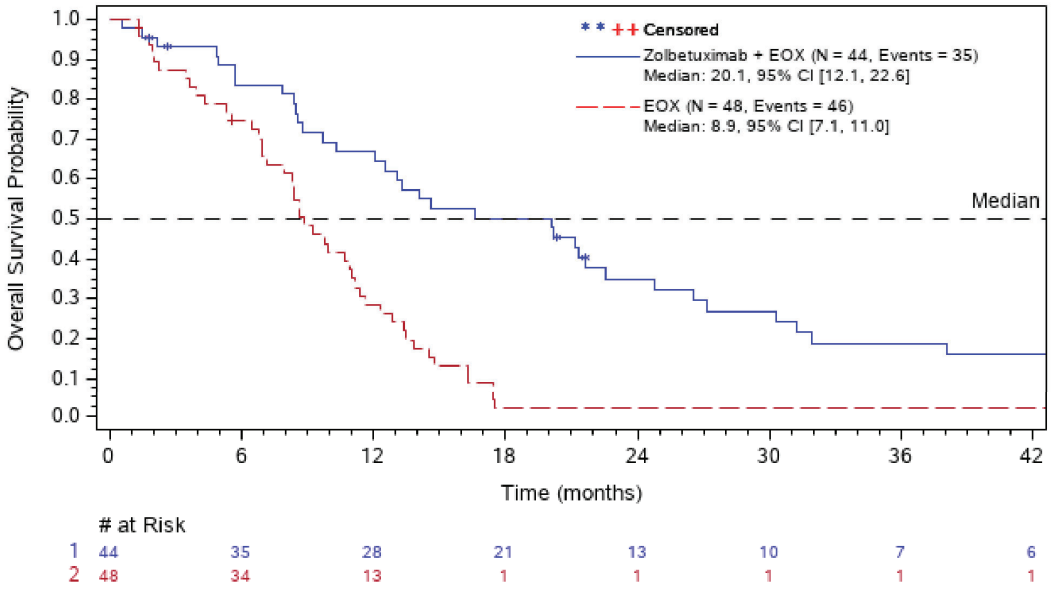
Figure GM03.1.1002.1: Kaplan-Meier Plot of Overall Survival - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.1002.1.1: Kaplan-Meier Plot of Overall Survival by Age Group 1 - mITT Analysis Set

Age Group 1: <=65 years

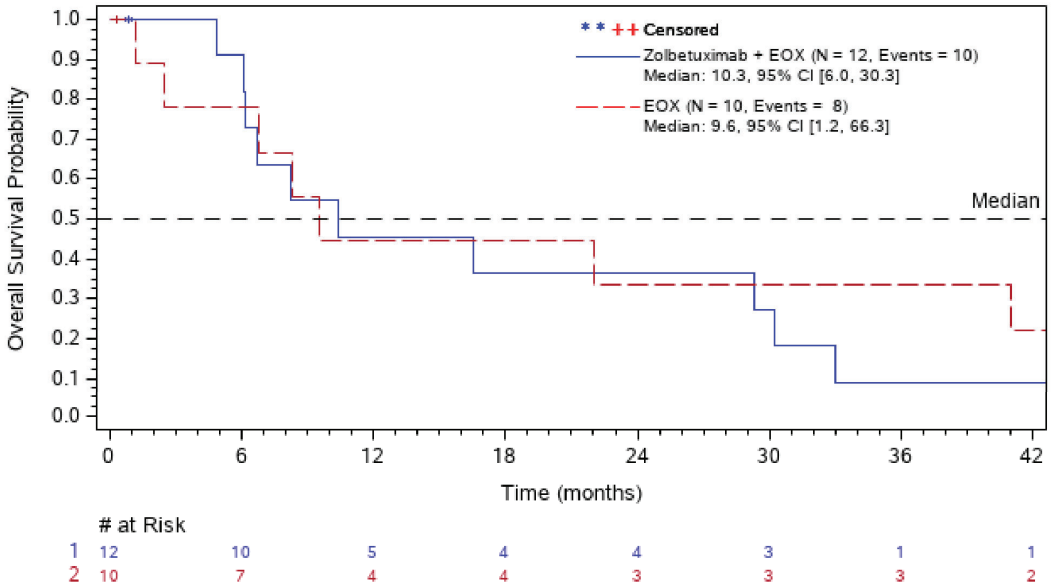


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.1002.1.1: Kaplan-Meier Plot of Overall Survival by Age Group 1 - mITT Analysis Set

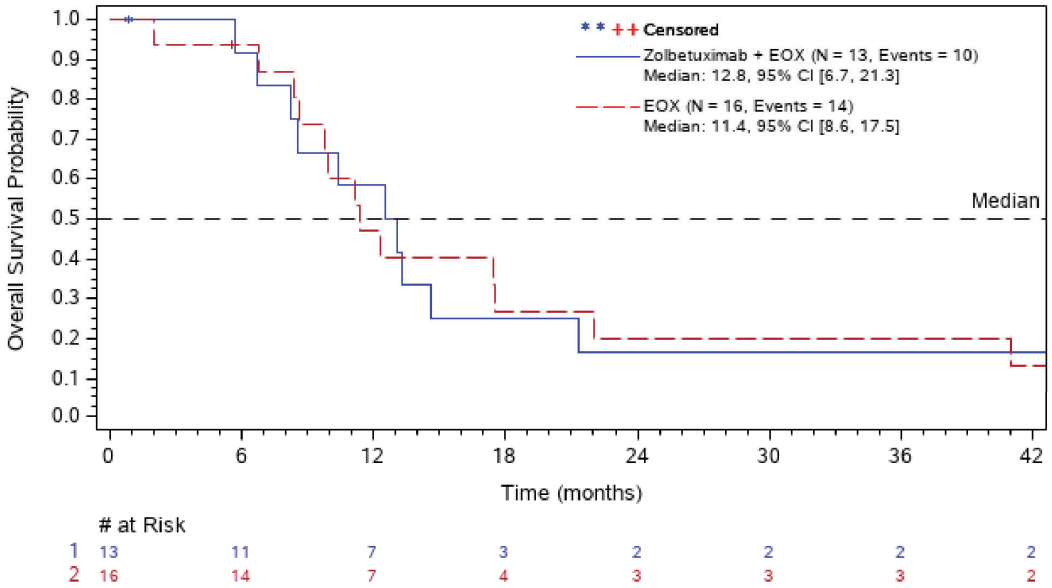
Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.

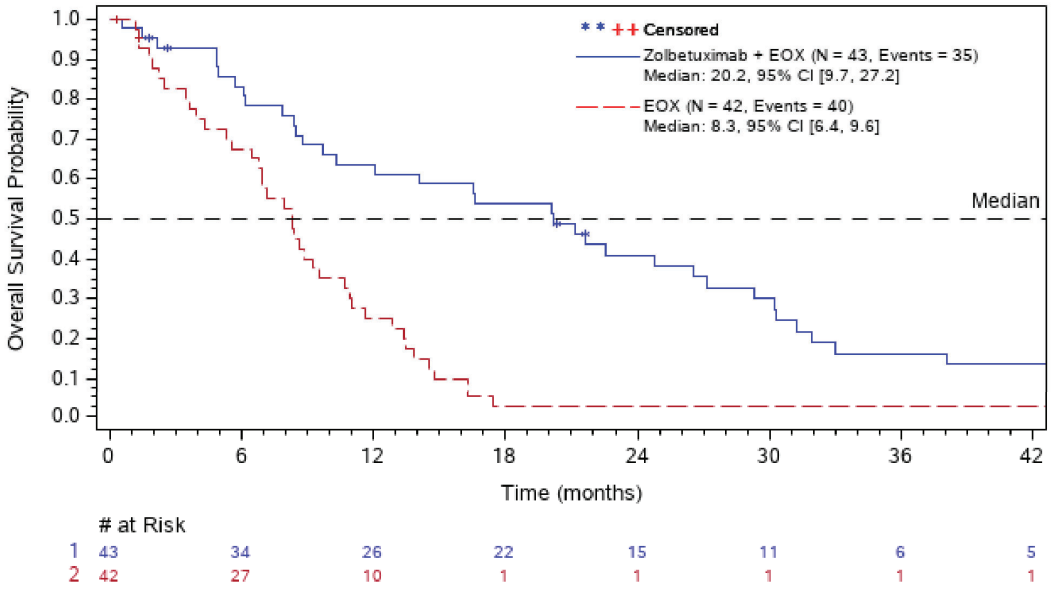
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.1002.1.4: Kaplan-Meier Plot of Overall Survival by Prior Gastrectomy (total or partial) - mITT Analysis Set
Prior Gastrectomy: Yes



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.1002.1.4: Kaplan-Meier Plot of Overall Survival by Prior Gastrectomy (total or partial) - mITT Analysis Set
Prior Gastrectomy: No



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G2 Progressionsfreies Überleben (IRC und INV)

1. Time-to-Event-Analysen

Table GM03.1.1002.2.1: Summary of Progression-Free Survival (IRC) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	31 (55.4%)	44 (75.9%)	
Number of patients censored	25 (44.6%)	14 (24.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.0 [6.0, 12.4]	5.7 [4.3, 7.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.387 [0.231, 0.646]
Log-rank test			
Two-sided stratified log-rank p-value			0.0002

Abbreviations: CI=confidence interval; HR=hazard ratio; IRC=independent review committee; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
Note: The stratification factor is presence of disease at baseline (non-measurable vs. measurable).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.2.2: Type of Events and Censoring of Progression-Free Survival (IRC) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Number of patients at risk	56 (100.0%)	58 (100.0%)
Number of patients with events	31 (55.4%)	44 (75.9%)
Death	7 (12.5%)	12 (20.7%)
PD	24 (42.9%)	32 (55.2%)
Number of patients censored	25 (44.6%)	14 (24.1%)
Censored at End of Study	25 (44.6%)	14 (24.1%)

Abbreviations: IRC=independent review committee; mITT=modified intention-to-treat; N=number of patients; PD=progressive disease.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	23 (52.3)	9.0 [7.1, 12.4]	48	36 (75.0)	5.6 [4.0, 7.2]	0.358 [0.203, 0.632]	0.0002	0.1953
>65 years	12	8 (66.7)	7.1 [4.2, 18.3]	10	8 (80.0)	8.0 [1.2, 11.5]	0.706 [0.253, 1.972]	0.4916	
Sex									
Male	32	17 (53.1)	10.3 [6.0, 18.1]	37	28 (75.7)	5.6 [3.7, 7.2]	0.290 [0.145, 0.579]	0.0002	0.1145
Female	24	14 (58.3)	7.1 [4.9, 20.0]	21	16 (76.2)	7.2 [2.8, 9.8]	0.577 [0.266, 1.251]	0.1605	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	11.3 [4.2, 21.5]	18	12 (66.7)	9.6 [4.3, 11.5]	0.422 [0.148, 1.207]	0.0976	0.3317
>=3	38	25 (65.8)	7.5 [4.9, 12.4]	40	32 (80.0)	5.3 [2.8, 6.8]	0.374 [0.207, 0.676]	0.0008	
Prior Gastrectomy (total or partial)									
Yes	13	4 (30.8)	18.1 [4.4, NC]	16	12 (75.0)	7.9 [4.0, 9.8]	0.439 [0.139, 1.380]	0.1479	0.7066
No	43	27 (62.8)	8.4 [5.6, 12.4]	42	32 (76.2)	5.3 [3.0, 7.2]	0.384 [0.219, 0.675]	0.0006	
Histology (Tumor Type)									
Diffuse	30	16 (53.3)	11.6 [7.1, 18.3]	27	20 (74.1)	6.5 [3.0, 7.3]	0.288 [0.132, 0.628]	0.0009	0.3053
Intestinal	13	8 (61.5)	5.6 [4.2, 12.4]	15	11 (73.3)	7.9 [2.4, 8.8]	0.770 [0.305, 1.945]	0.5791	
Mixed/Other	8	4 (50.0)	14.9 [5.2, 21.5]	10	8 (80.0)	5.6 [1.3, 10.6]	0.246 [0.064, 0.944]	0.0278	
Tumor Location 1									
Gastric	49	29 (59.2)	9.0 [5.6, 12.4]	49	37 (75.5)	5.7 [4.3, 7.3]	0.433 [0.257, 0.730]	0.0013	0.2588
GEJ	7	2 (28.6)	NC [7.1, NC]	9	7 (77.8)	6.8 [1.7, 11.3]	0.258 [0.052, 1.277]	0.0760	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; IRC=independent review committee; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients;
n=number of patients with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Tumor Location 2									
Gastric Proximal	41	25 (61.0)	10.3 [5.6, 12.4]	33	26 (78.8)	5.7 [2.8, 7.7]	0.419 [0.233, 0.753]	0.0028	0.7018
Gastric Distal	6	3 (50.0)	8.2 [4.2, NC]	12	10 (83.3)	7.2 [4.0, 8.0]	0.529 [0.144, 1.943]	0.3365	
Tumor Location 3									
GEJ Proximal	1	0 (0.0)	NC [NC, NC]	2	1 (50.0)	NC [2.8, NC]	0.000 [0.000, NC]	0.4795	0.9991
GEJ Distal	5	1 (20.0)	NC [7.1, NC]	5	4 (80.0)	6.8 [3.7, 11.3]	0.170 [0.018, 1.612]	0.0867	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; IRC=independent review committee; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients;
n=number of patients with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.3.1: Summary of Progression-Free Survival (INV) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	39 (69.6%)	45 (77.6%)	
Number of patients censored	17 (30.4%)	13 (22.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.0 [5.6, 11.6]	6.0 [5.1, 7.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.470 [0.295, 0.749]
Log-rank test			
Two-sided stratified log-rank p-value			0.0012

Abbreviations: CI=confidence interval; HR=hazard ratio; INV=investigator; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
Note: The stratification factor is presence of disease at baseline (non-measurable vs. measurable).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.3.2: Type of Events and Censoring of Progression-Free Survival (INV) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Number of patients at risk	56 (100.0%)	58 (100.0%)
Number of patients with events	39 (69.6%)	45 (77.6%)
Death	5 (8.9%)	11 (19.0%)
PD	34 (60.7%)	34 (58.6%)
Number of patients censored	17 (30.4%)	13 (22.4%)
Censored at End of Study	17 (30.4%)	13 (22.4%)

Abbreviations: INV=investigator; mITT=modified intention-to-treat; N=number of patients; PD=progressive disease.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.3.3: Summary of Progression-Free Survival (INV) by Subgroups - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	32 (72.7)	9.0 [5.6, 11.6]	48	37 (77.1)	5.7 [4.3, 7.3]	0.514 [0.309, 0.853]	0.0087	0.7782
>65 years	12	7 (58.3)	11.7 [4.2, 53.3]	10	8 (80.0)	7.0 [1.2, 11.5]	0.480 [0.162, 1.420]	0.1763	
Sex									
Male	32	22 (68.8)	11.0 [4.4, 21.8]	37	29 (78.4)	5.7 [4.0, 7.2]	0.394 [0.212, 0.735]	0.0026	0.1410
Female	24	17 (70.8)	8.2 [4.9, 9.4]	21	16 (76.2)	7.2 [4.2, 8.8]	0.636 [0.313, 1.295]	0.2015	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	11.6 [9.1, NC]	18	12 (66.7)	10.6 [5.7, 15.2]	0.493 [0.192, 1.265]	0.1335	0.6635
>=3	38	32 (84.2)	7.1 [4.4, 9.0]	40	33 (82.5)	5.6 [3.0, 7.2]	0.500 [0.290, 0.864]	0.0111	
Prior Gastrectomy (total or partial)									
Yes	13	4 (30.8)	9.3 [4.4, 53.3]	16	12 (75.0)	8.0 [4.0, 11.5]	0.276 [0.077, 0.987]	0.0347	0.5443
No	43	35 (81.4)	7.5 [4.8, 11.0]	42	33 (78.6)	5.7 [4.2, 7.2]	0.492 [0.290, 0.834]	0.0071	
Histology (Tumor Type)									
Diffuse	30	20 (66.7)	9.4 [7.1, 22.1]	27	21 (77.8)	6.8 [3.0, 8.6]	0.409 [0.205, 0.817]	0.0088	0.1217
Intestinal	13	11 (84.6)	5.3 [1.5, 14.4]	15	11 (73.3)	7.2 [2.8, 8.8]	1.210 [0.509, 2.875]	0.6660	
Mixed/Other	8	5 (62.5)	9.0 [4.1, 46.1]	10	8 (80.0)	5.7 [1.3, 10.6]	0.359 [0.106, 1.218]	0.0875	
Tumor Location 1									
Gastric	49	35 (71.4)	9.0 [5.2, 11.6]	49	38 (77.6)	7.0 [5.1, 7.7]	0.506 [0.310, 0.828]	0.0056	0.7998
GEJ	7	4 (57.1)	9.3 [1.4, 36.2]	9	7 (77.8)	5.7 [1.7, 11.8]	0.406 [0.102, 1.618]	0.1883	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients; n=number of patients
with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1002.3.3: Summary of Progression-Free Survival (INV) by Subgroups - mITT Analysis Set

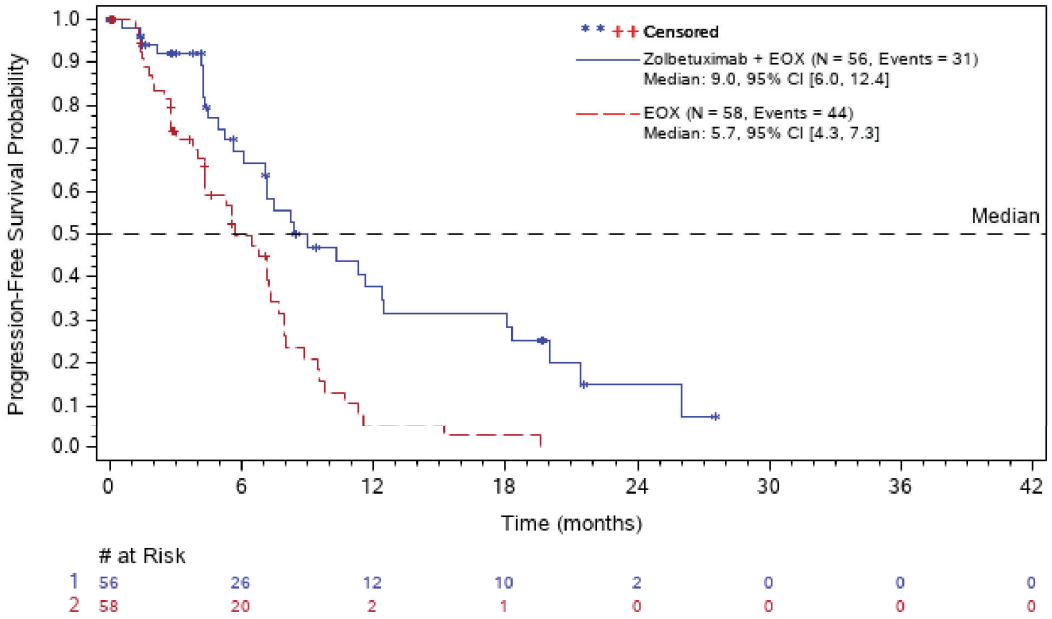
	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Tumor Location 2									
Gastric Proximal	41	29 (70.7)	9.0 [5.2, 14.4]	33	27 (81.8)	6.0 [3.0, 8.6]	0.524 [0.302, 0.909]	0.0185	0.2830
Gastric Distal	6	4 (66.7)	15.2 [4.4, 55.0]	12	10 (83.3)	7.0 [4.0, 7.2]	0.218 [0.045, 1.046]	0.0412	
Tumor Location 3									
GEJ Proximal	1	0 (0.0)	NC [NC, NC]	2	1 (50.0)	4.2 [NC, NC]	NC [NC, NC]	NC	0.9975
GEJ Distal	5	3 (60.0)	22.8 [1.4, 36.2]	5	4 (80.0)	6.8 [3.7, 13.8]	0.373 [0.065, 2.158]	0.2556	

Abbreviations: CI=confidence interval; GEJ=Gastro-esophageal junction; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate of time to event (months); mITT=modified intention-to-treat; N=number of patients; n=number of patients
with event; NC=not calculated.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from Cox proportional hazards model, [c] Based on 2-sided log-rank test, unadjusted for multiplicity, and [d] Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G2 Progressionsfreies Überleben (IRC und INV)

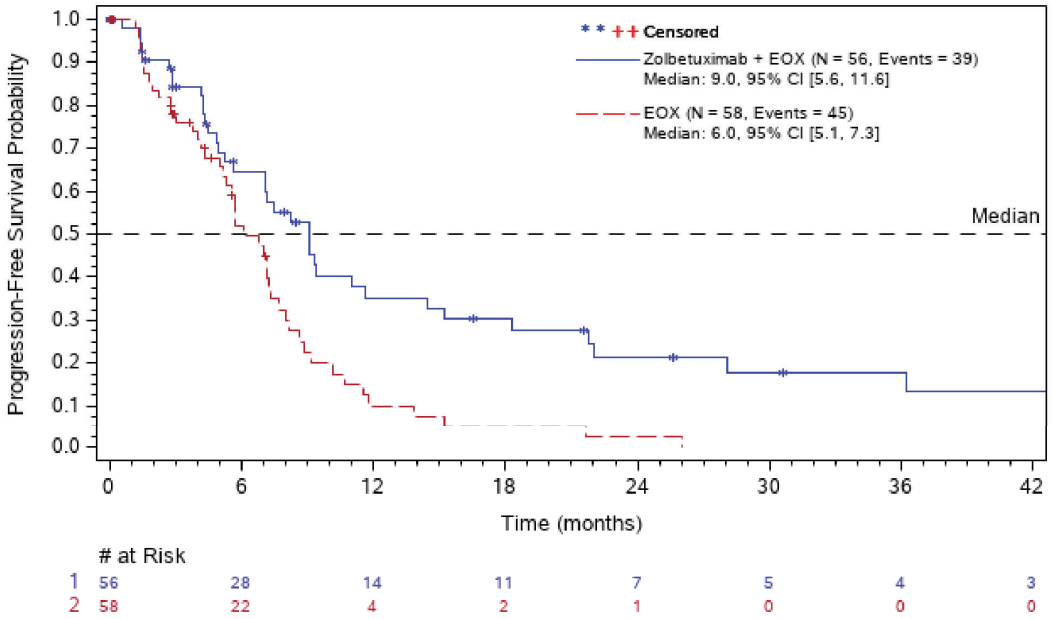
2. Kaplan-Meier-Plots

Figure GM03.1.1002.2: Kaplan-Meier Plot of Progression-Free Survival (IRC) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.1002.3: Kaplan-Meier Plot of Progression-Free Survival (INV) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; mITT=modified intention-to-treat; N=number of patients; NC=not calculated.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte

Anhang 4-G2 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

1. Rücklaufquoten

Table GM03.1.3001.1: EORTC QLQ-C30 - Completion Status - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.2: EORTC QLQ-STO22 - Completion Status - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	44/ 55 (80.0%)	44/ 55 (80.0%)	44/ 56 (78.6%)	42/ 57 (73.7%)	42/ 57 (73.7%)	42/ 58 (72.4%)
Cycle 5	30/ 40 (75.0%)	31/ 41 (75.6%)	31/ 56 (55.4%)	31/ 41 (75.6%)	31/ 41 (75.6%)	31/ 58 (53.4%)
End Of Eox Treatment	26/ 42 (61.9%)	35/ 52 (67.3%)	35/ 56 (62.5%)	28/ 45 (62.2%)	36/ 56 (64.3%)	36/ 58 (62.1%)
Imab362 Continuing Treatment Cycle 02	14/ 23 (60.9%)	14/ 23 (60.9%)	14/ 56 (25.0%)	8/ 16 (50.0%)	8/ 16 (50.0%)	8/ 58 (13.8%)
Imab362 Continuing Treatment Cycle 05	10/ 17 (58.8%)	11/ 18 (61.1%)	11/ 56 (19.6%)	3/ 12 (25.0%)	3/ 12 (25.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 08	7/ 13 (53.8%)	7/ 13 (53.8%)	7/ 56 (12.5%)	2/ 9 (22.2%)	2/ 9 (22.2%)	2/ 58 (3.4%)
Imab362 Continuing Treatment Cycle 11	7/ 12 (58.3%)	7/ 12 (58.3%)	7/ 56 (12.5%)	1/ 4 (25.0%)	1/ 4 (25.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 14	6/ 11 (54.5%)	6/ 11 (54.5%)	6/ 56 (10.7%)	1/ 5 (20.0%)	1/ 5 (20.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 17	3/ 9 (33.3%)	3/ 9 (33.3%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 20	6/ 9 (66.7%)	6/ 9 (66.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 23	5/ 7 (71.4%)	5/ 7 (71.4%)	5/ 56 (8.9%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 26	5/ 7 (71.4%)	5/ 7 (71.4%)	5/ 56 (8.9%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	4/ 7 (57.1%)	4/ 7 (57.1%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	0/ 5 (0.0%)	1/ 6 (16.7%)	1/ 56 (1.8%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	2/ 5 (40.0%)	2/ 5 (40.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	2/ 5 (40.0%)	2/ 5 (40.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	1/ 4 (25.0%)	1/ 4 (25.0%)	1/ 56 (1.8%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	1/ 3 (33.3%)	1/ 3 (33.3%)	1/ 56 (1.8%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	1/ 3 (33.3%)	1/ 3 (33.3%)	1/ 56 (1.8%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 56 (0.0%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 56 (0.0%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 56 (1.8%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 56 (1.8%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 56 (1.8%)	0	0	0
Imab362 Continuing Treatment Cycle 68	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 56 (0.0%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.3: EORTC QLQ-C30 - Completion Status of Global Health Status - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.4: EORTC QLQ-C30 - Completion Status of Physical Functioning - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.5: EORTC QLQ-C30 - Completion Status of Role Functioning - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.6: EORTC QLQ-C30 - Completion Status of Emotional Functioning - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.7: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.8: EORTC QLQ-C30 - Completion Status of Social Functioning - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.9: EORTC QLQ-C30 - Completion Status of Fatigue - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.10: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.11: EORTC QLQ-C30 - Completion Status of Pain - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.12: EORTC QLQ-C30 - Completion Status of Dyspnoea - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.13: EORTC QLQ-C30 - Completion Status of Insomnia - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.14: EORTC QLQ-C30 - Completion Status of Appetite Loss - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.15: EORTC QLQ-C30 - Completion Status of Constipation - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.16: EORTC QLQ-C30 - Completion Status of Diarrhea - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.17: EORTC QLQ-C30 - Completion Status of Financial Difficulties - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

2. Verlauf über die Zeit (Observed Means and Change from Baseline)

Table GM03.1.3002.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	51.39	16.73	16.7	50.00	83.3	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	52.31	18.22	33.3	50.00	100.0	35	0.48	15.38	-33.3	0.00	58.3
End Of Eox Treatment	42	52.18	22.62	0.0	50.00	91.7	41	-1.83	18.77	-50.0	0.00	41.7
Imab362 Continuing Treatment Cycle 02	16	58.85	18.38	16.7	58.33	83.3	15	1.11	15.39	-33.3	0.00	25.0
Imab362 Continuing Treatment Cycle 05	15	64.44	22.81	25.0	66.67	100.0	14	8.93	22.75	-41.7	4.17	58.3
Imab362 Continuing Treatment Cycle 08	12	59.72	20.36	25.0	62.50	100.0	12	7.64	19.29	-41.7	8.33	33.3
Imab362 Continuing Treatment Cycle 11	11	65.91	23.70	33.3	66.67	100.0	11	13.64	15.03	-16.7	16.67	41.7
EOX (N = 58)												
Cycle 1	57	49.71	20.53	0.0	50.00	91.7	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	35	47.38	17.94	0.0	50.00	83.3	35	-2.38	15.47	-41.7	0.00	33.3
End Of Eox Treatment	45	46.30	21.80	0.0	50.00	100.0	43	-4.46	21.77	-33.3	-8.33	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.4: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	55	76.65	21.19	13.3	86.67	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	73.16	18.44	33.3	76.67	100.0	38	-2.51	18.88	-46.7	-3.33	46.7
End Of Eox Treatment	43	70.97	21.89	13.3	80.00	100.0	43	-7.84	20.54	-60.0	-6.67	53.3
Imab362 Continuing Treatment Cycle 02	19	79.74	15.60	40.0	86.67	100.0	19	2.19	21.52	-20.0	-5.00	60.0
Imab362 Continuing Treatment Cycle 05	15	82.67	16.29	46.7	86.67	100.0	15	7.11	23.83	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 08	11	80.61	16.98	53.3	86.67	100.0	11	10.91	19.61	-26.7	6.67	40.0
Imab362 Continuing Treatment Cycle 11	11	85.45	14.85	53.3	86.67	100.0	11	5.45	11.48	-6.7	0.00	26.7
EOX (N = 58)												
Cycle 1	57	73.68	20.83	13.3	80.00	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	73.20	20.88	6.7	73.33	100.0	38	-3.99	13.87	-46.7	-1.67	26.7
End Of Eox Treatment	46	65.80	25.20	0.0	73.33	100.0	44	-8.79	21.65	-73.3	-6.67	46.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	55	70.61	27.59	0.0	66.67	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	37	73.42	22.38	33.3	83.33	100.0	37	4.95	31.64	-66.7	0.00	100.0
End Of Eox Treatment	42	65.48	28.37	0.0	66.67	100.0	42	-6.75	33.35	-66.7	0.00	66.7
Imab362 Continuing Treatment Cycle 02	19	78.95	19.91	33.3	83.33	100.0	19	3.51	27.54	-50.0	0.00	66.7
Imab362 Continuing Treatment Cycle 05	16	77.08	20.97	33.3	83.33	100.0	16	8.33	36.00	-66.7	0.00	83.3
Imab362 Continuing Treatment Cycle 08	12	81.94	21.86	33.3	91.67	100.0	12	19.44	31.65	-16.7	8.33	66.7
Imab362 Continuing Treatment Cycle 11	11	81.82	15.73	66.7	83.33	100.0	11	13.64	24.52	-16.7	16.67	66.7
EOX (N = 58)												
Cycle 1	55	70.30	28.27	0.0	83.33	100.0	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	67.11	27.80	0.0	66.67	100.0	36	-4.63	22.04	-66.7	0.00	33.3
End Of Eox Treatment	46	59.42	29.11	0.0	66.67	100.0	42	-10.71	28.47	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.5.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning by Sex - mITT Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	Zolbetuximab + EOX (N = 32)												
	Cycle 1	31	66.13	30.58	0.0	66.67	100.0	31	0.00	0.00	0.0	0.00	0.0
	Cycle 5	21	72.22	21.94	33.3	66.67	100.0	21	7.94	36.75	-66.7	0.00	100.0
	End Of Eox Treatment	22	67.42	27.45	16.7	66.67	100.0	22	1.52	32.08	-66.7	0.00	66.7
	Imab362 Continuing Treatment	10	81.67	19.95	50.0	83.33	100.0	10	6.67	27.44	-50.0	8.33	50.0
	Cycle 02												
	Imab362 Continuing Treatment	11	77.27	18.67	33.3	83.33	100.0	11	6.06	37.47	-66.7	0.00	83.3
	Cycle 05												
	EOX (N = 37)												
	Cycle 1	35	72.86	26.84	16.7	83.33	100.0	34	0.00	0.00	0.0	0.00	0.0
	Cycle 5	23	71.74	26.32	16.7	83.33	100.0	22	-7.58	21.04	-66.7	0.00	33.3
	End Of Eox Treatment	31	57.53	32.16	0.0	66.67	100.0	28	-14.29	28.59	-83.3	-16.67	50.0
Female	Zolbetuximab + EOX (N = 24)												
	Cycle 1	24	76.39	22.48	33.3	75.00	100.0	24	0.00	0.00	0.0	0.00	0.0
	Cycle 5	16	75.00	23.57	33.3	83.33	100.0	16	1.04	23.94	-33.3	0.00	50.0
	End Of Eox Treatment	20	63.33	29.91	0.0	66.67	100.0	20	-15.83	33.10	-66.7	-33.33	66.7
	EOX (N = 21)												
	Cycle 1	20	65.83	30.81	0.0	66.67	100.0	20	0.00	0.00	0.0	0.00	0.0
	Cycle 5	15	60.00	29.41	0.0	66.67	100.0	14	0.00	23.57	-50.0	0.00	33.3
	End Of Eox Treatment	15	63.33	22.00	33.3	66.67	100.0	14	-3.57	27.87	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
Table is provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	78.81	19.26	8.3	83.33	100.0	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	79.86	18.19	33.3	83.33	100.0	35	0.24	18.47	-33.3	0.00	58.3
End Of Eox Treatment	43	76.16	23.96	0.0	75.00	100.0	42	-4.96	24.00	-75.0	0.00	66.7
Imab362 Continuing Treatment Cycle 02	18	80.25	23.68	33.3	83.33	100.0	17	-2.29	26.17	-47.2	0.00	75.0
Imab362 Continuing Treatment Cycle 05	15	85.00	18.95	33.3	91.67	100.0	14	3.57	20.34	-33.3	0.00	58.3
Imab362 Continuing Treatment Cycle 08	12	79.86	17.57	50.0	79.17	100.0	12	1.39	25.58	-41.7	0.00	66.7
Imab362 Continuing Treatment Cycle 11	11	81.82	20.69	41.7	91.67	100.0	11	0.00	13.44	-16.7	0.00	25.0
EOX (N = 58)												
Cycle 1	57	71.93	24.28	0.0	75.00	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	75.23	26.54	0.0	83.33	100.0	36	0.23	15.23	-33.3	0.00	50.0
End Of Eox Treatment	45	72.78	23.06	0.0	75.00	100.0	43	-4.07	20.20	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.6.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning by Age Group 1 - mITT Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
<=65 years	Zolbetuximab + EOX (N = 44)												
	Cycle 1	43	77.26	20.01	8.3	83.33	100.0	43	0.00	0.00	0.0	0.00	0.0
	Cycle 5	27	81.48	18.10	33.3	83.33	100.0	26	3.53	18.13	-33.3	0.00	58.3
	End Of Eox Treatment	35	78.57	21.42	25.0	75.00	100.0	34	-1.23	22.39	-75.0	0.00	66.7
	Imab362 Continuing Treatment	15	86.11	19.84	33.3	100.00	100.0	14	4.17	23.74	-41.7	0.00	75.0
	Cycle 02												
	Imab362 Continuing Treatment	12	85.42	21.06	33.3	95.83	100.0	11	3.79	21.85	-33.3	0.00	58.3
	Cycle 05												
	EOX (N = 48)												
	Cycle 1	48	72.92	24.40	0.0	75.00	100.0	47	0.00	0.00	0.0	0.00	0.0
	Cycle 5	30	73.89	27.40	0.0	83.33	100.0	30	-0.56	15.31	-33.3	0.00	50.0
	End Of Eox Treatment	38	72.15	23.43	0.0	70.83	100.0	37	-3.83	21.39	-50.0	0.00	33.3
>65 years	Zolbetuximab + EOX (N = 12)												
	Cycle 1	11	84.85	15.28	58.3	91.67	100.0	11	0.00	0.00	0.0	0.00	0.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
Table is provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	52	90.71	15.63	50.0	100.00	100.0	52	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	89.35	15.51	33.3	100.00	100.0	34	0.00	18.80	-50.0	0.00	50.0
End Of Eox Treatment	43	83.33	21.21	16.7	83.33	100.0	41	-8.13	18.30	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 02	18	88.89	18.96	33.3	100.00	100.0	17	1.96	20.31	-33.3	0.00	50.0
Imab362 Continuing Treatment Cycle 05	15	91.11	18.76	33.3	100.00	100.0	14	2.38	21.54	-50.0	0.00	33.3
Imab362 Continuing Treatment Cycle 08	12	86.11	15.62	66.7	91.67	100.0	12	1.39	16.60	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 11	11	90.91	15.57	66.7	100.00	100.0	11	1.52	18.94	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	57	88.01	18.30	16.7	100.00	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	86.57	21.01	0.0	91.67	100.0	36	-0.46	18.03	-50.0	0.00	33.3
End Of Eox Treatment	46	84.42	21.20	0.0	91.67	100.0	44	-4.17	20.69	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	79.63	21.88	33.3	83.33	100.0	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	74.54	20.89	33.3	66.67	100.0	35	-5.24	23.49	-50.0	0.00	50.0
End Of Eox Treatment	43	73.26	26.51	0.0	83.33	100.0	42	-7.54	30.18	-100.0	0.00	50.0
Imab362 Continuing Treatment Cycle 02	18	80.56	25.72	16.7	91.67	100.0	17	-2.94	26.51	-50.0	0.00	50.0
Imab362 Continuing Treatment Cycle 05	15	84.44	26.33	16.7	100.00	100.0	14	1.19	31.67	-83.3	0.00	50.0
Imab362 Continuing Treatment Cycle 08	12	86.11	15.62	66.7	91.67	100.0	12	8.33	24.10	-33.3	8.33	50.0
Imab362 Continuing Treatment Cycle 11	11	80.30	14.56	66.7	83.33	100.0	11	0.00	19.72	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	56	75.60	26.96	0.0	83.33	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	77.31	25.25	0.0	83.33	100.0	36	-0.93	18.66	-33.3	0.00	50.0
End Of Eox Treatment	46	73.55	28.02	0.0	83.33	100.0	43	-5.43	30.15	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.8.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning by Sex - mITT Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	Zolbetuximab + EOX (N = 32)												
	Cycle 1	31	79.57	20.95	33.3	83.33	100.0	31	0.00	0.00	0.0	0.00	0.0
	Cycle 5	21	76.98	20.73	33.3	83.33	100.0	21	-1.59	19.65	-50.0	0.00	33.3
	End Of Eox Treatment	23	77.54	29.56	0.0	100.00	100.0	23	-2.17	29.86	-100.0	0.00	50.0
	Imab362 Continuing Treatment Cycle 05	11	86.36	25.62	16.7	100.00	100.0	11	-1.52	32.02	-83.3	0.00	50.0
	EOX (N = 37)												
	Cycle 1	35	82.86	21.57	33.3	100.00	100.0	34	0.00	0.00	0.0	0.00	0.0
	Cycle 5	21	86.51	20.15	16.7	100.00	100.0	21	-6.35	17.06	-33.3	0.00	33.3
	End Of Eox Treatment	31	73.12	31.23	0.0	83.33	100.0	28	-13.69	27.98	-83.3	-16.67	33.3
Female	Zolbetuximab + EOX (N = 24)												
	Cycle 1	23	79.71	23.55	33.3	83.33	100.0	23	0.00	0.00	0.0	0.00	0.0
	Cycle 5	15	71.11	21.33	33.3	66.67	100.0	14	-10.71	28.20	-50.0	-16.67	50.0
	End Of Eox Treatment	20	68.33	22.23	33.3	66.67	100.0	19	-14.04	30.05	-66.7	-16.67	50.0
	EOX (N = 21)												
	Cycle 1	21	63.49	31.01	0.0	66.67	100.0	21	0.00	0.00	0.0	0.00	0.0
	Cycle 5	15	64.44	26.63	0.0	66.67	100.0	15	6.67	18.69	-33.3	0.00	50.0
	End Of Eox Treatment	15	74.44	20.77	33.3	83.33	100.0	15	10.00	28.73	-33.3	0.00	83.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
Table is provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	55	38.59	21.79	0.0	33.33	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	39.47	18.17	11.1	33.33	83.3	38	0.00	21.65	-66.7	0.00	38.9
End Of Eox Treatment	43	47.29	27.44	0.0	33.33	100.0	43	10.08	30.27	-77.8	0.00	77.8
Imab362 Continuing Treatment Cycle 02	18	33.33	19.43	0.0	33.33	66.7	18	-6.17	26.46	-88.9	0.00	22.2
Imab362 Continuing Treatment Cycle 05	16	30.56	24.17	0.0	22.22	100.0	16	-9.72	31.66	-88.9	-11.11	66.7
Imab362 Continuing Treatment Cycle 08	12	27.78	20.38	0.0	33.33	66.7	12	-16.67	19.82	-55.6	-16.67	22.2
Imab362 Continuing Treatment Cycle 11	11	26.26	20.65	0.0	33.33	66.7	11	-10.10	15.28	-33.3	0.00	11.1
EOX (N = 58)												
Cycle 1	56	41.07	24.06	0.0	33.33	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	37	43.09	26.17	0.0	33.33	100.0	36	4.17	15.85	-22.2	0.00	33.3
End Of Eox Treatment	46	45.41	26.17	0.0	33.33	100.0	43	6.46	22.90	-33.3	0.00	88.9

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	14.81	19.87	0.0	8.33	83.3	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	37	20.27	21.56	0.0	16.67	66.7	36	6.48	23.66	-33.3	0.00	66.7
End Of Eox Treatment	43	24.03	29.84	0.0	16.67	100.0	42	11.11	30.72	-33.3	0.00	100.0
Imab362 Continuing Treatment Cycle 02	18	8.33	17.39	0.0	0.00	66.7	17	-4.90	14.15	-33.3	0.00	16.7
Imab362 Continuing Treatment Cycle 05	15	10.00	18.69	0.0	0.00	66.7	14	-3.57	17.52	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 08	12	9.72	15.01	0.0	0.00	33.3	12	-2.78	9.62	-16.7	0.00	16.7
Imab362 Continuing Treatment Cycle 11	11	10.61	18.67	0.0	0.00	50.0	11	1.52	17.41	-16.7	0.00	33.3
EOX (N = 58)												
Cycle 1	57	13.16	18.83	0.0	0.00	83.3	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	37	13.06	15.28	0.0	16.67	50.0	37	3.15	16.59	-33.3	0.00	50.0
End Of Eox Treatment	46	13.04	19.54	0.0	0.00	100.0	44	3.03	13.10	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	53	22.33	23.56	0.0	16.67	83.3	53	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	16.20	20.11	0.0	8.33	66.7	34	-7.35	27.89	-83.3	0.00	33.3
End Of Eox Treatment	43	26.74	29.13	0.0	16.67	100.0	41	4.07	34.92	-83.3	0.00	100.0
Imab362 Continuing Treatment Cycle 02	18	17.59	22.49	0.0	16.67	66.7	16	-8.33	21.94	-66.7	0.00	16.7
Imab362 Continuing Treatment Cycle 05	15	15.56	21.33	0.0	0.00	66.7	14	-9.52	30.46	-83.3	-8.33	50.0
Imab362 Continuing Treatment Cycle 08	12	16.67	17.41	0.0	16.67	50.0	12	-15.28	19.41	-50.0	-8.33	0.0
Imab362 Continuing Treatment Cycle 11	11	10.61	17.12	0.0	0.00	50.0	11	-13.64	23.35	-66.7	0.00	0.0
EOX (N = 58)												
Cycle 1	57	24.56	24.01	0.0	16.67	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	35	19.05	20.67	0.0	16.67	83.3	35	-2.86	16.41	-50.0	0.00	33.3
End Of Eox Treatment	44	31.06	25.57	0.0	33.33	83.3	42	7.94	22.46	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	15.43	23.09	0.0	0.00	66.7	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	13.89	21.64	0.0	0.00	66.7	36	1.85	25.13	-66.7	0.00	66.7
End Of Eox Treatment	43	20.16	28.30	0.0	0.00	100.0	43	4.65	29.62	-66.7	0.00	100.0
Imab362 Continuing Treatment Cycle 02	19	7.02	13.96	0.0	0.00	33.3	19	-3.51	21.93	-66.7	0.00	33.3
Imab362 Continuing Treatment Cycle 05	16	4.17	11.39	0.0	0.00	33.3	16	-10.42	20.07	-66.7	0.00	0.0
Imab362 Continuing Treatment Cycle 08	12	8.33	15.08	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 11	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	57	15.20	26.78	0.0	0.00	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	18.42	22.86	0.0	0.00	100.0	38	4.39	23.47	-66.7	0.00	33.3
End Of Eox Treatment	46	21.74	29.16	0.0	0.00	100.0	44	8.33	21.72	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	55	25.45	27.94	0.0	33.33	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	24.56	27.60	0.0	33.33	100.0	38	-2.63	17.98	-33.3	0.00	33.3
End Of Eox Treatment	42	28.57	29.05	0.0	33.33	100.0	42	3.97	24.64	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 02	19	22.81	27.34	0.0	0.00	66.7	19	1.75	28.27	-66.7	0.00	66.7
Imab362 Continuing Treatment Cycle 05	16	20.83	20.64	0.0	33.33	66.7	16	-6.25	25.00	-66.7	0.00	33.3
Imab362 Continuing Treatment Cycle 08	12	30.56	22.29	0.0	33.33	66.7	12	0.00	24.62	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 11	11	27.27	25.03	0.0	33.33	66.7	11	0.00	21.08	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	57	33.33	29.55	0.0	33.33	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	23.68	27.84	0.0	16.67	100.0	38	-9.65	24.39	-100.0	0.00	33.3
End Of Eox Treatment	46	35.51	32.51	0.0	33.33	100.0	44	0.76	24.37	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	55	30.91	31.98	0.0	33.33	100.0	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	28.95	27.04	0.0	33.33	100.0	38	-1.75	35.47	-100.0	0.00	33.3
End Of Eox Treatment	42	32.54	33.32	0.0	33.33	100.0	42	1.59	34.49	-100.0	0.00	66.7
Imab362 Continuing Treatment Cycle 02	19	17.54	28.04	0.0	0.00	66.7	19	-12.28	31.84	-100.0	0.00	33.3
Imab362 Continuing Treatment Cycle 05	16	20.83	29.50	0.0	0.00	100.0	16	-8.33	44.72	-100.0	-16.67	100.0
Imab362 Continuing Treatment Cycle 08	12	16.67	22.47	0.0	0.00	66.7	12	-16.67	33.33	-100.0	0.00	33.3
Imab362 Continuing Treatment Cycle 11	11	21.21	22.47	0.0	33.33	66.7	11	-3.03	27.71	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	57	33.92	31.17	0.0	33.33	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	38	35.96	31.37	0.0	33.33	100.0	38	6.14	27.79	-33.3	0.00	66.7
End Of Eox Treatment	46	35.51	26.67	0.0	33.33	100.0	44	3.79	39.52	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	21.60	29.07	0.0	0.00	100.0	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	12.96	22.93	0.0	0.00	100.0	35	-12.38	29.25	-100.0	0.00	33.3
End Of Eox Treatment	43	19.38	29.31	0.0	0.00	100.0	42	-4.76	31.73	-100.0	0.00	66.7
Imab362 Continuing Treatment Cycle 02	18	12.96	23.26	0.0	0.00	66.7	17	-11.76	38.98	-100.0	0.00	33.3
Imab362 Continuing Treatment Cycle 05	15	11.11	20.57	0.0	0.00	66.7	14	-11.90	30.96	-100.0	0.00	33.3
Imab362 Continuing Treatment Cycle 08	12	8.33	20.72	0.0	0.00	66.7	12	-19.44	26.43	-66.7	0.00	0.0
Imab362 Continuing Treatment Cycle 11	11	12.12	30.81	0.0	0.00	100.0	11	0.00	39.44	-66.7	0.00	100.0
EOX (N = 58)												
Cycle 1	57	23.98	30.05	0.0	0.00	100.0	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	13.89	24.40	0.0	0.00	100.0	36	-4.63	25.39	-66.7	0.00	33.3
End Of Eox Treatment	46	13.77	22.85	0.0	0.00	100.0	44	-6.82	30.99	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhea - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	54	7.41	16.72	0.0	0.00	66.7	54	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	10.19	19.22	0.0	0.00	66.7	35	4.76	20.04	-66.7	0.00	66.7
End Of Eox Treatment	43	12.40	20.60	0.0	0.00	66.7	42	3.97	23.52	-66.7	0.00	66.7
Imab362 Continuing Treatment Cycle 02	17	5.88	17.62	0.0	0.00	66.7	16	0.00	21.08	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 05	15	6.67	13.80	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 08	12	8.33	15.08	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 11	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	56	10.12	18.98	0.0	0.00	66.7	55	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	18.52	29.22	0.0	0.00	100.0	35	9.52	26.29	-33.3	0.00	100.0
End Of Eox Treatment	46	15.94	23.03	0.0	0.00	66.7	44	8.33	27.02	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	51	20.92	24.91	0.0	0.00	66.7	51	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	29.63	32.64	0.0	33.33	100.0	33	12.12	20.10	-33.3	0.00	66.7
End Of Eox Treatment	43	27.91	34.06	0.0	0.00	100.0	39	8.55	26.18	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 02	18	29.63	32.11	0.0	33.33	100.0	15	15.56	24.77	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 05	15	37.78	35.34	0.0	33.33	100.0	14	16.67	33.97	-33.3	33.33	66.7
Imab362 Continuing Treatment Cycle 08	12	19.44	26.43	0.0	0.00	66.7	11	-6.06	13.48	-33.3	0.00	0.0
Imab362 Continuing Treatment Cycle 11	11	33.33	33.33	0.0	33.33	66.7	10	13.33	17.21	0.0	0.00	33.3
EOX (N = 58)												
Cycle 1	57	28.65	27.05	0.0	33.33	66.7	56	0.00	0.00	0.0	0.00	0.0
Cycle 5	36	27.78	31.37	0.0	33.33	100.0	36	2.78	32.24	-66.7	0.00	100.0
End Of Eox Treatment	46	29.71	26.51	0.0	33.33	100.0	44	7.58	29.52	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

3. Time-to-Event-Analysen - Zeit bis zur ersten Verschlechterung

Table GM03.1.3003.3.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	19 (33.9%)	27 (46.6%)	
Number of patients censored	37 (66.1%)	31 (53.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.9[6.3, NC]	6.0[4.9, 7.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.400[0.215, 0.745]
Log-rank test			
Two-sided stratified log-rank p-value			0.0031

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.3.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	15 (34.1)	9.6 [5.8, NC]	48	23 (47.9)	6.0 [4.6, 8.0]	0.442 [0.224, 0.871]	0.0158	0.6606
>65 years	12	4 (33.3)	10.5 [5.2, NC]	10	4 (40.0)	5.7 [2.8, NC]	0.323 [0.070, 1.501]	0.1373	
Sex									
Male	32	9 (28.1)	NC [5.4, NC]	37	17 (45.9)	6.0 [4.6, 8.0]	0.370 [0.160, 0.859]	0.0173	0.4152
Female	24	10 (41.7)	7.1 [5.2, 24.0]	21	10 (47.6)	5.2 [2.9, 11.3]	0.480 [0.192, 1.198]	0.1096	
Number of Organs with Metastatic Sites									
0-2	18	5 (27.8)	13.9 [3.2, NC]	18	10 (55.6)	5.8 [3.0, 11.3]	0.396 [0.123, 1.278]	0.1120	0.7589
>=3	38	14 (36.8)	9.6 [6.2, NC]	40	17 (42.5)	6.0 [3.0, 8.0]	0.411 [0.196, 0.861]	0.0162	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.4.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	24 (42.9%)	27 (46.6%)	
Number of patients censored	32 (57.1%)	31 (53.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.1[3.2, NC]	5.7[4.6, 7.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.669[0.380, 1.179]
Log-rank test			
Two-sided stratified log-rank p-value			0.1591

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.4.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	18 (40.9)	7.9 [3.0, NC]	48	22 (45.8)	5.7 [3.1, 8.0]	0.710 [0.377, 1.340]	0.2781	0.9743
>65 years	12	6 (50.0)	7.1 [2.9, 25.7]	10	5 (50.0)	5.7 [2.8, NC]	0.658 [0.187, 2.324]	0.5134	
Sex									
Male	32	12 (37.5)	11.8 [3.0, NC]	37	19 (51.4)	5.7 [4.6, 7.2]	0.523 [0.243, 1.126]	0.0898	0.4011
Female	24	12 (50.0)	5.8 [3.0, NC]	21	8 (38.1)	5.2 [3.0, NC]	0.906 [0.367, 2.240]	0.8287	
Number of Organs with Metastatic Sites									
0-2	18	8 (44.4)	5.7 [2.9, NC]	18	9 (50.0)	5.8 [3.0, NC]	1.103 [0.424, 2.865]	0.8372	0.3504
>=3	38	16 (42.1)	7.9 [3.2, NC]	40	18 (45.0)	5.6 [3.0, 8.0]	0.556 [0.276, 1.119]	0.0934	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.5.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	23 (41.1%)	25 (43.1%)	
Number of patients censored	33 (58.9%)	33 (56.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.7[3.2, NC]	5.7[3.1, 6.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.689[0.387, 1.229]
Log-rank test			
Two-sided stratified log-rank p-value			0.2051

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.5.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	20 (45.5)	6.7 [3.1, NC]	48	20 (41.7)	5.8 [3.6, 8.0]	0.867 [0.462, 1.626]	0.6555	0.0580
>65 years	12	3 (25.0)	NC [4.4, NC]	10	5 (50.0)	3.1 [1.5, NC]	0.211 [0.049, 0.906]	0.0221	
Sex									
Male	32	9 (28.1)	NC [4.4, NC]	37	19 (51.4)	5.0 [3.0, 6.0]	0.372 [0.164, 0.840]	0.0135	0.0356
Female	24	14 (58.3)	5.6 [3.0, 6.7]	21	6 (28.6)	6.3 [3.0, NC]	1.483 [0.568, 3.868]	0.4194	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	6.7 [3.1, NC]	18	12 (66.7)	3.6 [2.9, 6.3]	0.481 [0.186, 1.244]	0.1247	0.3825
>=3	38	16 (42.1)	7.9 [3.2, NC]	40	13 (32.5)	5.7 [3.1, NC]	0.869 [0.415, 1.822]	0.7085	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.6.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	22 (39.3%)	21 (36.2%)	
Number of patients censored	34 (60.7%)	37 (63.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.9[5.7, 27.5]	8.2[5.7, 11.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.813[0.435, 1.517]
Log-rank test			
Two-sided stratified log-rank p-value			0.5115

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.6.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	15 (34.1)	13.3 [5.9, NC]	48	18 (37.5)	8.2 [5.6, 11.3]	0.591 [0.290, 1.205]	0.1441	0.0130
>65 years	12	7 (58.3)	3.0 [2.8, 6.0]	10	3 (30.0)	17.5 [2.8, 17.5]	4.152 [0.823, 20.955]	0.0656	
Sex									
Male	32	14 (43.8)	11.6 [3.2, NC]	37	14 (37.8)	7.2 [5.6, 11.2]	0.714 [0.325, 1.568]	0.3962	0.4030
Female	24	8 (33.3)	6.2 [3.2, NC]	21	7 (33.3)	11.3 [3.2, 17.5]	1.189 [0.419, 3.369]	0.7352	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	5.9 [2.9, NC]	18	8 (44.4)	11.3 [3.6, 17.5]	1.306 [0.470, 3.628]	0.6072	0.2842
>=3	38	15 (39.5)	11.6 [5.8, 27.5]	40	13 (32.5)	7.2 [4.6, 10.2]	0.613 [0.275, 1.365]	0.2300	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.7.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	25 (44.6%)	24 (41.4%)	
Number of patients censored	31 (55.4%)	34 (58.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.8[3.2, NC]	6.0[4.6, 11.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.922[0.522, 1.629]
Log-rank test			
Two-sided stratified log-rank p-value			0.7937

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.7.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	19 (43.2)	7.1 [3.2, NC]	48	21 (43.8)	5.7 [3.2, 9.0]	0.747 [0.397, 1.406]	0.3695	0.1549
>65 years	12	6 (50.0)	5.7 [2.8, NC]	10	3 (30.0)	17.5 [3.0, 17.5]	3.166 [0.630, 15.901]	0.1406	
Sex									
Male	32	10 (31.3)	13.3 [3.7, NC]	37	14 (37.8)	6.0 [5.6, 11.2]	0.611 [0.265, 1.408]	0.2505	0.3003
Female	24	15 (62.5)	4.4 [2.9, 5.8]	21	10 (47.6)	3.2 [2.8, 17.5]	1.140 [0.509, 2.553]	0.7183	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	5.8 [2.9, NC]	18	7 (38.9)	9.0 [3.0, 17.5]	1.154 [0.404, 3.297]	0.7805	0.4403
>=3	38	18 (47.4)	5.7 [3.1, NC]	40	17 (42.5)	5.6 [3.1, 7.2]	0.769 [0.388, 1.523]	0.4732	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.8.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	25 (44.6%)	25 (43.1%)	
Number of patients censored	31 (55.4%)	33 (56.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.9[3.0, NC]	6.0[4.6, 8.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.885[0.498, 1.572]
Log-rank test			
Two-sided stratified log-rank p-value			0.6578

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.8.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	19 (43.2)	8.1 [3.2, NC]	48	21 (43.8)	6.0 [3.1, 8.2]	0.712 [0.375, 1.353]	0.2943	0.1718
>65 years	12	6 (50.0)	2.9 [2.8, NC]	10	4 (40.0)	5.7 [3.0, 19.5]	2.927 [0.685, 12.499]	0.1401	
Sex									
Male	32	11 (34.4)	13.8 [4.4, NC]	37	19 (51.4)	4.6 [2.9, 6.0]	0.414 [0.189, 0.907]	0.0239	0.0017
Female	24	14 (58.3)	2.9 [2.9, 8.1]	21	6 (28.6)	11.3 [5.2, 19.5]	3.219 [1.151, 9.004]	0.0205	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	8.1 [2.9, NC]	18	10 (55.6)	6.2 [3.6, 19.5]	0.698 [0.249, 1.952]	0.4825	0.8358
>=3	38	19 (50.0)	5.9 [2.9, 13.8]	40	15 (37.5)	5.6 [3.0, 8.2]	0.909 [0.454, 1.820]	0.7821	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.9.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	27 (48.2%)	31 (53.4%)	
Number of patients censored	29 (51.8%)	27 (46.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.2[3.0, 15.4]	5.6[3.1, 5.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.771[0.454, 1.308]
Log-rank test			
Two-sided stratified log-rank p-value			0.3415

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.9.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	20 (45.5)	5.7 [3.0, NC]	48	27 (56.3)	4.9 [3.0, 6.2]	0.663 [0.367, 1.197]	0.1695	0.3064
>65 years	12	7 (58.3)	4.3 [2.8, 5.7]	10	4 (40.0)	5.7 [2.8, NC]	1.868 [0.519, 6.728]	0.3330	
Sex									
Male	32	13 (40.6)	5.4 [3.1, NC]	37	19 (51.4)	5.7 [3.1, 6.6]	0.733 [0.354, 1.517]	0.4058	0.9962
Female	24	14 (58.3)	3.2 [2.9, NC]	21	12 (57.1)	3.1 [2.9, 6.2]	0.753 [0.347, 1.634]	0.4727	
Number of Organs with Metastatic Sites									
0-2	18	9 (50.0)	5.7 [3.0, NC]	18	13 (72.2)	5.7 [2.9, 6.2]	0.680 [0.289, 1.600]	0.3780	0.7237
>=3	38	18 (47.4)	3.2 [2.9, NC]	40	18 (45.0)	5.6 [3.0, 6.6]	0.852 [0.438, 1.659]	0.6451	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.10.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	25 (44.6%)	26 (44.8%)	
Number of patients censored	31 (55.4%)	32 (55.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.7[3.1, 13.8]	5.7[3.2, 8.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.947[0.535, 1.676]
Log-rank test			
Two-sided stratified log-rank p-value			0.8583

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.10.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	21 (47.7)	3.4 [3.0, 13.8]	48	21 (43.8)	5.7 [3.2, 8.0]	1.092 [0.594, 2.007]	0.7774	0.2436
>65 years	12	4 (33.3)	27.8 [2.9, 27.8]	10	5 (50.0)	5.7 [1.5, 15.4]	0.482 [0.114, 2.047]	0.2981	
Sex									
Male	32	13 (40.6)	11.6 [2.9, 27.8]	37	17 (45.9)	5.7 [3.0, 7.4]	0.704 [0.330, 1.501]	0.3600	0.3301
Female	24	12 (50.0)	3.4 [2.9, NC]	21	9 (42.9)	8.2 [2.9, 15.4]	1.200 [0.504, 2.855]	0.6941	
Number of Organs with Metastatic Sites									
0-2	18	9 (50.0)	3.1 [2.8, 5.7]	18	10 (55.6)	5.7 [3.0, 15.4]	2.006 [0.782, 5.147]	0.1216	0.0730
>=3	38	16 (42.1)	11.6 [3.2, 27.8]	40	16 (40.0)	7.2 [3.0, 8.0]	0.626 [0.297, 1.318]	0.2072	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.11.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	EOX (N= 58)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	23 (41.1%)	22 (37.9%)	
Number of patients censored	33 (58.9%)	36 (62.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.3[5.4, NC]	6.0[5.7, 6.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.816[0.447, 1.492]
Log-rank test			
Two-sided stratified log-rank p-value			0.5213

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.11.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	18 (40.9)	7.3 [3.4, NC]	48	17 (35.4)	6.0 [5.7, NC]	0.962 [0.491, 1.884]	0.9176	0.3074
>65 years	12	5 (41.7)	5.7 [3.0, 34.0]	10	5 (50.0)	4.4 [2.8, 7.3]	0.420 [0.111, 1.580]	0.1935	
Sex									
Male	32	11 (34.4)	9.7 [5.7, NC]	37	14 (37.8)	6.0 [5.7, 7.3]	0.519 [0.224, 1.205]	0.1260	0.2262
Female	24	12 (50.0)	5.7 [3.0, 5.9]	21	8 (38.1)	5.8 [2.9, NC]	1.257 [0.513, 3.079]	0.6125	
Number of Organs with Metastatic Sites									
0-2	18	8 (44.4)	5.7 [2.8, NC]	18	9 (50.0)	5.8 [3.0, 7.3]	0.970 [0.371, 2.536]	0.9394	0.6884
>=3	38	15 (39.5)	7.9 [3.4, NC]	40	13 (32.5)	6.0 [5.2, NC]	0.749 [0.347, 1.617]	0.4810	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.12.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	18 (32.1%)	17 (29.3%)	
Number of patients censored	38 (67.9%)	41 (70.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	15.4[5.9, NC]	NC [3.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.775[0.394, 1.524]
Log-rank test			
Two-sided stratified log-rank p-value			0.4651

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.12.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	14 (31.8)	15.4 [5.9, NC]	48	15 (31.3)	7.4 [3.1, NC]	0.741 [0.351, 1.564]	0.4293	0.4934
>65 years	12	4 (33.3)	11.2 [3.0, NC]	10	2 (20.0)	NC [2.8, NC]	1.489 [0.271, 8.186]	0.6447	
Sex									
Male	32	9 (28.1)	15.4 [7.6, NC]	37	11 (29.7)	7.4 [3.1, NC]	0.602 [0.238, 1.524]	0.2790	0.5270
Female	24	9 (37.5)	NC [3.0, NC]	21	6 (28.6)	NC [2.9, NC]	0.947 [0.337, 2.665]	0.9280	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	7.6 [3.0, NC]	18	6 (33.3)	NC [3.2, NC]	1.203 [0.387, 3.734]	0.7447	0.3730
>=3	38	12 (31.6)	15.4 [5.9, NC]	40	11 (27.5)	7.4 [3.0, NC]	0.608 [0.260, 1.426]	0.2550	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.13.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	18 (32.1%)	13 (22.4%)	
Number of patients censored	38 (67.9%)	45 (77.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	11.6[6.3, NC]	11.3[6.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.968[0.463, 2.025]
Log-rank test			
Two-sided stratified log-rank p-value			0.9304

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.13.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	15 (34.1)	11.6 [6.2, NC]	48	11 (22.9)	11.3 [5.7, NC]	0.933 [0.417, 2.088]	0.8657	0.9748
>65 years	12	3 (25.0)	7.5 [3.0, NC]	10	2 (20.0)	NC [1.5, NC]	1.028 [0.167, 6.317]	0.9764	
Sex									
Male	32	10 (31.3)	13.3 [7.6, NC]	37	8 (21.6)	NC [5.7, NC]	0.782 [0.291, 2.099]	0.6247	0.3887
Female	24	8 (33.3)	6.2 [5.6, NC]	21	5 (23.8)	11.3 [6.2, 11.3]	1.550 [0.505, 4.760]	0.4415	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	NC [5.4, NC]	18	5 (27.8)	11.3 [5.7, NC]	1.296 [0.394, 4.265]	0.6749	0.5068
>=3	38	12 (31.6)	11.6 [6.3, NC]	40	8 (20.0)	7.1 [5.7, NC]	0.734 [0.283, 1.906]	0.5235	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.14.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	21 (37.5%)	25 (43.1%)	
Number of patients censored	35 (62.5%)	33 (56.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.0[3.2, NC]	5.8[3.6, 9.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.746[0.408, 1.362]
Log-rank test			
Two-sided stratified log-rank p-value			0.3459

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.14.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	17 (38.6)	9.7 [3.1, NC]	48	20 (41.7)	5.8 [3.6, 9.0]	0.834 [0.431, 1.614]	0.5856	0.5730
>65 years	12	4 (33.3)	5.7 [2.9, NC]	10	5 (50.0)	4.5 [2.8, 15.4]	0.645 [0.160, 2.601]	0.5528	
Sex									
Male	32	11 (34.4)	9.7 [3.2, NC]	37	17 (45.9)	5.8 [3.1, 7.4]	0.573 [0.260, 1.264]	0.1652	0.3477
Female	24	10 (41.7)	3.4 [2.9, NC]	21	8 (38.1)	11.3 [2.9, 15.4]	1.061 [0.417, 2.697]	0.9052	
Number of Organs with Metastatic Sites									
0-2	18	5 (27.8)	NC [2.9, NC]	18	11 (61.1)	5.8 [2.9, 11.3]	0.560 [0.194, 1.615]	0.2823	0.4368
>=3	38	16 (42.1)	6.0 [3.1, 21.4]	40	14 (35.0)	5.7 [3.1, 7.4]	0.873 [0.420, 1.818]	0.7224	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.15.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	EOX (N= 58)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	16 (28.6%)	15 (25.9%)	
Number of patients censored	40 (71.4%)	43 (74.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.3[6.0, NC]	9.2[6.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.793[0.384, 1.638]
Log-rank test			
Two-sided stratified log-rank p-value			0.5320

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.15.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	11 (25.0)	13.3 [7.9, NC]	48	13 (27.1)	8.8 [6.0, NC]	0.664 [0.291, 1.514]	0.3242	0.3265
>65 years	12	5 (41.7)	6.0 [4.3, 19.5]	10	2 (20.0)	11.3 [2.8, NC]	1.324 [0.240, 7.300]	0.7465	
Sex									
Male	32	9 (28.1)	19.5 [7.9, NC]	37	8 (21.6)	9.2 [5.7, NC]	0.684 [0.248, 1.886]	0.4612	0.4696
Female	24	7 (29.2)	5.9 [5.6, NC]	21	7 (33.3)	8.8 [6.9, 11.3]	1.166 [0.401, 3.394]	0.7776	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	9.3 [3.2, NC]	18	5 (27.8)	11.3 [5.7, NC]	1.488 [0.453, 4.887]	0.5094	0.2343
>=3	38	10 (26.3)	13.3 [5.9, NC]	40	10 (25.0)	7.2 [5.7, NC]	0.558 [0.217, 1.429]	0.2189	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.16.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	14 (25.0%)	20 (34.5%)	
Number of patients censored	42 (75.0%)	38 (65.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	26.1[9.7, NC]	6.2[5.7, 15.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.408[0.200, 0.834]
Log-rank test			
Two-sided stratified log-rank p-value			0.0115

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.16.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhea by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	9 (20.5)	NC [11.6, NC]	48	14 (29.2)	7.4 [5.7, NC]	0.479 [0.205, 1.123]	0.0835	0.9021
>65 years	12	5 (41.7)	9.7 [3.0, NC]	10	6 (60.0)	5.7 [1.5, 15.4]	0.337 [0.093, 1.218]	0.0813	
Sex									
Male	32	7 (21.9)	NC [9.7, NC]	37	14 (37.8)	5.9 [3.1, NC]	0.295 [0.116, 0.754]	0.0076	0.1194
Female	24	7 (29.2)	26.1 [3.4, 26.1]	21	6 (28.6)	15.4 [2.9, 15.4]	0.727 [0.233, 2.261]	0.5856	
Number of Organs with Metastatic Sites									
0-2	18	3 (16.7)	26.1 [9.7, NC]	18	9 (50.0)	5.9 [4.6, 15.4]	0.197 [0.042, 0.934]	0.0238	0.5580
>=3	38	11 (28.9)	13.3 [6.0, NC]	40	11 (27.5)	7.4 [3.1, NC]	0.517 [0.217, 1.230]	0.1307	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.17.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	25 (44.6%)	20 (34.5%)	
Number of patients censored	31 (55.4%)	38 (65.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.0[3.4, 7.6]	6.0[5.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.242[0.682, 2.265]
Log-rank test			
Two-sided stratified log-rank p-value			0.4719

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.17.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties by Subgroups (MID=10) - mITT Analysis Set

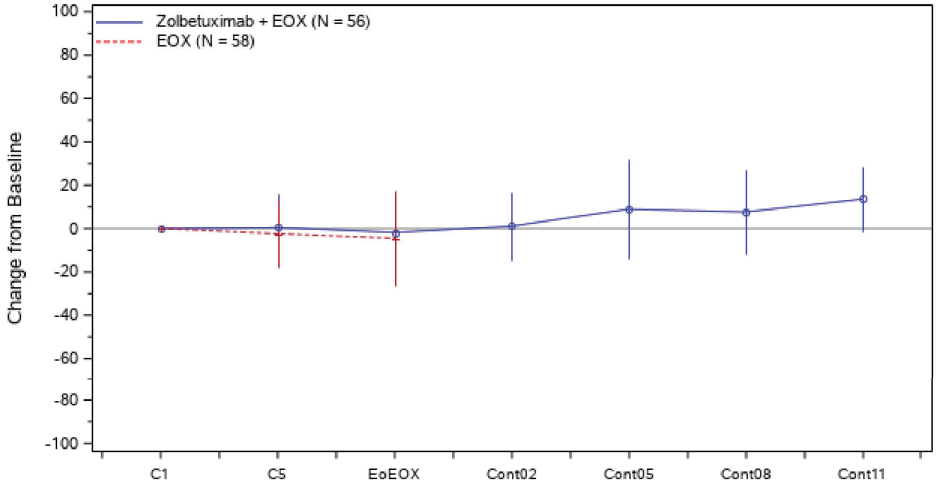
	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	18 (40.9)	6.7 [3.4, 9.7]	48	17 (35.4)	6.0 [5.7, 8.2]	0.998 [0.510, 1.953]	0.9940	0.2553
>65 years	12	7 (58.3)	4.4 [2.9, 6.0]	10	3 (30.0)	NC [1.5, NC]	2.217 [0.570, 8.620]	0.2384	
Sex									
Male	32	18 (56.3)	6.0 [3.1, 7.6]	37	13 (35.1)	6.0 [5.7, NC]	1.222 [0.585, 2.552]	0.5811	0.6769
Female	24	7 (29.2)	5.9 [3.2, NC]	21	7 (33.3)	5.7 [2.9, NC]	0.966 [0.338, 2.764]	0.9378	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	5.9 [2.8, 7.6]	18	6 (33.3)	NC [2.9, NC]	2.474 [0.824, 7.425]	0.0911	0.0640
>=3	38	18 (47.4)	6.0 [3.7, 9.7]	40	14 (35.0)	6.0 [5.6, 8.2]	0.777 [0.369, 1.638]	0.5162	

Abbreviations: CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

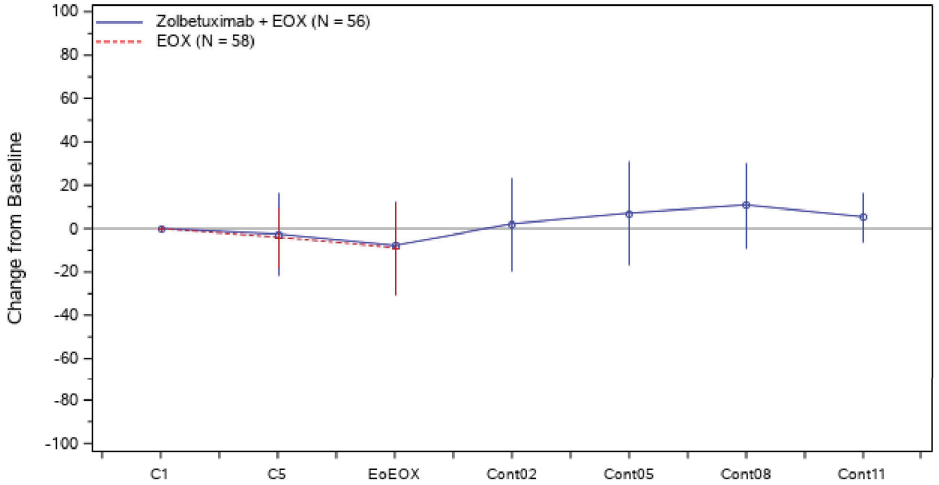
4. Graphische Darstellung des Verlaufs (Mean Change from Baseline)

Figure GM03.1.3002.3: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Global Health Status - mITT Analysis Set



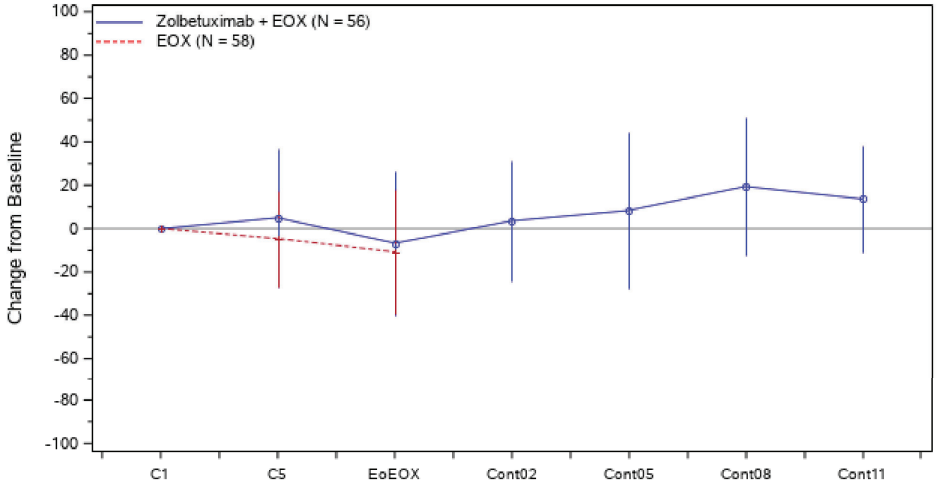
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.4: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Physical Functioning - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

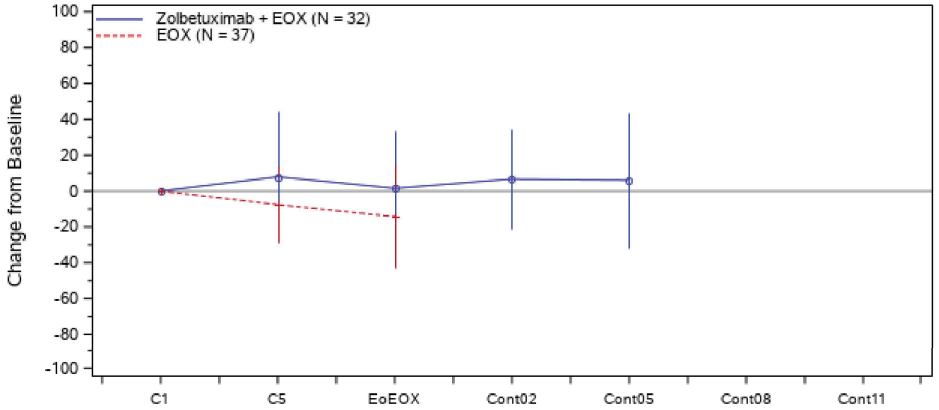
Figure GM03.1.3002.5: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.5.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - mITT Analysis Set

Sex: Male



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

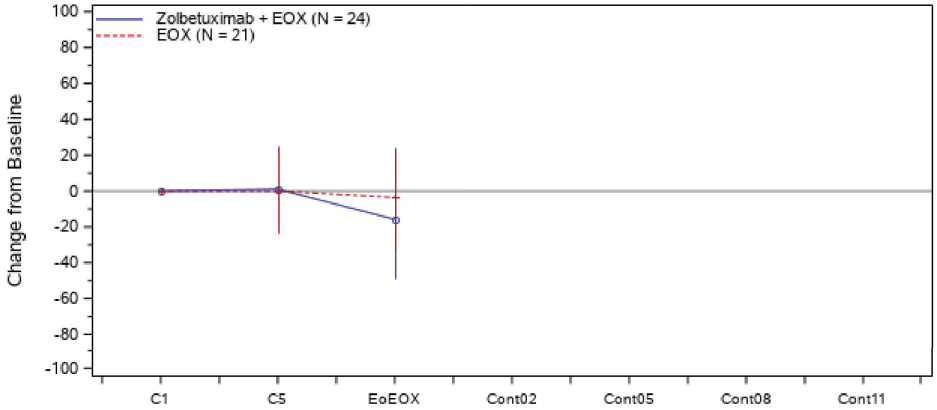
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).

ASTELLAS Data Cutoff Date: 31JAN2019

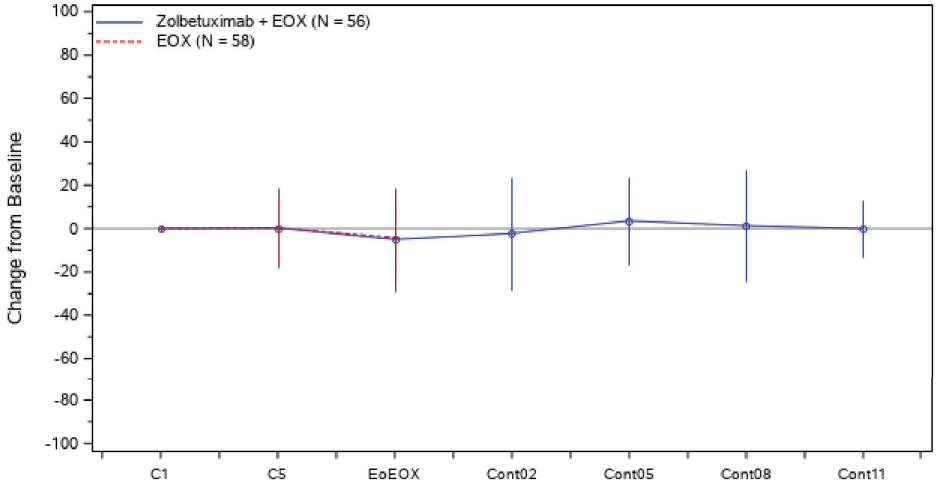
Figure GM03.1.3002.5.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Role Functioning by Sex - mITT Analysis Set

Sex: Female



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).
ASTELLAS Data Cutoff Date: 31JAN2019

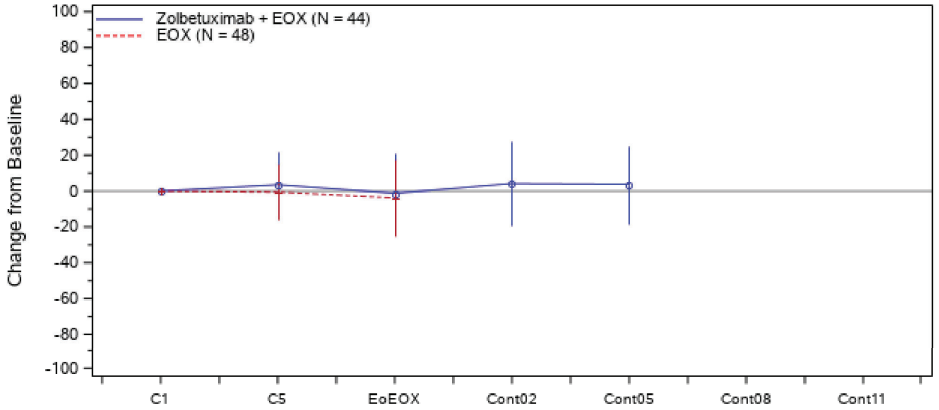
Figure GM03.1.3002.6: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.6.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age Group 1 - mITT Analysis Set

Age Group 1: <=65 years



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

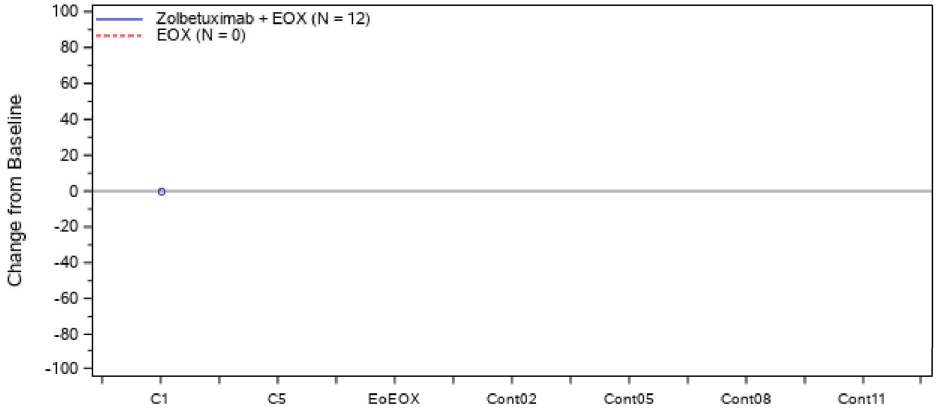
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.6.1: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Emotional Functioning by Age Group 1 - mITT Analysis Set

Age Group 1: >65 years



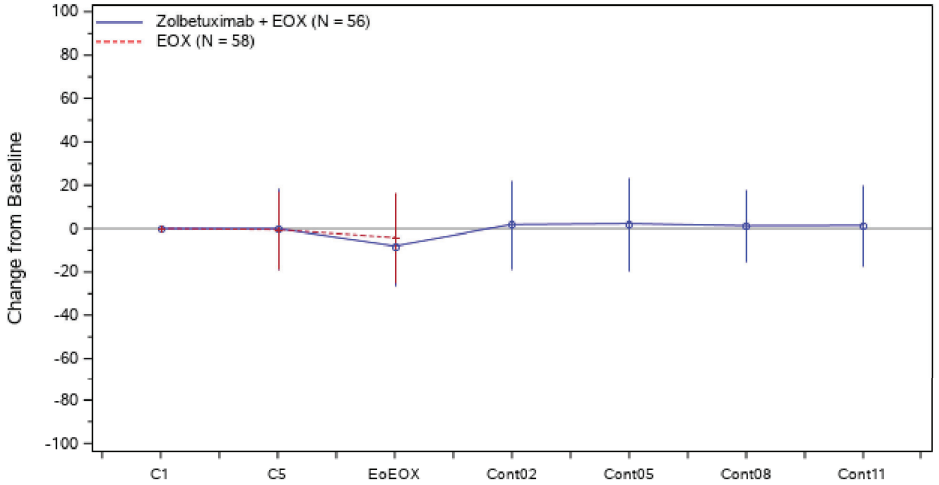
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).

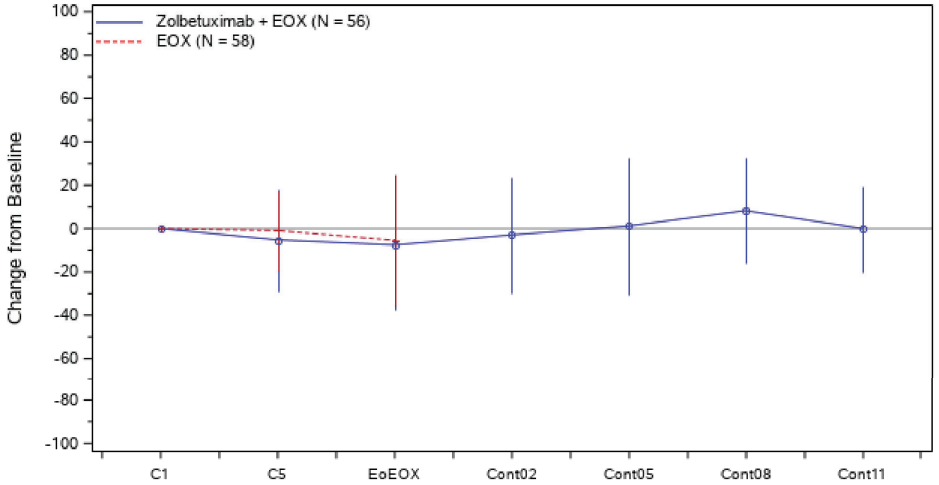
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.7: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Cognitive Functioning - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

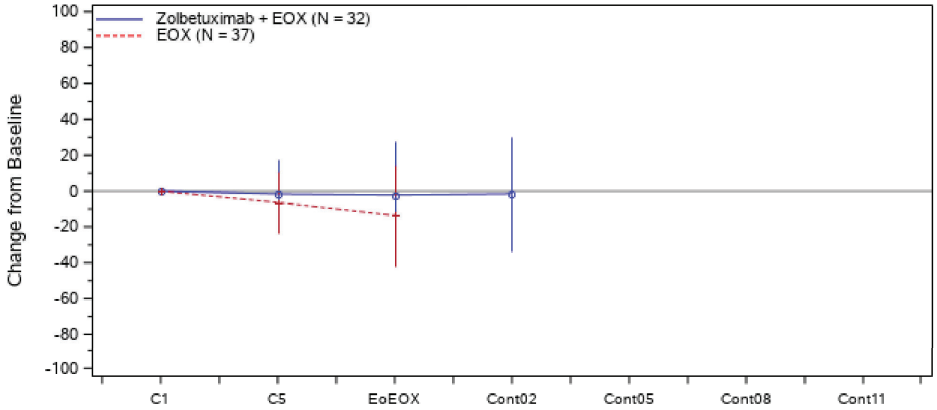
Figure GM03.1.3002.8: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.8.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - mITT Analysis Set

Sex: Male



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

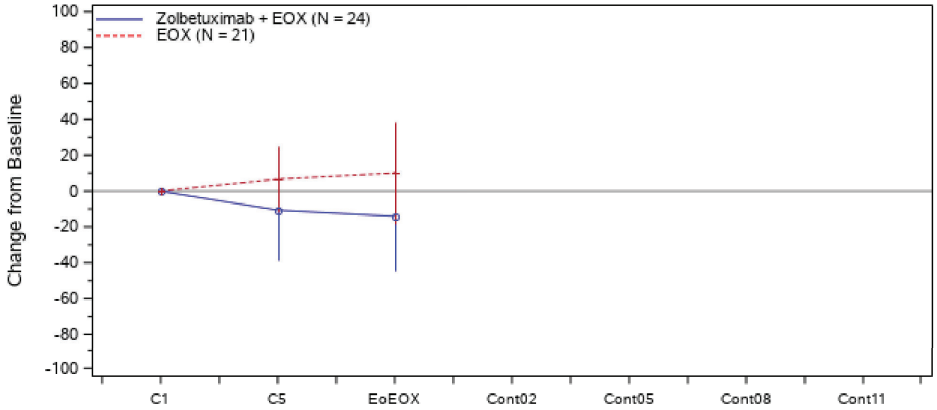
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).

ASTELLAS Data Cutoff Date: 31JAN2019

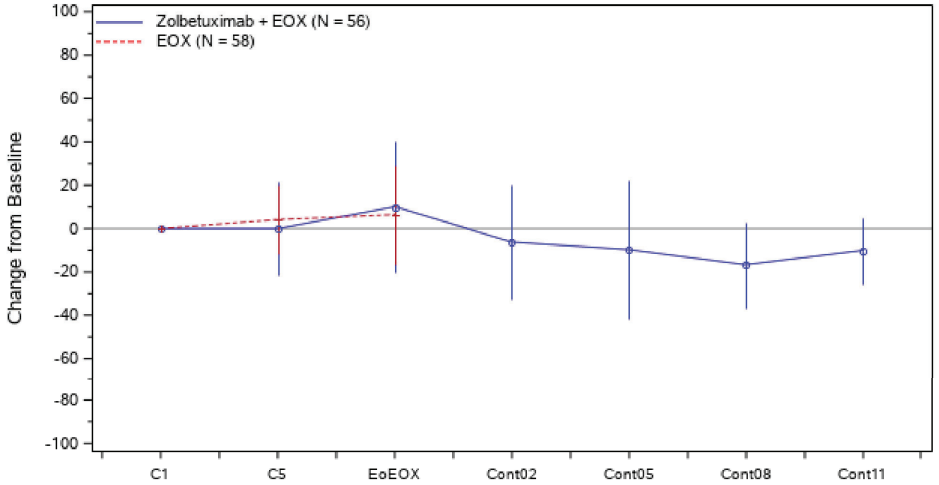
Figure GM03.1.3002.8.2: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Social Functioning by Sex - mITT Analysis Set

Sex: Female



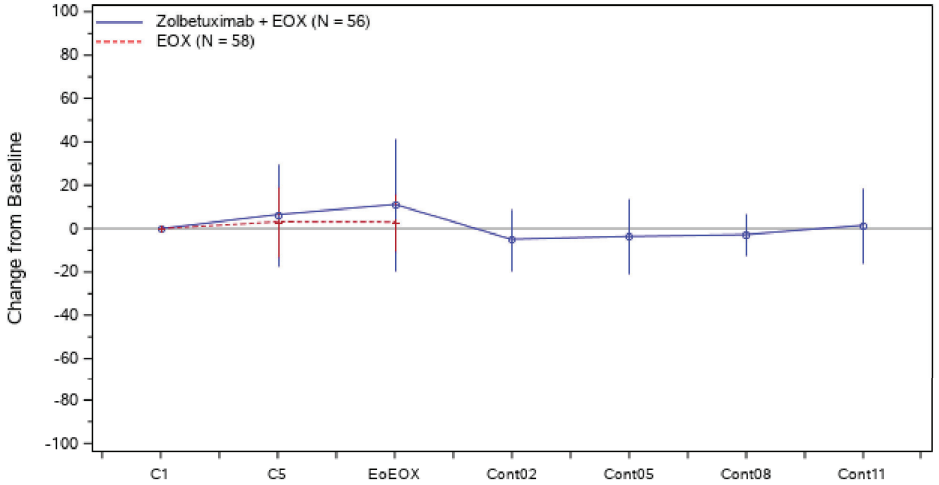
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant (p<0.05).
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.9: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Fatigue - mITT Analysis Set



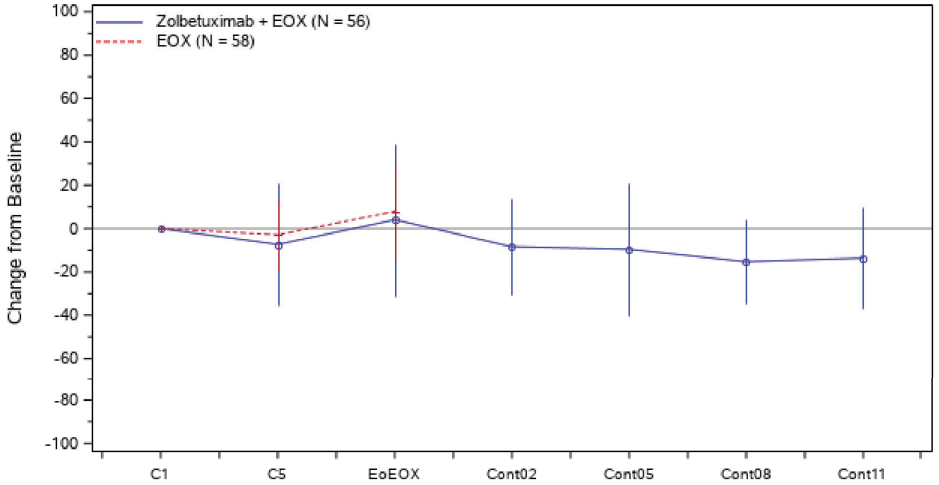
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.10: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Nausea and Vomiting - mITT Analysis Set



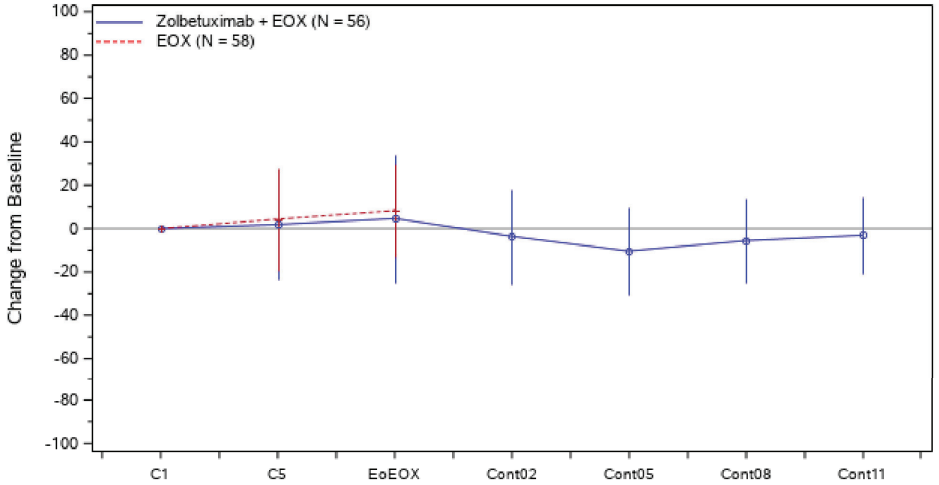
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.11: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Pain - mITT Analysis Set



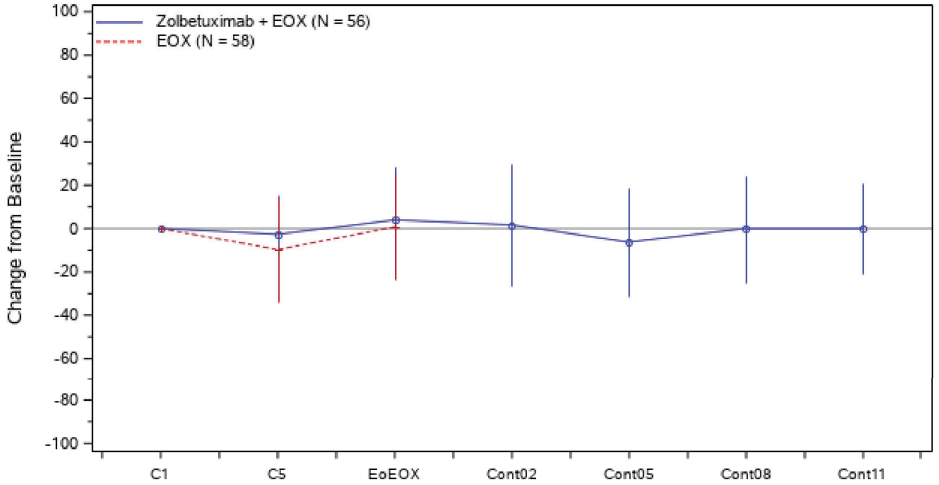
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.12: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Dyspnoea - mITT Analysis Set



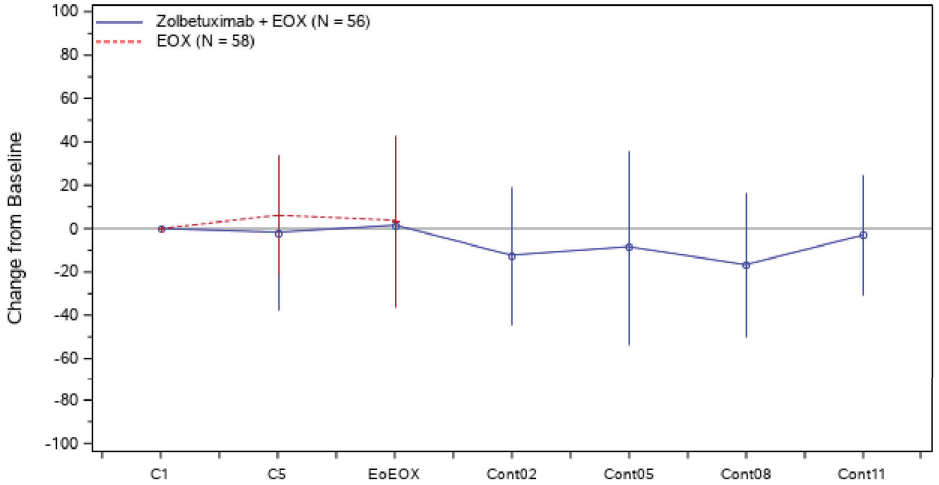
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.13: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Insomnia - mITT Analysis Set



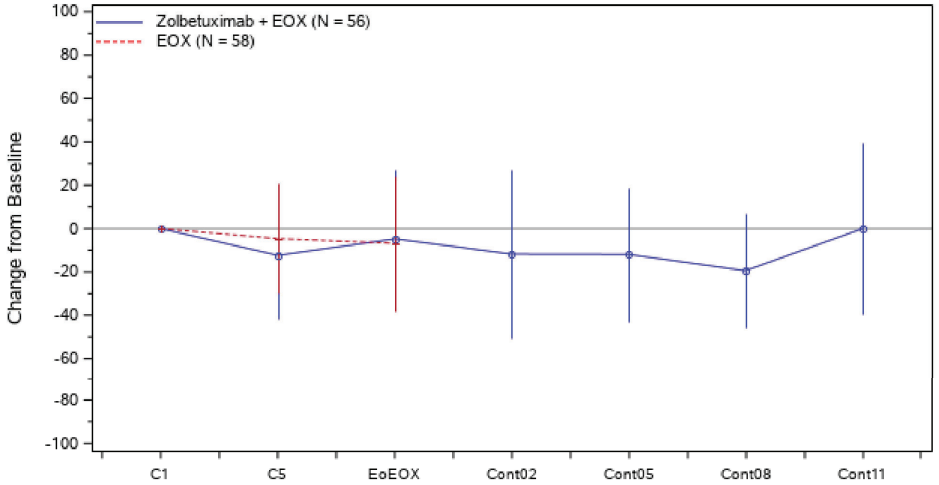
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.14: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Appetite Loss - mITT Analysis Set



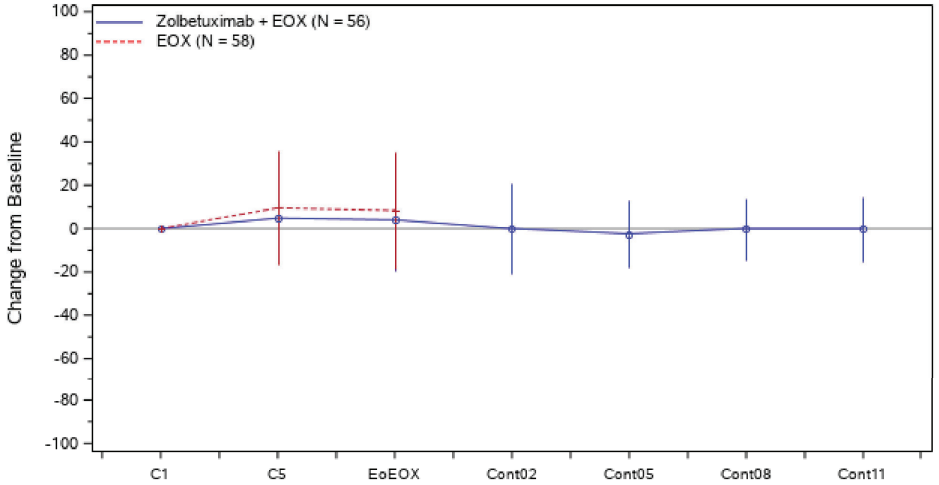
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.15: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Constipation - mITT Analysis Set



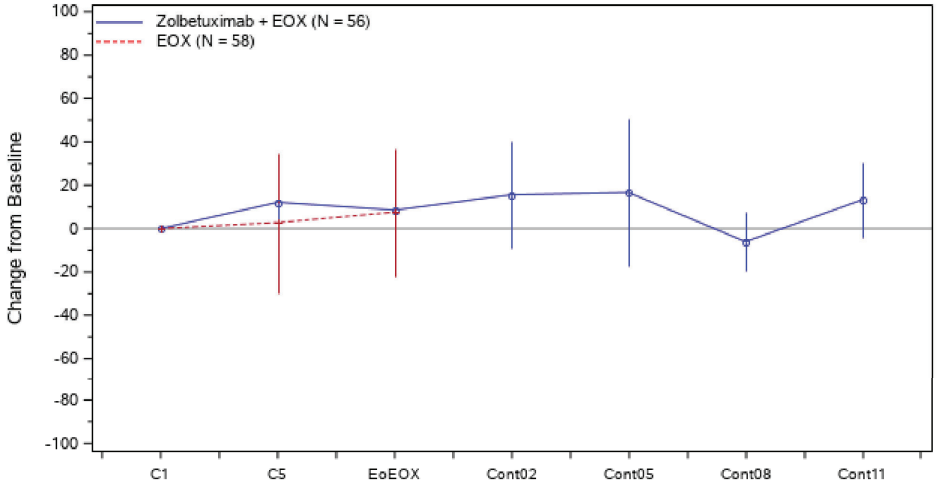
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.16: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Diarrhea - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.17: EORTC QLQ-C30 - Plot of Mean Change from Baseline of Financial Difficulties - mITT Analysis Set

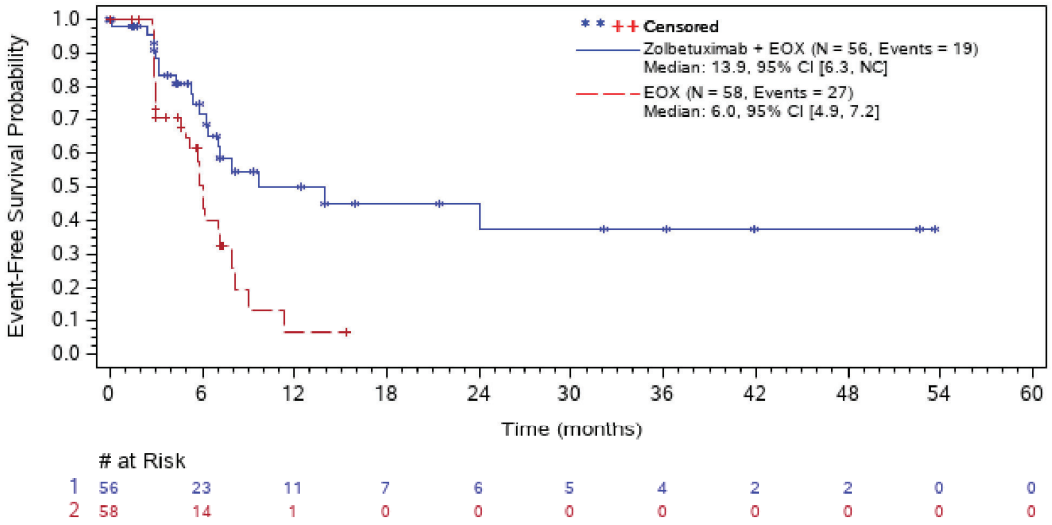


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-C30= European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

5. Kaplan-Meier-Plots

Figure GM03.1.3003.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Global Health Status (MID=10) - mITT Analysis Set



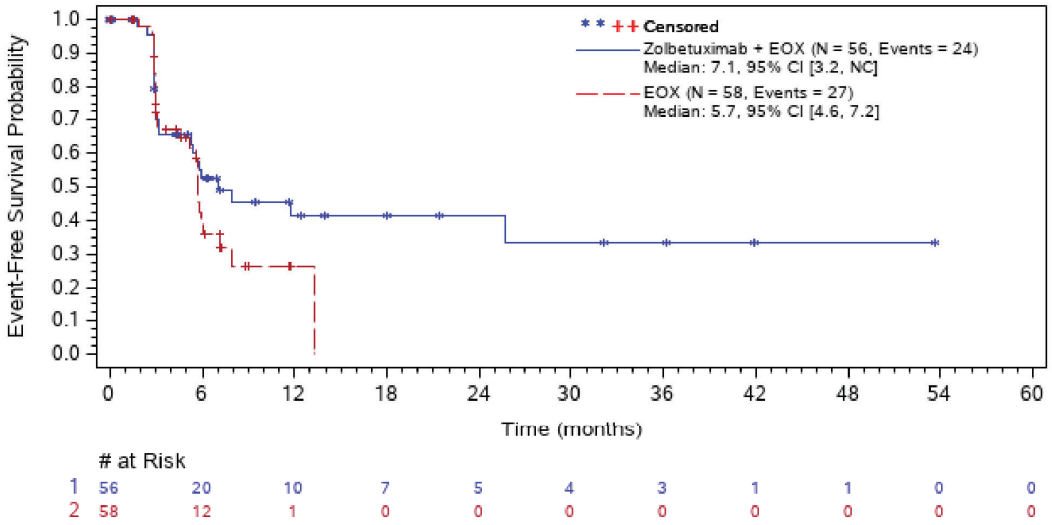
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.4: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Physical Functioning (MID=10) - mITT Analysis Set



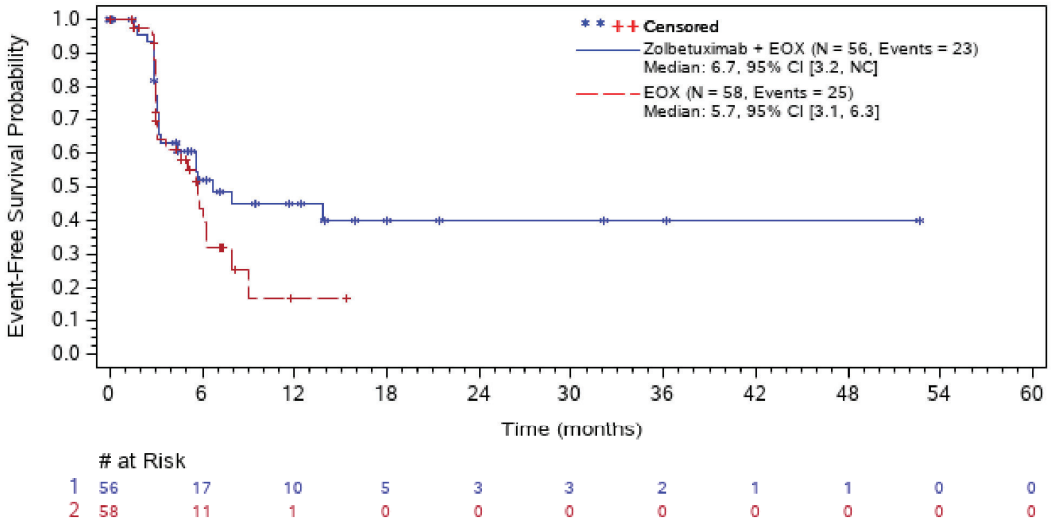
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.5: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

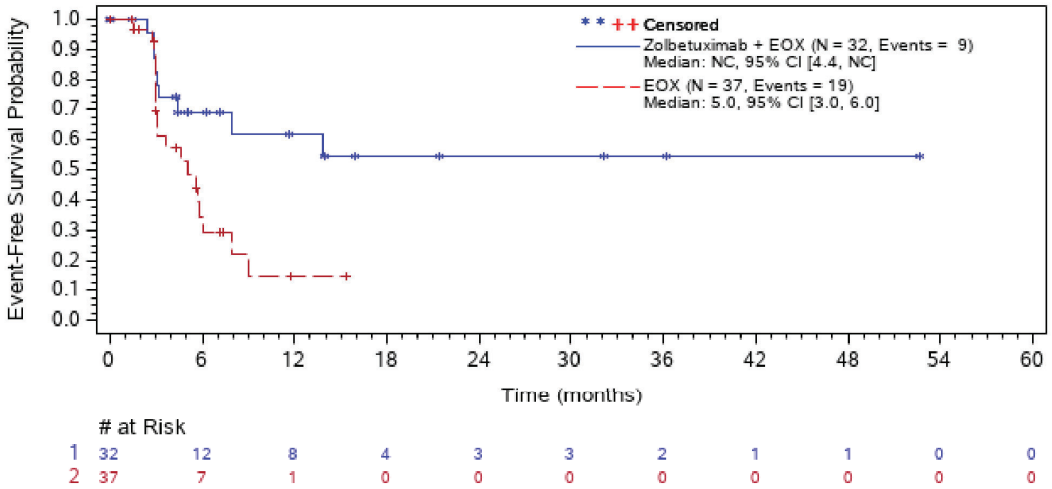
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.5.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning by Sex (MID=10) - mITT Analysis Set

Sex: Male



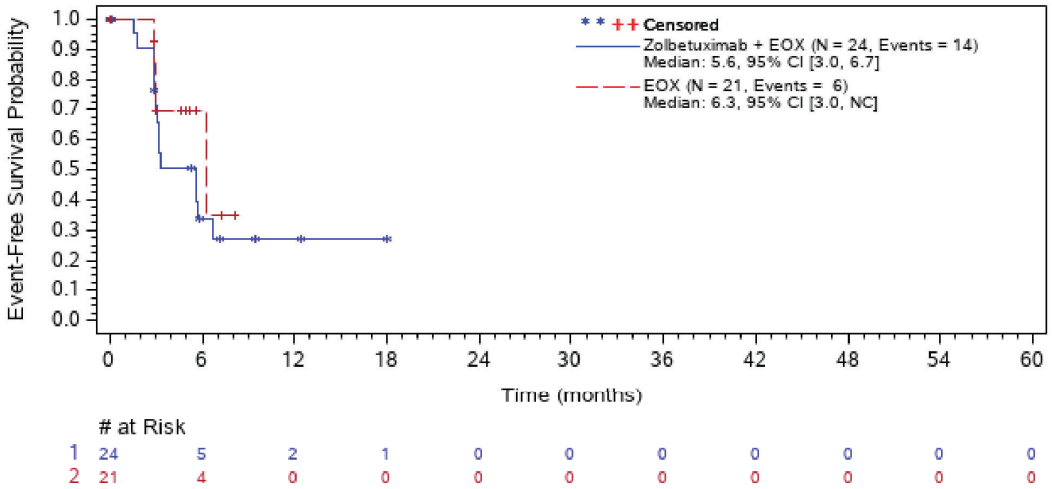
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.5.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning by Sex (MID=10) - mITT Analysis Set
Sex: Female



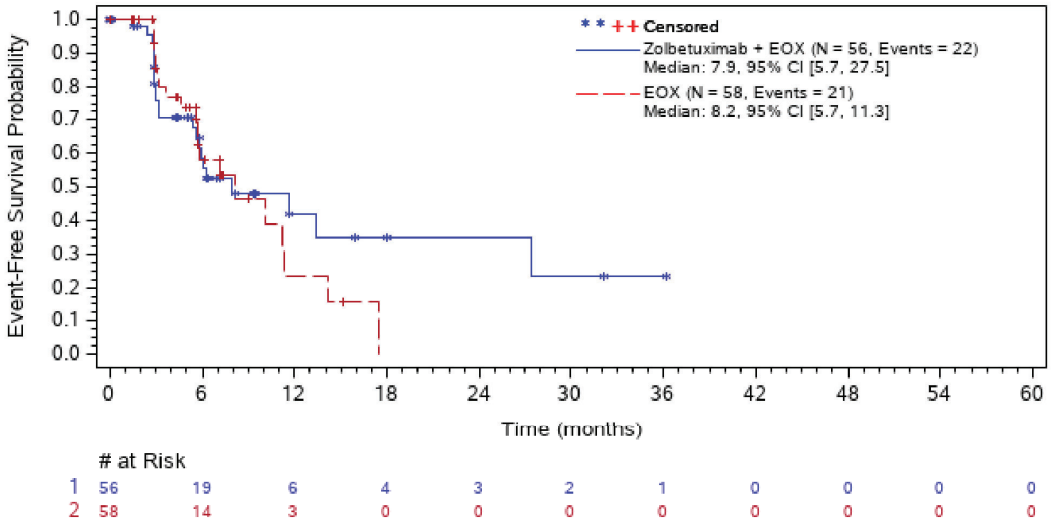
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.6: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Emotional Functioning (MID=10) - mITT Analysis Set



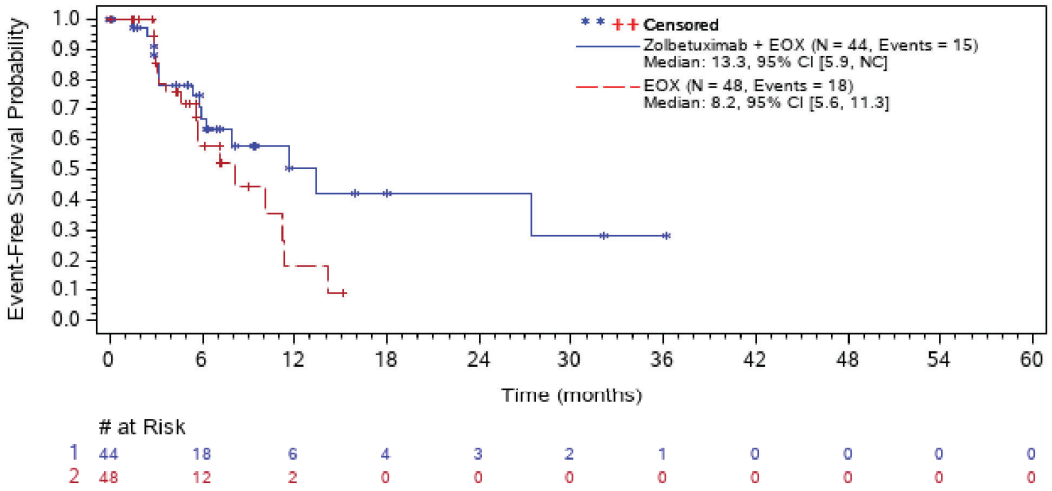
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.6.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Emotional Functioning by Age Group 1 (MID=10) - mITT Analysis Set
Age Group 1: <=65 years



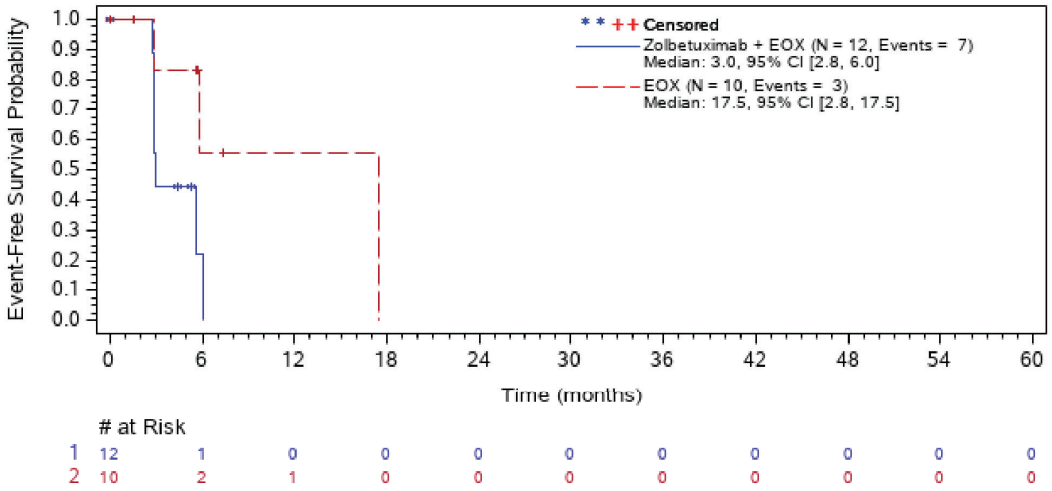
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.6.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Emotional Functioning by Age Group 1 (MID=10) - mITT Analysis Set
Age Group 1: >65 years



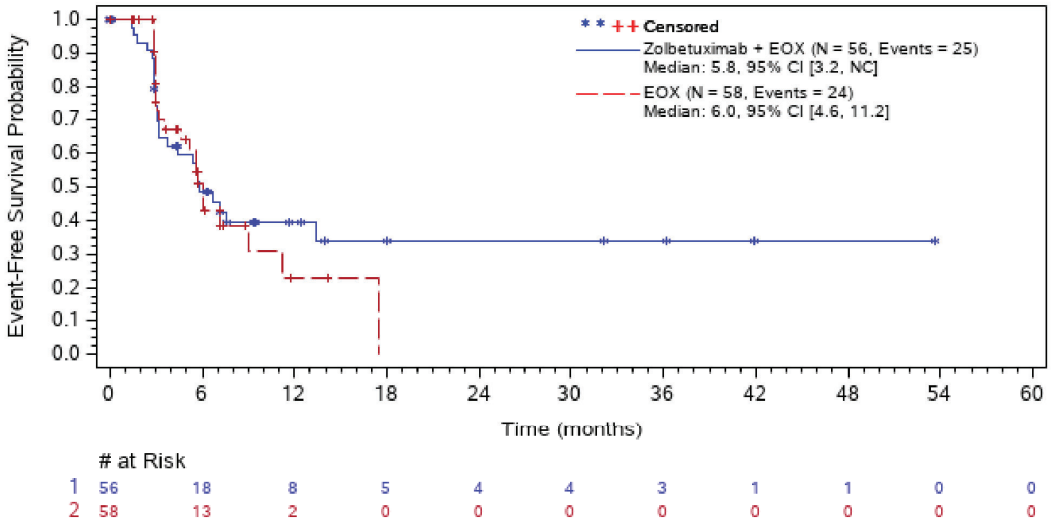
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.7: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Cognitive Functioning (MID=10) - mITT Analysis Set



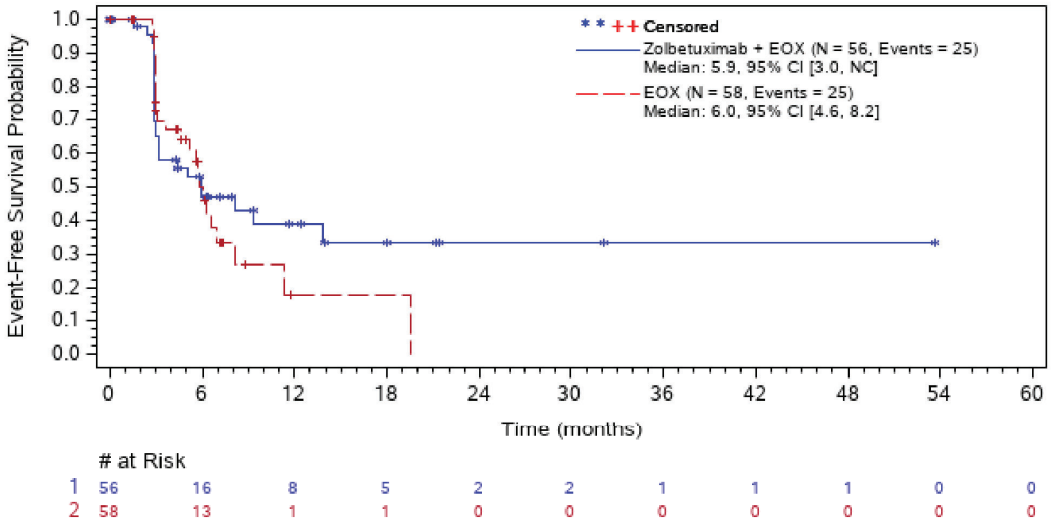
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.8: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Social Functioning (MID=10) - mITT Analysis Set



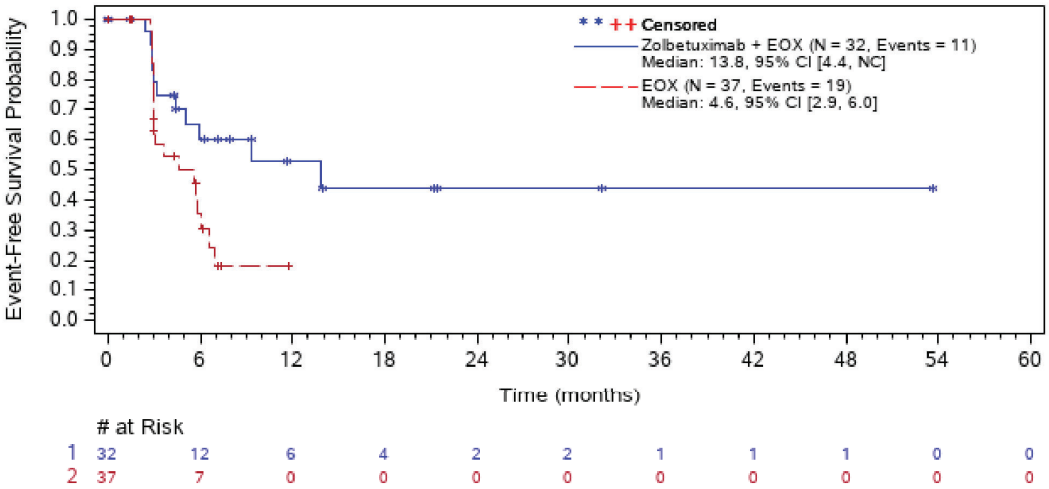
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.8.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Social Functioning by Sex (MID=10) - mITT Analysis Set
Sex: Male



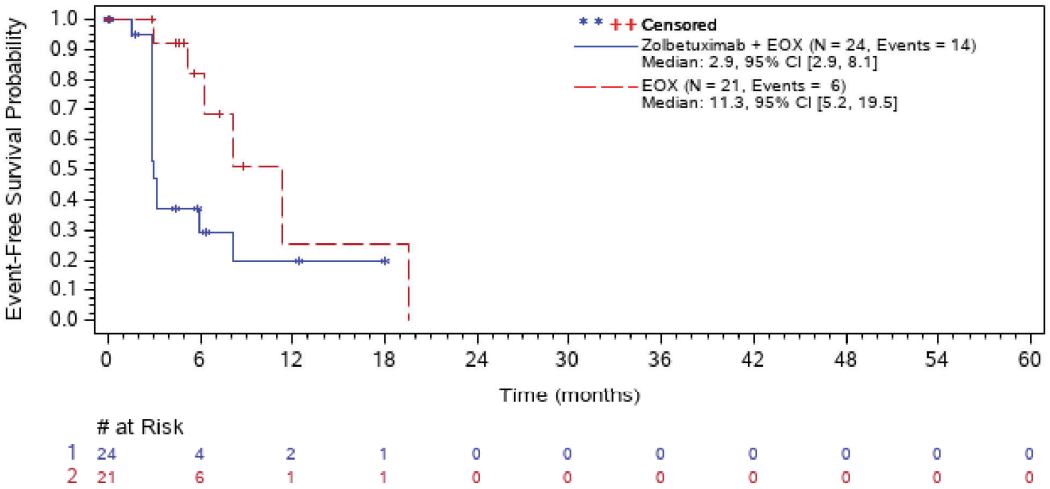
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.8.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Social Functioning by Sex (MID=10) - mITT Analysis Set
Sex: Female



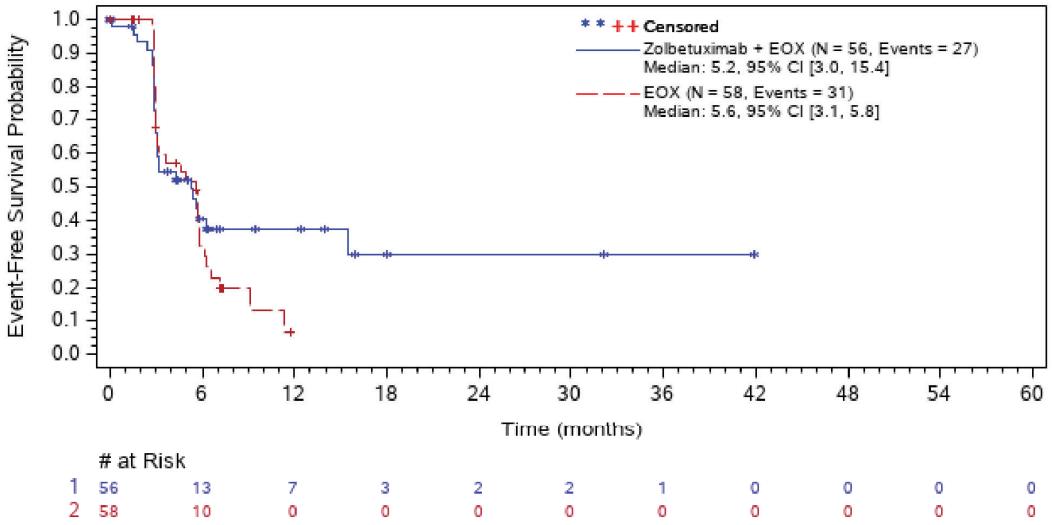
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.9: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue (MID=10) - mITT Analysis Set



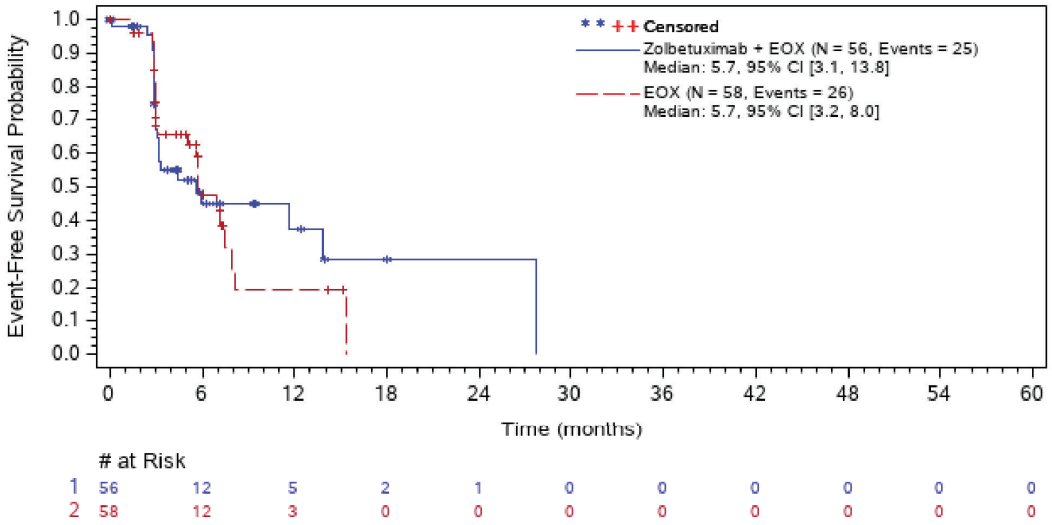
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.10: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Nausea and Vomiting (MID=10) - mITT Analysis Set



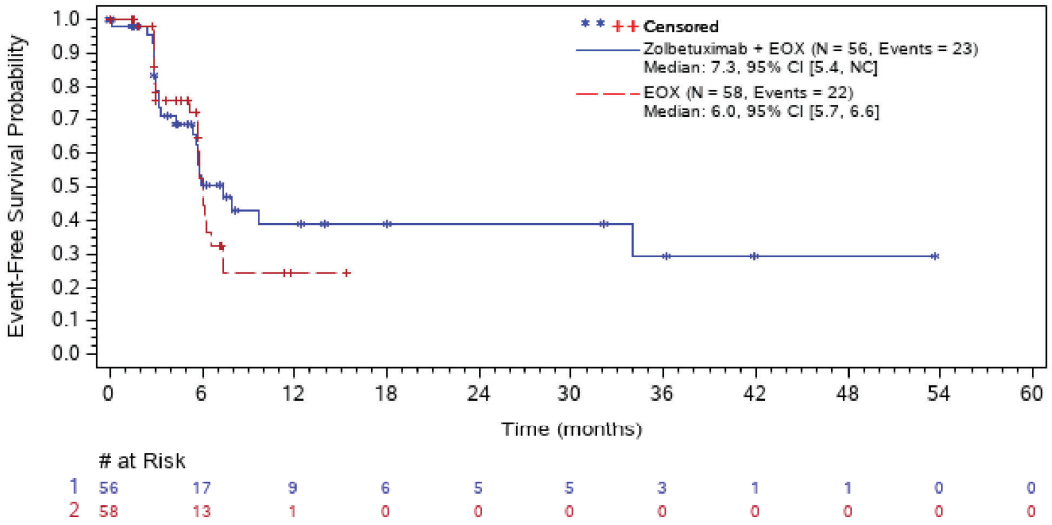
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.11: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain (MID=10) - mITT Analysis Set



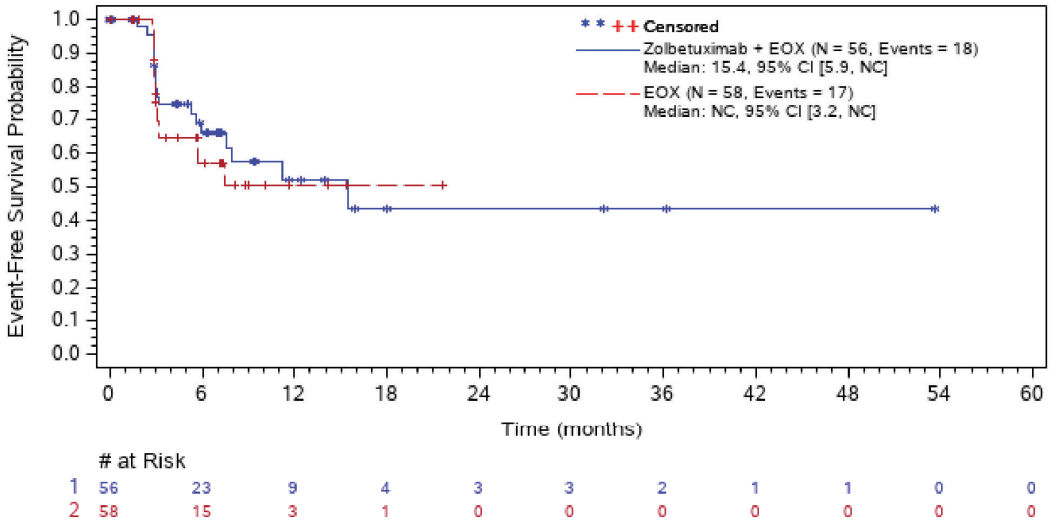
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.12: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea (MID=10) - mITT Analysis Set



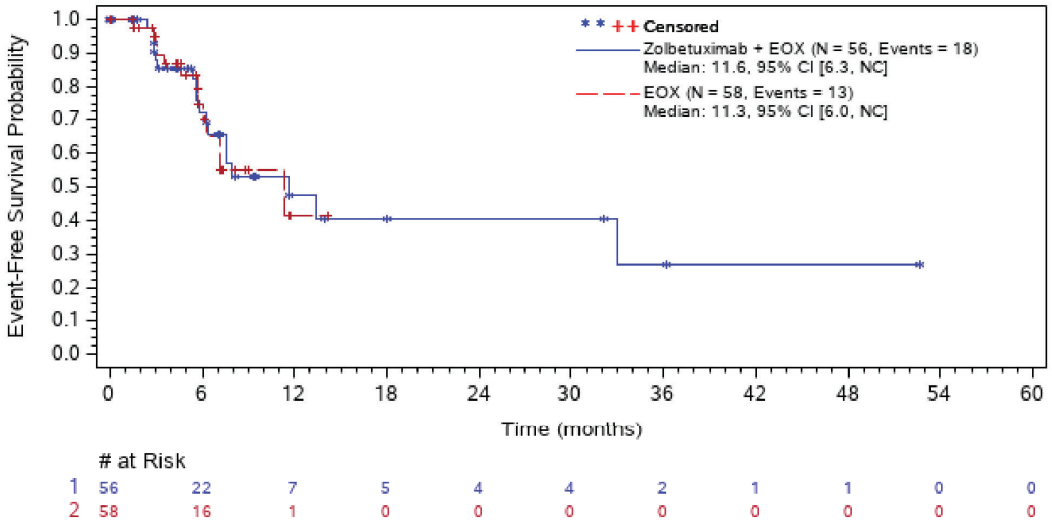
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.13: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Insomnia (MID=10) - mITT Analysis Set



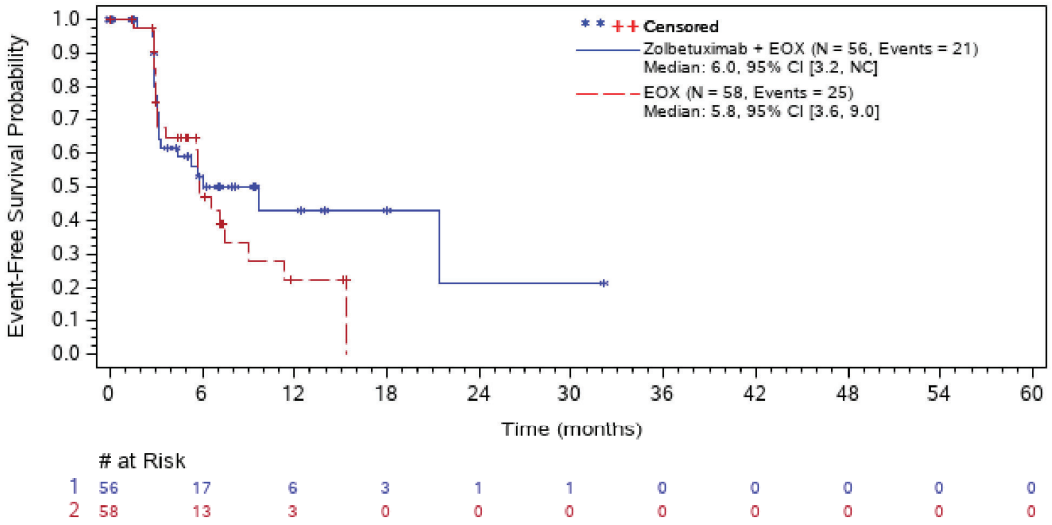
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.14: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Appetite Loss (MID=10) - mITT Analysis Set



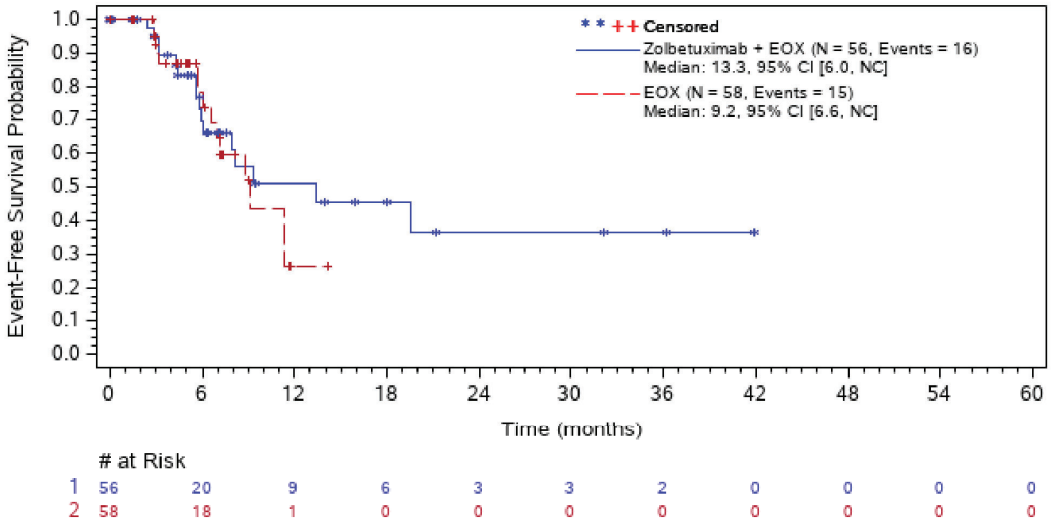
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.15: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation (MID=10) - mITT Analysis Set



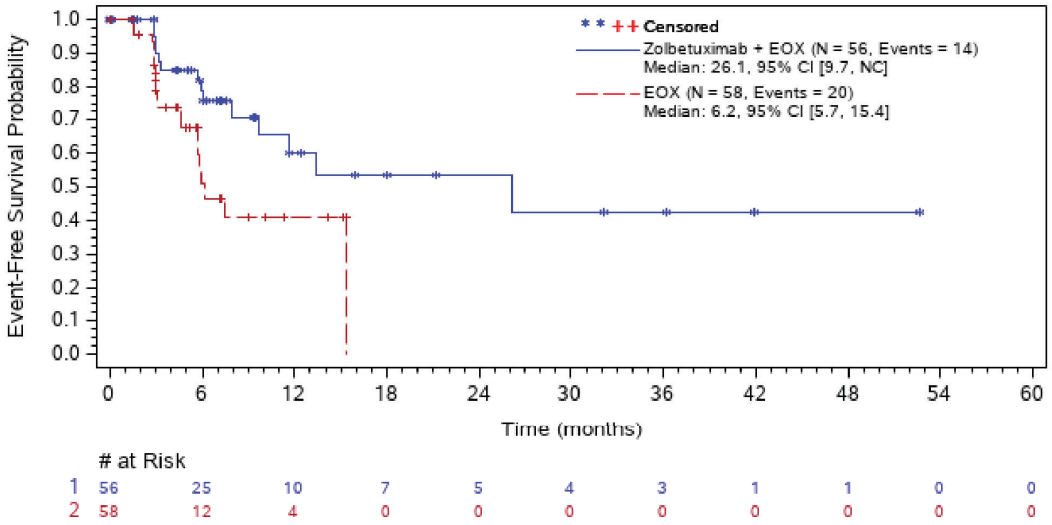
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.16: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhea (MID=10) - mITT Analysis Set



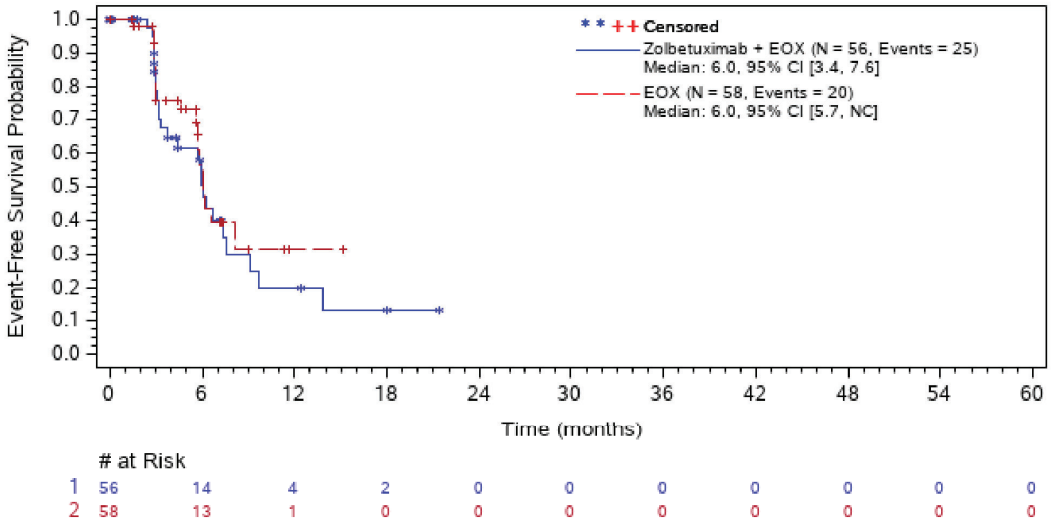
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.17: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Financial Difficulties (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)

Anhang 4-G2 Symptomatik anhand des EORTC QLQ-STO22

1. Rücklaufquoten

Table GM03.1.3001.18: EORTC QLQ-STO22 - Completion Status of Functioning - Body Image - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.19: EORTC QLQ-STO22 - Completion Status of Dysphagia - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.20: EORTC QLQ-STO22 - Completion Status of Pain - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.21: EORTC QLQ-STO22 - Completion Status of Reflux Symptoms - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.22: EORTC QLQ-STO22 - Completion Status of Eating Symptoms - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.23: EORTC QLQ-STO22 - Completion Status of Anxiety - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.24: EORTC QLQ-STO22 - Completion Status of Dry Mouth - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.25: EORTC QLQ-STO22 - Completion Status of Taste - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.26: EORTC QLQ-STO22 - Completion Status of Symptom - Body Image - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3001.27: EORTC QLQ-STO22 - Completion Status of Hair Loss - mITT Analysis Set

Analysis Visit	Zolbetuximab + EOX (N= 56)			EOX (N= 58)		
	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]	Compliance Rate (based on expected assessments)[1]	Compliance Rate (adjusted for deaths)[2]	Completion Rate (unadjusted)[3]
Cycle 1	55/ 55 (100.0%)	55/ 55 (100.0%)	55/ 56 (98.2%)	57/ 57 (100.0%)	57/ 57 (100.0%)	57/ 58 (98.3%)
Cycle 5	37/ 40 (92.5%)	38/ 41 (92.7%)	38/ 56 (67.9%)	38/ 41 (92.7%)	38/ 41 (92.7%)	38/ 58 (65.5%)
End Of Eox Treatment	33/ 42 (78.6%)	43/ 52 (82.7%)	43/ 56 (76.8%)	35/ 45 (77.8%)	46/ 56 (82.1%)	46/ 58 (79.3%)
Imab362 Continuing Treatment Cycle 02	19/ 23 (82.6%)	19/ 23 (82.6%)	19/ 56 (33.9%)	9/ 16 (56.3%)	9/ 16 (56.3%)	9/ 58 (15.5%)
Imab362 Continuing Treatment Cycle 05	15/ 17 (88.2%)	16/ 18 (88.9%)	16/ 56 (28.6%)	5/ 12 (41.7%)	5/ 12 (41.7%)	5/ 58 (8.6%)
Imab362 Continuing Treatment Cycle 08	12/ 13 (92.3%)	12/ 13 (92.3%)	12/ 56 (21.4%)	4/ 9 (44.4%)	4/ 9 (44.4%)	4/ 58 (6.9%)
Imab362 Continuing Treatment Cycle 11	11/ 12 (91.7%)	11/ 12 (91.7%)	11/ 56 (19.6%)	3/ 4 (75.0%)	3/ 4 (75.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 14	9/ 11 (81.8%)	9/ 11 (81.8%)	9/ 56 (16.1%)	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 58 (5.2%)
Imab362 Continuing Treatment Cycle 17	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 20	8/ 9 (88.9%)	8/ 9 (88.9%)	8/ 56 (14.3%)	1/ 2 (50.0%)	1/ 2 (50.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 23	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 58 (1.7%)
Imab362 Continuing Treatment Cycle 26	7/ 7 (100.0%)	7/ 7 (100.0%)	7/ 56 (12.5%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 29	6/ 7 (85.7%)	6/ 7 (85.7%)	6/ 56 (10.7%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 32	2/ 5 (40.0%)	3/ 6 (50.0%)	3/ 56 (5.4%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 35	3/ 5 (60.0%)	3/ 5 (60.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 38	4/ 5 (80.0%)	4/ 5 (80.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 41	2/ 4 (50.0%)	2/ 4 (50.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 44	4/ 4 (100.0%)	4/ 4 (100.0%)	4/ 56 (7.1%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 47	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 3 (0.0%)	0/ 3 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 50	3/ 3 (100.0%)	3/ 3 (100.0%)	3/ 56 (5.4%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 53	2/ 3 (66.7%)	2/ 3 (66.7%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 56	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 59	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 2 (0.0%)	0/ 2 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 62	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0/ 1 (0.0%)	0/ 1 (0.0%)	0/ 58 (0.0%)
Imab362 Continuing Treatment Cycle 65	2/ 2 (100.0%)	2/ 2 (100.0%)	2/ 56 (3.6%)	0	0	0
Imab362 Continuing Treatment Cycle 68	1/ 1 (100.0%)	1/ 1 (100.0%)	1/ 56 (1.8%)	0	0	0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; PRO=patient reported outcome.
[1] Compliance (or adjusted completion) rate is calculated as the number of subjects with minimum requirements for scoring divided by the number of subjects with study PRO visit from ITT without patients not expected due to progression, death or other reasons at respective visit. Minimum requirements for scoring is defined as at least one scale with non-missing values.
[2] Compliance rate (adjusted for deaths) is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects with study PRO visit from ITT without patients not expected due to death at respective visit.
[3] Unadjusted completion rate is calculated as the number of subjects with minimum requirements for scoring divided by number of subjects in the ITT Population.
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Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik anhand des EORTC QLQ-STO22

2. Verlauf über die Zeit (Observed Means and Change from Baseline)

Table GM03.1.3002.18: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Functioning - Body Image - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	66.67	31.34	0.0	66.67	100.0	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	58.06	33.30	0.0	66.67	100.0	30	-6.67	25.37	-66.7	0.00	33.3
End Of Eox Treatment	35	59.05	36.23	0.0	66.67	100.0	33	-11.11	39.67	-100.0	0.00	100.0
Imab362 Continuing Treatment Cycle 02	14	69.05	35.72	0.0	83.33	100.0	14	4.76	48.67	-100.0	0.00	100.0
Imab362 Continuing Treatment Cycle 05	11	78.79	34.23	0.0	100.00	100.0	11	12.12	42.88	-66.7	0.00	100.0
EOX (N = 58)												
Cycle 1	42	70.63	31.41	0.0	66.67	100.0	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	30	67.78	29.66	0.0	66.67	100.0	29	-3.45	30.01	-66.7	0.00	66.7
End Of Eox Treatment	35	58.10	32.68	0.0	66.67	100.0	33	-14.14	39.11	-100.0	-33.33	66.7

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.19: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Dysphagia - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	11.36	17.85	0.0	5.56	66.7	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	9.32	15.48	0.0	0.00	66.7	30	0.37	18.33	-55.6	0.00	55.6
End Of Eox Treatment	35	10.48	15.70	0.0	0.00	55.6	33	0.67	17.33	-55.6	0.00	44.4
Imab362 Continuing Treatment Cycle 02	14	7.14	11.20	0.0	0.00	33.3	14	-2.38	16.98	-44.4	0.00	33.3
Imab362 Continuing Treatment Cycle 05	11	5.05	13.48	0.0	0.00	44.4	11	-5.05	9.11	-22.2	0.00	11.1
EOX (N = 58)												
Cycle 1	42	15.34	18.84	0.0	11.11	88.9	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	13.98	21.46	0.0	11.11	88.9	30	-0.37	20.32	-44.4	0.00	77.8
End Of Eox Treatment	35	20.32	24.77	0.0	11.11	100.0	33	3.70	29.22	-88.9	0.00	66.7

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.19.2: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Dysphagia by Sex - mITT Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Male	Zolbetuximab + EOX (N = 32)												
	Cycle 1	24	9.72	19.19	0.0	0.00	66.7	24	0.00	0.00	0.0	0.00	0.0
	Cycle 5	16	3.47	5.32	0.0	0.00	11.1	15	-0.74	5.09	-11.1	0.00	11.1
	End Of Eox Treatment	18	5.56	10.95	0.0	0.00	44.4	16	-4.17	15.11	-55.6	0.00	11.1
	EOX (N = 37)												
	Cycle 1	29	14.18	20.34	0.0	11.11	88.9	28	0.00	0.00	0.0	0.00	0.0
	Cycle 5	20	15.00	25.31	0.0	5.56	88.9	19	3.51	21.61	-33.3	0.00	77.8
	End Of Eox Treatment	25	20.89	27.09	0.0	11.11	100.0	23	6.28	30.86	-88.9	0.00	66.7
Female	Zolbetuximab + EOX (N = 24)												
	Cycle 1	20	13.33	16.36	0.0	11.11	66.7	20	0.00	0.00	0.0	0.00	0.0
	Cycle 5	15	15.56	20.05	0.0	11.11	66.7	15	1.48	25.84	-55.6	0.00	55.6
	End Of Eox Treatment	17	15.69	18.45	0.0	11.11	55.6	17	5.23	18.47	-22.2	0.00	44.4
	EOX (N = 21)												
	Cycle 1	13	17.95	15.41	0.0	11.11	44.4	13	0.00	0.00	0.0	0.00	0.0
	Cycle 5	11	12.12	12.62	0.0	11.11	33.3	11	-7.07	16.68	-44.4	-11.11	11.1
	End Of Eox Treatment	10	18.89	18.92	0.0	11.11	55.6	10	-2.22	25.55	-44.4	0.00	44.4

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
Table is provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant ($p<0.05$).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.20: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Pain - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	21.28	17.27	0.0	16.67	66.7	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	20.16	17.05	0.0	16.67	66.7	30	0.83	20.69	-41.7	0.00	41.7
End Of Eox Treatment	35	23.10	18.42	0.0	25.00	66.7	33	3.45	22.33	-58.3	0.00	50.0
Imab362 Continuing Treatment Cycle 02	14	14.29	13.25	0.0	16.67	33.3	14	-5.36	21.83	-58.3	-4.17	16.7
Imab362 Continuing Treatment Cycle 05	11	12.88	13.62	0.0	8.33	33.3	11	-9.85	20.35	-58.3	-8.33	8.3
EOX (N = 58)												
Cycle 1	42	21.23	15.87	0.0	16.67	77.8	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	17.47	18.18	0.0	16.67	91.7	30	-0.83	13.15	-25.0	0.00	33.3
End Of Eox Treatment	35	23.10	21.30	0.0	16.67	100.0	33	2.02	18.57	-41.7	0.00	50.0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
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Table GM03.1.3002.21: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Reflux Symptoms - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	20.33	18.40	0.0	11.11	77.8	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	10.04	15.00	0.0	0.00	66.7	30	-7.22	18.86	-55.6	0.00	33.3
End Of Eox Treatment	34	10.62	19.07	0.0	0.00	66.7	32	-6.25	19.79	-44.4	-11.11	44.4
Imab362 Continuing Treatment Cycle 02	14	12.30	19.51	0.0	0.00	55.6	14	-5.16	21.84	-44.4	-11.11	50.0
Imab362 Continuing Treatment Cycle 05	11	12.12	18.89	0.0	0.00	55.6	11	-5.56	17.74	-44.4	-11.11	22.2
EOX (N = 58)												
Cycle 1	42	15.61	18.54	0.0	11.11	66.7	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	12.54	11.74	0.0	11.11	33.3	30	-2.59	14.50	-33.3	0.00	22.2
End Of Eox Treatment	35	13.33	16.35	0.0	11.11	66.7	33	-1.68	14.20	-44.4	0.00	22.2

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.22: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Eating Symptoms - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	20.71	19.53	0.0	16.67	83.3	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	20.97	19.94	0.0	16.67	75.0	30	3.89	19.04	-41.7	0.00	50.0
End Of Eox Treatment	35	23.81	22.25	0.0	16.67	91.7	33	4.55	17.44	-50.0	0.00	41.7
Imab362 Continuing Treatment Cycle 02	14	16.27	18.93	0.0	8.33	50.0	14	-0.99	17.79	-50.0	0.00	25.0
Imab362 Continuing Treatment Cycle 05	11	10.86	14.46	0.0	8.33	50.0	11	-5.81	15.24	-41.7	0.00	11.1
EOX (N = 58)												
Cycle 1	42	23.61	19.21	0.0	25.00	83.3	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	19.09	18.78	0.0	16.67	91.7	30	-2.50	22.55	-58.3	0.00	58.3
End Of Eox Treatment	35	22.14	21.10	0.0	16.67	91.7	33	-1.77	29.74	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.23: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Anxiety - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	59.47	19.15	22.2	55.56	100.0	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	50.90	22.73	0.0	44.44	100.0	30	-6.85	21.62	-66.7	-11.11	33.3
End Of Eox Treatment	35	56.03	25.36	0.0	55.56	100.0	33	-0.51	18.86	-44.4	0.00	44.4
Imab362 Continuing Treatment Cycle 02	14	49.21	19.84	11.1	55.56	77.8	14	-7.14	18.29	-55.6	0.00	22.2
Imab362 Continuing Treatment Cycle 05	11	45.96	24.61	0.0	55.56	88.9	11	-8.59	31.17	-88.9	0.00	33.3
EOX (N = 58)												
Cycle 1	42	65.61	21.65	22.2	66.67	100.0	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	52.51	25.81	11.1	50.00	100.0	30	-14.63	16.92	-55.6	-11.11	11.1
End Of Eox Treatment	35	56.19	25.84	0.0	55.56	100.0	33	-7.74	20.88	-66.7	-11.11	44.4

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.24: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Dry Mouth - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	19.70	28.14	0.0	0.00	100.0	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	22.58	23.39	0.0	33.33	66.7	30	3.33	26.77	-66.7	0.00	66.7
End Of Eox Treatment	35	24.76	28.40	0.0	33.33	100.0	33	7.07	23.21	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 02	14	11.90	16.57	0.0	0.00	33.3	14	0.00	22.65	-33.3	0.00	33.3
Imab362 Continuing Treatment Cycle 05	11	6.06	20.10	0.0	0.00	66.7	11	-6.06	20.10	-33.3	0.00	33.3
EOX (N = 58)												
Cycle 1	42	18.25	21.08	0.0	0.00	66.7	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	36.56	32.61	0.0	33.33	100.0	30	18.89	33.54	-66.7	33.33	66.7
End Of Eox Treatment	35	34.29	34.76	0.0	33.33	100.0	33	19.19	34.39	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.25: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Taste - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	10.61	20.04	0.0	0.00	66.7	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	20.43	26.77	0.0	0.00	66.7	30	13.33	22.49	-33.3	0.00	66.7
End Of Eox Treatment	34	27.45	31.22	0.0	33.33	100.0	33	23.23	30.60	-33.3	0.00	100.0
Imab362 Continuing Treatment Cycle 02	14	14.29	21.54	0.0	0.00	66.7	14	9.52	24.21	-33.3	0.00	66.7
Imab362 Continuing Treatment Cycle 05	11	15.15	22.92	0.0	0.00	66.7	11	15.15	22.92	0.0	0.00	66.7
EOX (N = 58)												
Cycle 1	42	11.11	21.67	0.0	0.00	100.0	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	26.88	31.53	0.0	33.33	100.0	30	17.78	31.24	-33.3	0.00	100.0
End Of Eox Treatment	35	27.62	28.57	0.0	33.33	100.0	33	18.18	28.98	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.26: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Symptom - Body Image - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	44	33.33	31.34	0.0	33.33	100.0	44	0.00	0.00	0.0	0.00	0.0
Cycle 5	31	41.94	33.30	0.0	33.33	100.0	30	6.67	25.37	-33.3	0.00	66.7
End Of Eox Treatment	35	40.95	36.23	0.0	33.33	100.0	33	11.11	39.67	-100.0	0.00	100.0
Imab362 Continuing Treatment Cycle 02	14	30.95	35.72	0.0	16.67	100.0	14	-4.76	48.67	-100.0	0.00	100.0
Imab362 Continuing Treatment Cycle 05	11	21.21	34.23	0.0	0.00	100.0	11	-12.12	42.88	-100.0	0.00	66.7
EOX (N = 58)												
Cycle 1	42	29.37	31.41	0.0	33.33	100.0	41	0.00	0.00	0.0	0.00	0.0
Cycle 5	30	32.22	29.66	0.0	33.33	100.0	29	3.45	30.01	-66.7	0.00	66.7
End Of Eox Treatment	35	41.90	32.68	0.0	33.33	100.0	33	14.14	39.11	-66.7	33.33	100.0

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3002.27: EORTC QLQ-STO22 - Observed Means and Change from Baseline of Hair Loss - mITT Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + EOX (N = 56)												
Cycle 1	12	40.28	39.22	0.0	33.33	100.0	12	0.00	0.00	0.0	0.00	0.0
Cycle 5	27	53.70	28.62	16.7	50.00	100.0	8	16.67	36.73	-33.3	16.67	83.3
End Of Eox Treatment	26	51.92	29.56	0.0	50.00	100.0	7	16.67	30.43	-16.7	0.00	66.7
EOX (N = 58)												
Cycle 5	18	48.15	30.19	0.0	50.00	100.0	2	16.67	23.57	0.0	16.67	33.3
End Of Eox Treatment	21	38.10	28.94	0.0	33.33	100.0	2	16.67	23.57	0.0	16.67	33.3

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Max=Maximum; Med=Median; Min=Minimum; SD=standard deviation.
Summary statistics will not be provided for the treatment arm for the visit if that arm has less than 10 subjects at that visit.
Baseline is the last available measurement before the visit dose.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik anhand des EORTC QLQ-STO22

3. Time-to-Event-Analysen - Zeit bis zur ersten Verschlechterung

Table GM03.1.3003.18.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Functioning - Body Image (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	12 (21.4%)	11 (19.0%)	
Number of patients censored	44 (78.6%)	47 (81.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.8[4.4, 13.3]	5.6[3.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.565[0.234, 1.369]
Log-rank test			
Two-sided stratified log-rank p-value			0.2008

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.18.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Functioning - Body Image by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	10 (22.7)	7.4 [4.4, 13.3]	48	9 (18.8)	6.9 [3.0, NC]	0.775 [0.304, 1.975]	0.5823	0.1455
>65 years	12	2 (16.7)	9.7 [2.9, NC]	10	2 (20.0)	4.3 [3.0, 5.6]	0.232 [0.021, 2.563]	0.1933	
Sex									
Male	32	8 (25.0)	7.4 [2.9, 9.7]	37	8 (21.6)	3.1 [2.8, NC]	0.487 [0.173, 1.373]	0.1668	0.5084
Female	24	4 (16.7)	NC [2.8, NC]	21	3 (14.3)	7.1 [5.6, 7.2]	1.049 [0.230, 4.789]	0.9650	
Number of Organs with Metastatic Sites									
0-2	18	4 (22.2)	8.8 [2.8, NC]	18	3 (16.7)	6.9 [2.8, NC]	0.442 [0.073, 2.670]	0.3567	0.6393
>=3	38	8 (21.1)	7.4 [4.4, 13.3]	40	8 (20.0)	5.6 [3.0, NC]	0.617 [0.220, 1.729]	0.3468	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.19.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Dysphagia (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	16 (28.6%)	19 (32.8%)	
Number of patients censored	40 (71.4%)	39 (67.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.9[5.7, NC]	5.7[5.0, 8.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.612[0.308, 1.214]
Log-rank test			
Two-sided stratified log-rank p-value			0.1517

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.19.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Dysphagia by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	14 (31.8)	7.9 [3.4, NC]	48	16 (33.3)	6.0 [5.7, 11.3]	0.708 [0.339, 1.481]	0.3492	0.1282
>65 years	12	2 (16.7)	7.1 [2.9, NC]	10	3 (30.0)	3.0 [2.8, 5.8]	0.141 [0.015, 1.368]	0.0493	
Sex									
Male	32	6 (18.8)	NC [7.6, NC]	37	13 (35.1)	5.7 [3.2, NC]	0.297 [0.104, 0.847]	0.0161	0.0219
Female	24	10 (41.7)	5.9 [3.0, 7.1]	21	6 (28.6)	8.8 [3.0, 11.3]	1.993 [0.620, 6.404]	0.2416	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	7.6 [3.0, NC]	18	7 (38.9)	5.8 [3.0, NC]	0.690 [0.231, 2.063]	0.4922	0.8420
>=3	38	10 (26.3)	7.9 [3.4, NC]	40	12 (30.0)	5.7 [3.2, NC]	0.583 [0.243, 1.397]	0.2199	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.20.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Pain (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	18 (32.1%)	17 (29.3%)	
Number of patients censored	38 (67.9%)	41 (70.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.6[3.4, NC]	6.0[5.7, 11.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.866[0.435, 1.724]
Log-rank test			
Two-sided stratified log-rank p-value			0.6770

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.20.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	16 (36.4)	6.7 [3.2, NC]	48	15 (31.3)	7.2 [5.7, 11.3]	0.875 [0.416, 1.841]	0.7210	0.6509
>65 years	12	2 (16.7)	7.1 [2.9, NC]	10	2 (20.0)	5.9 [2.8, NC]	0.536 [0.073, 3.949]	0.5345	
Sex									
Male	32	7 (21.9)	15.6 [3.2, NC]	37	12 (32.4)	6.0 [5.7, 11.8]	0.450 [0.163, 1.243]	0.1185	0.1013
Female	24	11 (45.8)	5.8 [3.2, 26.1]	21	5 (23.8)	11.3 [2.9, 11.3]	1.487 [0.506, 4.367]	0.4696	
Number of Organs with Metastatic Sites									
0-2	18	8 (44.4)	6.7 [2.9, 15.6]	18	5 (27.8)	11.3 [3.0, NC]	1.303 [0.412, 4.118]	0.6584	0.2498
>=3	38	10 (26.3)	26.1 [3.4, NC]	40	12 (30.0)	6.0 [4.9, 11.8]	0.672 [0.278, 1.626]	0.3810	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.21.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Reflux Symptoms (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	15 (26.8%)	15 (25.9%)	
Number of patients censored	41 (73.2%)	43 (74.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	11.6[7.9, 15.6]	8.0[5.0, 11.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.526[0.232, 1.192]
Log-rank test			
Two-sided stratified log-rank p-value			0.1183

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.21.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Reflux Symptoms by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	13 (29.5)	11.6 [7.9, 15.6]	48	14 (29.2)	8.0 [5.0, 11.3]	0.479 [0.201, 1.143]	0.0909	0.5241
>65 years	12	2 (16.7)	5.7 [2.9, NC]	10	1 (10.0)	NC [3.0, NC]	1.064 [0.096, 11.757]	0.9597	
Sex									
Male	32	9 (28.1)	11.6 [7.9, 13.3]	37	12 (32.4)	5.7 [3.0, NC]	0.279 [0.086, 0.904]	0.0241	0.1842
Female	24	6 (25.0)	NC [3.0, NC]	21	3 (14.3)	11.3 [6.2, 11.3]	1.380 [0.344, 5.539]	0.6554	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	15.6 [3.0, 15.6]	18	5 (27.8)	11.3 [2.9, 11.3]	0.980 [0.297, 3.234]	0.9663	0.2917
>=3	38	8 (21.1)	11.6 [7.9, 13.3]	40	10 (25.0)	5.7 [3.2, 8.0]	0.256 [0.075, 0.872]	0.0209	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.22.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Eating Symptoms (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	18 (32.1%)	11 (19.0%)	
Number of patients censored	38 (67.9%)	47 (81.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.9[5.2, 17.8]	NC [5.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.292[0.596, 2.801]
Log-rank test			
Two-sided stratified log-rank p-value			0.5193

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.22.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Eating Symptoms by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	15 (34.1)	7.9 [3.2, 17.8]	48	9 (18.8)	NC [5.7, NC]	1.462 [0.622, 3.438]	0.3879	0.4584
>65 years	12	3 (25.0)	7.1 [2.9, NC]	10	2 (20.0)	5.8 [2.8, NC]	0.852 [0.138, 5.244]	0.8626	
Sex									
Male	32	7 (21.9)	15.4 [5.4, NC]	37	8 (21.6)	8.0 [4.6, NC]	0.662 [0.222, 1.977]	0.4601	0.0995
Female	24	11 (45.8)	5.6 [3.0, 17.8]	21	3 (14.3)	NC [3.0, NC]	2.665 [0.732, 9.706]	0.1277	
Number of Organs with Metastatic Sites									
0-2	18	6 (33.3)	5.4 [3.0, NC]	18	2 (11.1)	NC [5.8, NC]	3.101 [0.623, 15.427]	0.1471	0.2131
>=3	38	12 (31.6)	7.9 [5.2, 15.4]	40	9 (22.5)	8.0 [4.6, NC]	0.790 [0.309, 2.022]	0.6222	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.23.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Anxiety (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	21 (37.5%)	10 (17.2%)	
Number of patients censored	35 (62.5%)	48 (82.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.9[3.2, 15.6]	9.0[6.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.766[0.818, 3.816]
Log-rank test			
Two-sided stratified log-rank p-value			0.1419

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.23.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Anxiety by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	17 (38.6)	7.9 [3.2, 15.6]	48	8 (16.7)	9.0 [6.0, NC]	1.935 [0.819, 4.570]	0.1237	0.6579
>65 years	12	4 (33.3)	5.7 [2.9, 7.1]	10	2 (20.0)	5.8 [2.8, NC]	1.566 [0.268, 9.143]	0.6162	
Sex									
Male	32	12 (37.5)	7.9 [2.9, 21.4]	37	8 (21.6)	7.2 [5.8, NC]	1.360 [0.529, 3.495]	0.5161	0.3392
Female	24	9 (37.5)	5.7 [3.2, NC]	21	2 (9.5)	NC [2.8, NC]	2.977 [0.637, 13.916]	0.1473	
Number of Organs with Metastatic Sites									
0-2	18	8 (44.4)	5.7 [2.9, 15.6]	18	3 (16.7)	NC [5.8, NC]	2.750 [0.705, 10.731]	0.1294	0.3172
>=3	38	13 (34.2)	5.9 [3.2, 21.4]	40	7 (17.5)	6.6 [5.7, NC]	1.468 [0.574, 3.753]	0.4118	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.24.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Dry Mouth (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	18 (32.1%)	22 (37.9%)	
Number of patients censored	38 (67.9%)	36 (62.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.8[3.4, 49.2]	3.1[2.9, 6.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.519[0.272, 0.988]
Log-rank test			
Two-sided stratified log-rank p-value			0.0458

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.24.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Dry Mouth by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	16 (36.4)	8.8 [3.4, 13.8]	48	19 (39.6)	3.1 [2.9, 7.2]	0.633 [0.319, 1.254]	0.1915	0.2491
>65 years	12	2 (16.7)	NC [2.9, NC]	10	3 (30.0)	3.0 [2.8, 5.9]	0.293 [0.049, 1.765]	0.1546	
Sex									
Male	32	10 (31.3)	13.3 [3.1, 49.2]	37	14 (37.8)	5.9 [3.0, 6.6]	0.444 [0.186, 1.062]	0.0618	0.8639
Female	24	8 (33.3)	6.2 [2.9, NC]	21	8 (38.1)	2.9 [2.8, NC]	0.530 [0.197, 1.427]	0.2010	
Number of Organs with Metastatic Sites									
0-2	18	9 (50.0)	6.2 [2.9, NC]	18	7 (38.9)	3.0 [2.9, NC]	1.021 [0.378, 2.762]	0.9601	0.0948
>=3	38	9 (23.7)	13.3 [3.4, 49.2]	40	15 (37.5)	3.1 [2.9, 6.6]	0.291 [0.112, 0.759]	0.0075	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.25.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Taste (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	25 (44.6%)	20 (34.5%)	
Number of patients censored	31 (55.4%)	38 (65.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.4[3.0, 7.9]	5.7[3.0, 7.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.021[0.562, 1.855]
Log-rank test			
Two-sided stratified log-rank p-value			0.9480

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.25.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Taste by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	20 (45.5)	5.9 [3.0, 9.7]	48	18 (37.5)	5.7 [3.0, 7.2]	0.939 [0.491, 1.795]	0.8462	0.5877
>65 years	12	5 (41.7)	4.1 [2.9, 9.7]	10	2 (20.0)	5.8 [2.8, NC]	1.339 [0.227, 7.907]	0.7645	
Sex									
Male	32	13 (40.6)	7.6 [3.0, 9.7]	37	14 (37.8)	5.8 [3.1, 7.2]	0.766 [0.348, 1.687]	0.5086	0.4466
Female	24	12 (50.0)	4.4 [2.9, 6.3]	21	6 (28.6)	4.4 [2.8, NC]	1.156 [0.433, 3.087]	0.7722	
Number of Organs with Metastatic Sites									
0-2	18	9 (50.0)	5.7 [2.9, 9.7]	18	6 (33.3)	9.0 [2.9, NC]	1.422 [0.505, 4.003]	0.5049	0.3856
>=3	38	16 (42.1)	5.2 [2.9, 9.7]	40	14 (35.0)	5.7 [3.0, 6.6]	0.827 [0.394, 1.734]	0.6121	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.26.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Symptom - Body Image (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	EOX (N= 58)	Zolbetuximab + EOX vs. EOX
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	19 (33.9%)	19 (32.8%)	
Number of patients censored	37 (66.1%)	39 (67.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.7[3.1, NC]	5.7[3.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.968[0.511, 1.834]
Log-rank test			
Two-sided stratified log-rank p-value			0.9194

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.26.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Symptom - Body Image by Subgroups (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	14 (31.8)	5.8 [3.0, NC]	48	19 (39.6)	5.7 [3.0, 7.2]	0.787 [0.394, 1.573]	0.4910	0.9890
>65 years	12	5 (41.7)	5.2 [2.9, 5.7]	10	0 (0.0)	NC [NC , NC]	2.37E8 [0.000, NC]	0.0260	
Sex									
Male	32	7 (21.9)	NC [2.9, NC]	37	14 (37.8)	5.7 [2.9, NC]	0.626 [0.253, 1.554]	0.3010	0.1094
Female	24	12 (50.0)	5.2 [3.0, 5.8]	21	5 (23.8)	6.3 [3.0, NC]	2.088 [0.720, 6.053]	0.1682	
Number of Organs with Metastatic Sites									
0-2	18	7 (38.9)	5.7 [3.0, NC]	18	7 (38.9)	5.7 [2.9, NC]	0.877 [0.306, 2.513]	0.7968	0.8428
>=3	38	12 (31.6)	5.7 [2.9, NC]	40	12 (30.0)	5.7 [3.1, NC]	1.070 [0.478, 2.393]	0.8791	

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.27.1: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Hair Loss (MID=10) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**	**Zolbetuximab + EOX vs. EOX**
Number of patients at risk	56 (100.0%)	58 (100.0%)	
Number of patients with events	7 (12.5%)	1 (1.7%)	
Number of patients censored	49 (87.5%)	57 (98.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.0[2.8, 5.7]	NC [2.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			5.281[0.641, 43.508]
Log-rank test			
Two-sided stratified log-rank p-value			0.0767

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3003.27.2: EORTC QLQ-STO22 - Summary of Time to First Deterioration of Hair Loss by Subgroups (MID=10) - mITT Analysis Set

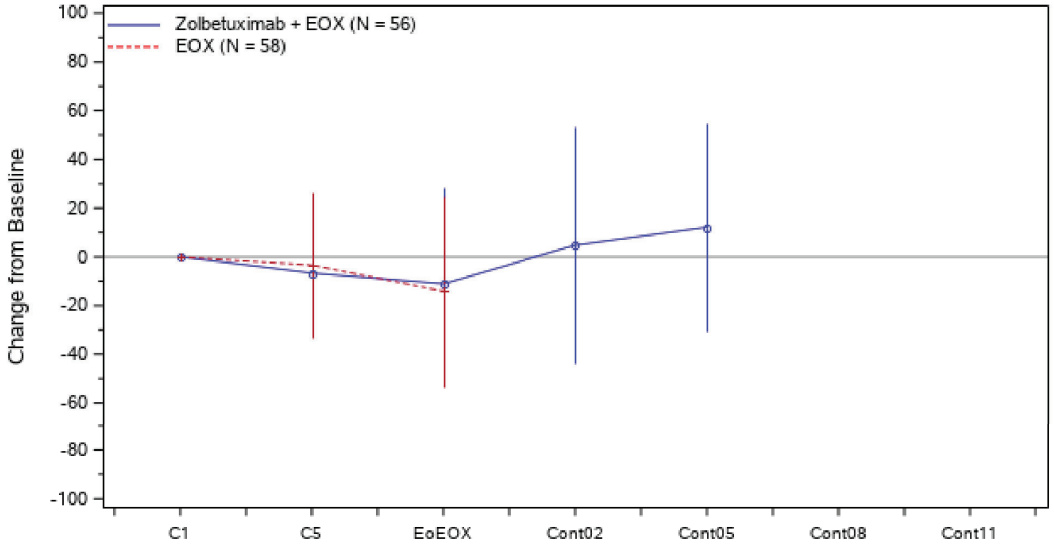
	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	4 (9.1)		48	1 (2.1)				
>65 years	12	3 (25.0)		10	0 (0.0)				
Sex									
Male	32	2 (6.3)		37	1 (2.7)				
Female	24	5 (20.8)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	18	4 (22.2)		18	1 (5.6)				
>=3	38	3 (7.9)		40	0 (0.0)				

Abbreviations: CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); MID=minimally important difference; mITT=modified intention to treat; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from unstratified Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik anhand des EORTC QLQ-STO22

4. Graphische Darstellung des Verlaufs (Mean Change from Baseline)

Figure GM03.1.3002.18: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Functioning - Body Image - mITT Analysis Set

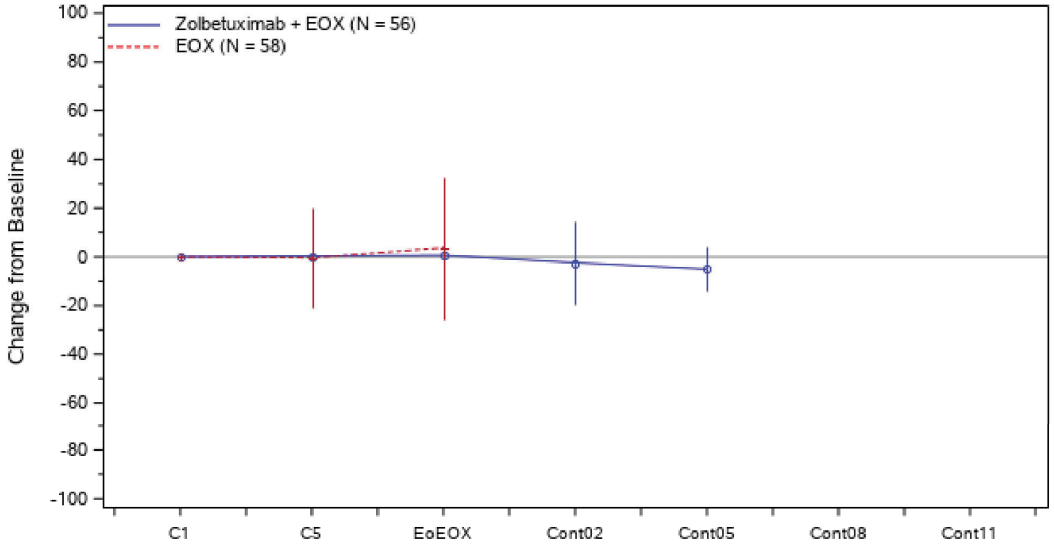


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.19: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Dysphagia - mITT Analysis Set



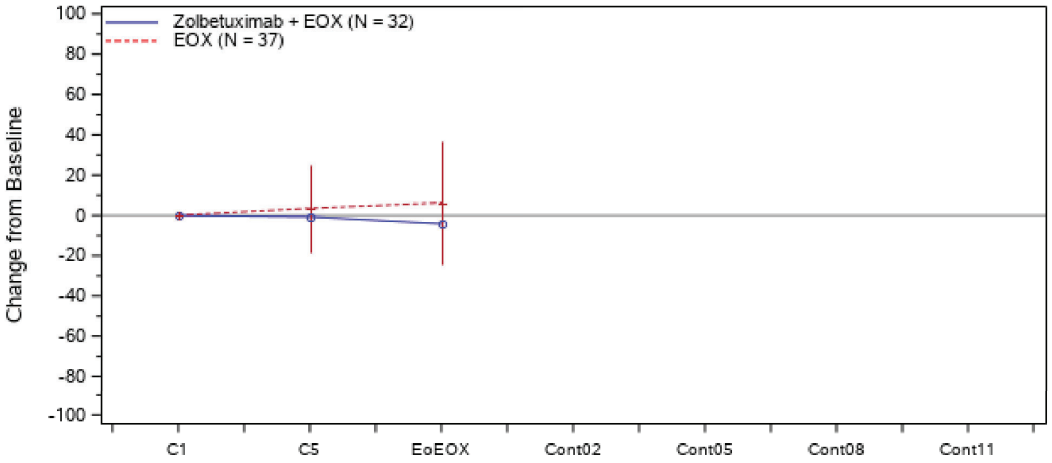
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.19.2: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Dysphagia by Sex - mITT Analysis Set

Sex: Male



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

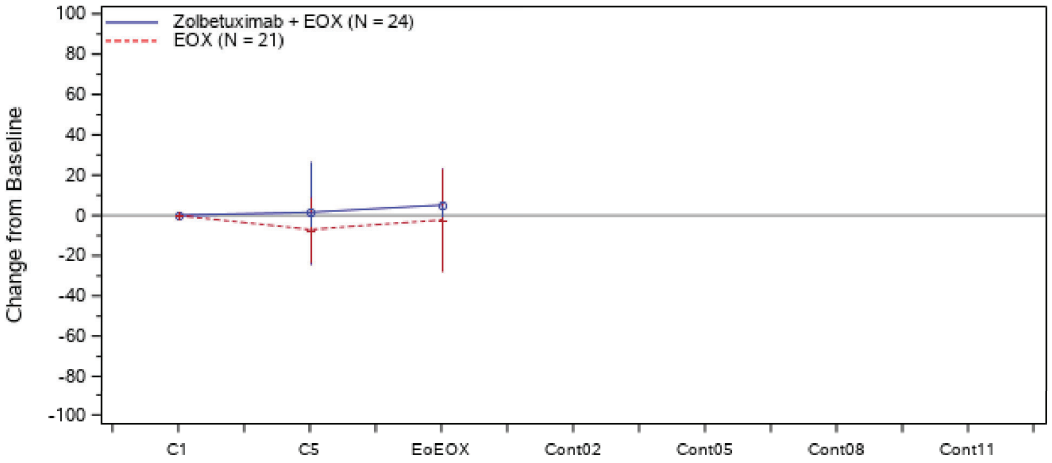
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant (p<0.05).

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.19.2: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Dysphagia by Sex - mITT Analysis Set

Sex: Female



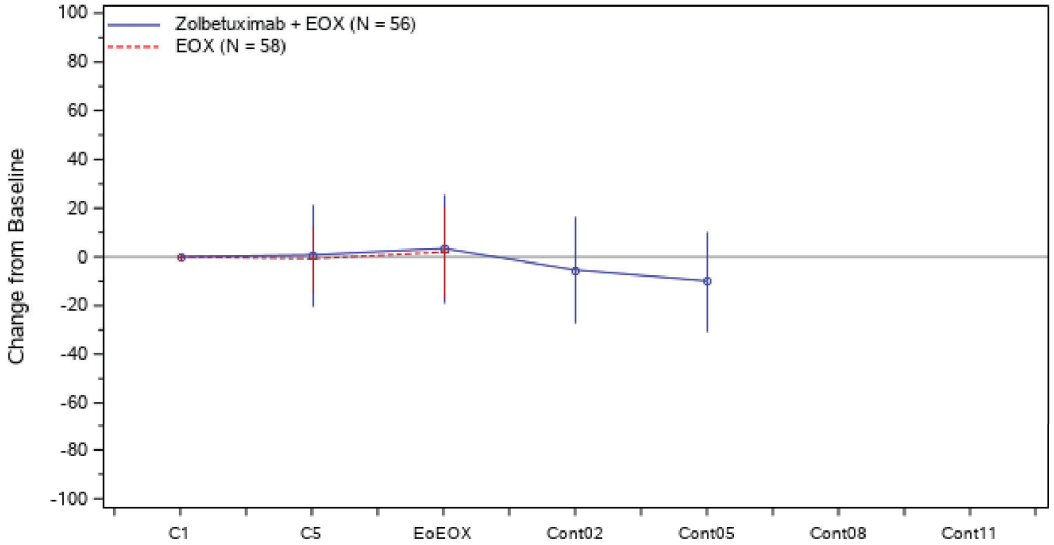
Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

Figure was provided if interaction p-value of subgroup from corresponding summary of time to first deterioration analysis was significant (p<0.05).

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.20: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Pain - mITT Analysis Set

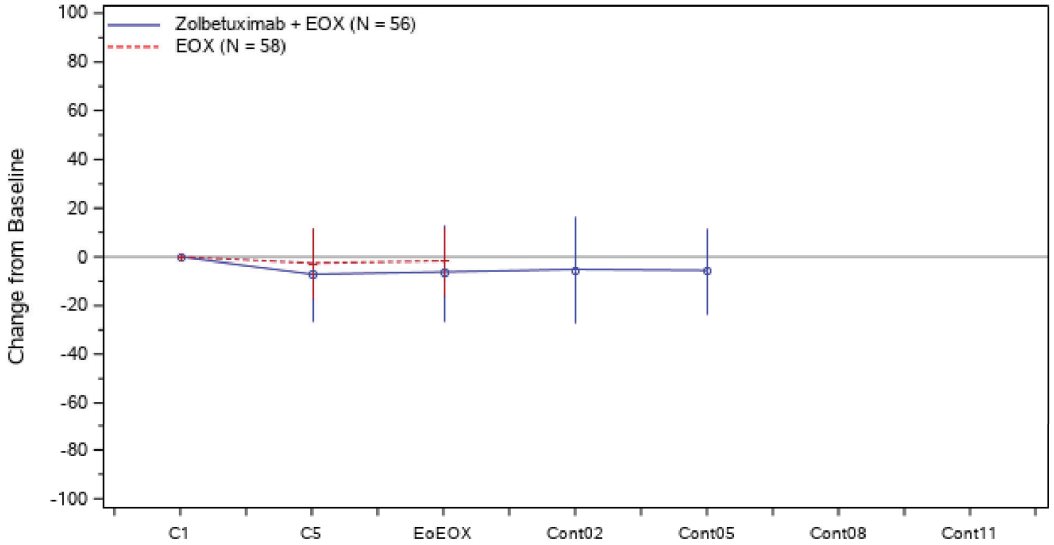


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.21: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Reflux Symptoms - mITT Analysis Set

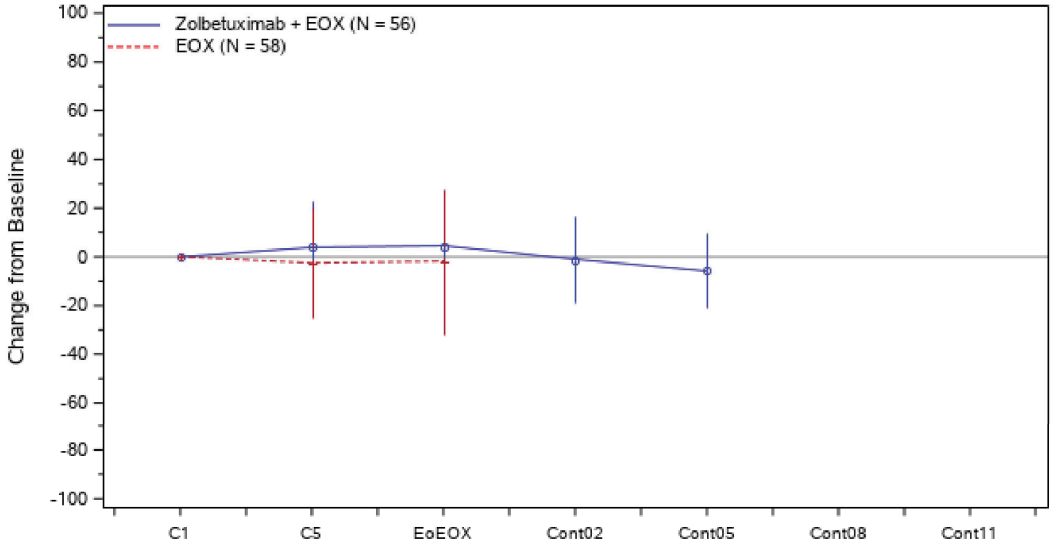


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.22: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Eating Symptoms - mITT Analysis Set

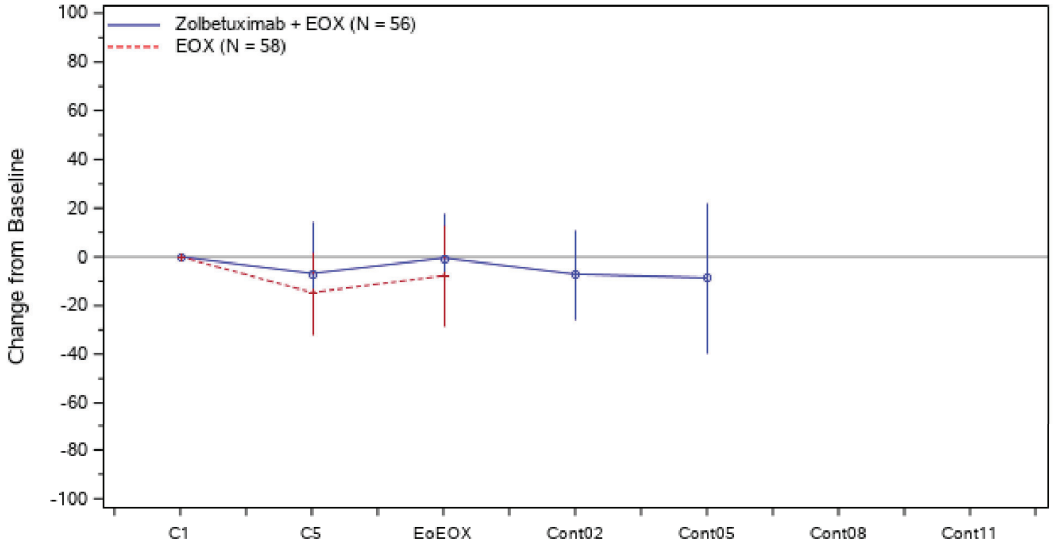


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.23: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Anxiety - mITT Analysis Set

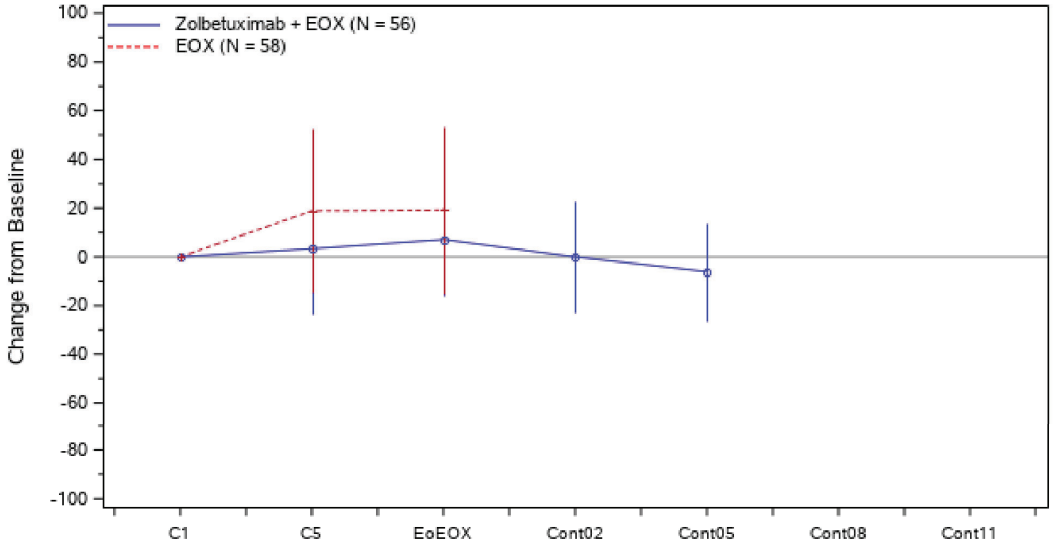


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.24: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Dry Mouth - mITT Analysis Set

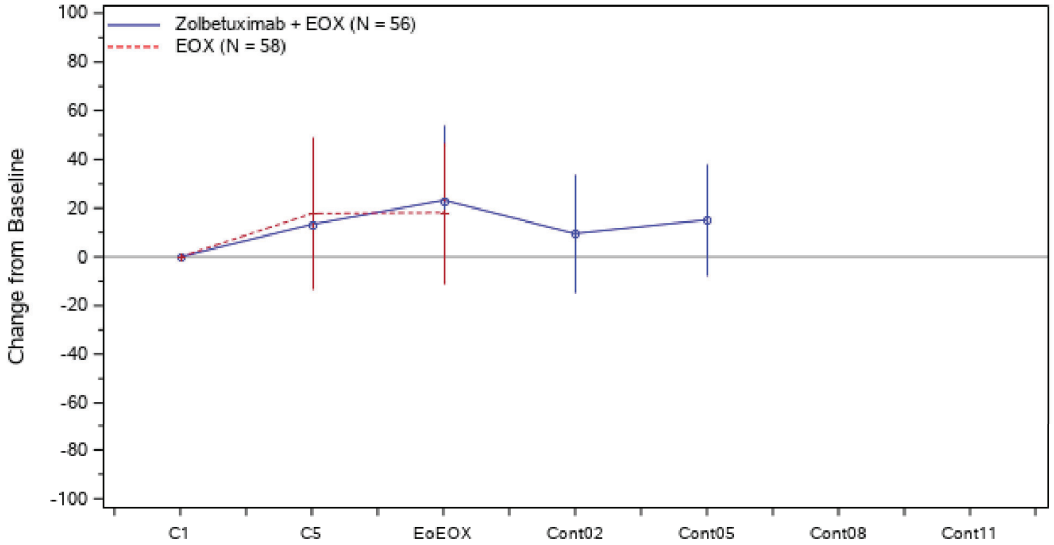


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.25: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Taste - mITT Analysis Set

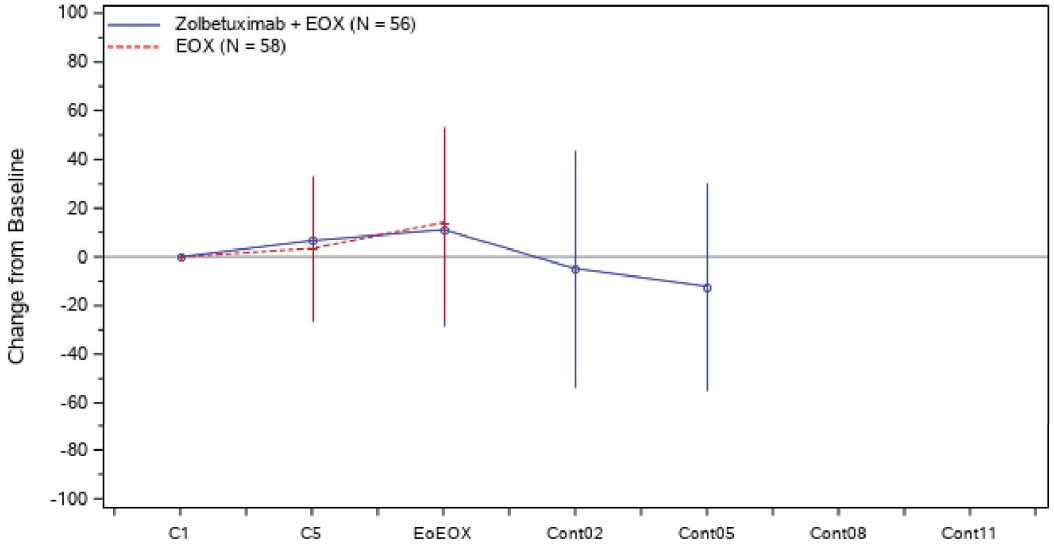


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.26: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Symptom - Body Image - mITT Analysis Set

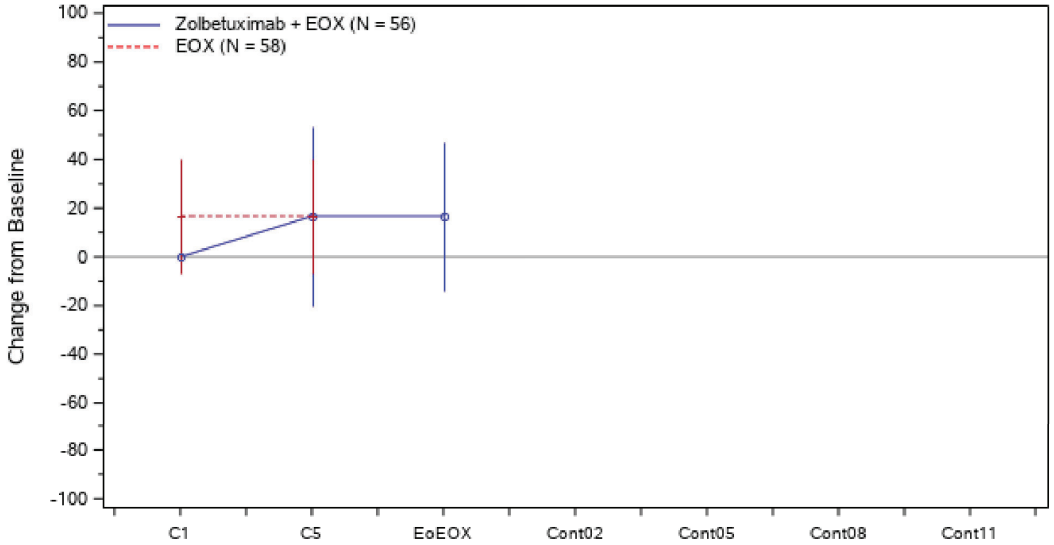


Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3002.27: EORTC QLQ-STO22 - Plot of Mean Change from Baseline of Hair Loss - mITT Analysis Set



Abbreviations: C=cycle; Cont=IMAB362 Continuing Treatment Cycle; EoEOX=end of EOX treatment; EORTC QLQ-STO22= European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; SD=Standard Deviation.

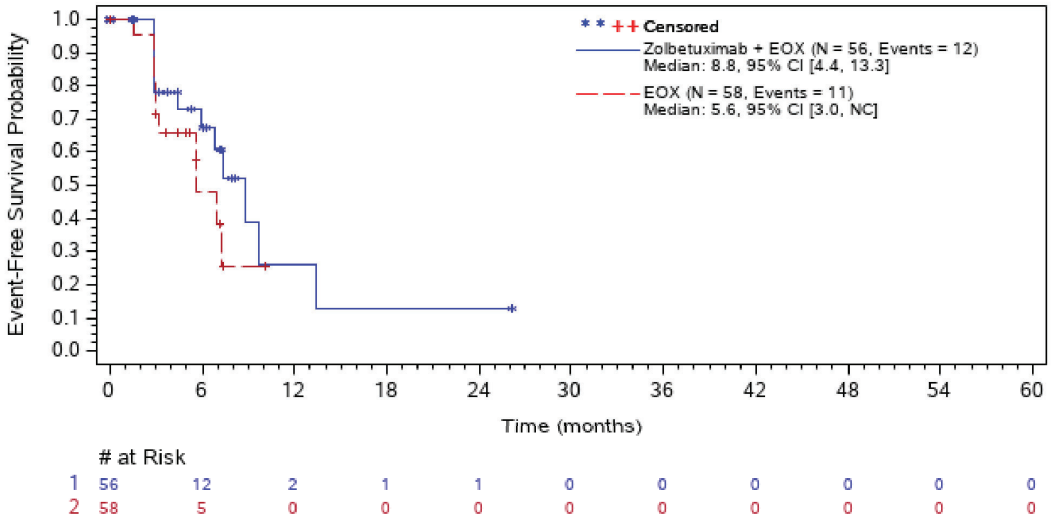
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.

ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Patientenberichtete Endpunkte (EORTC QLQ-C30, EORTC QLQ-STO22)
Anhang 4-G2 Symptomatik anhand des EORTC QLQ-STO22

5. Kaplan-Meier-Plots

Figure GM03.1.3003.18: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Functioning - Body Image (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

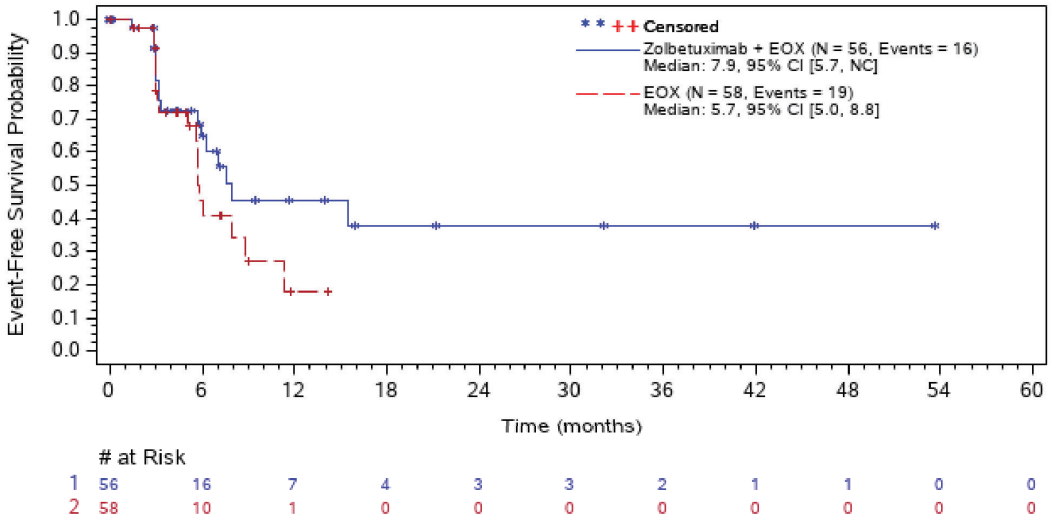
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.19: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

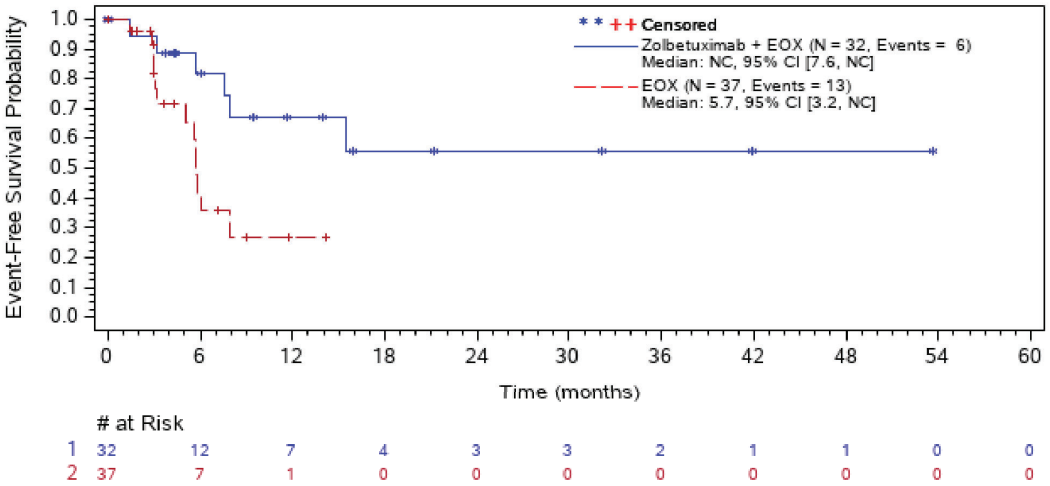
Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.19.2: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - mITT Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

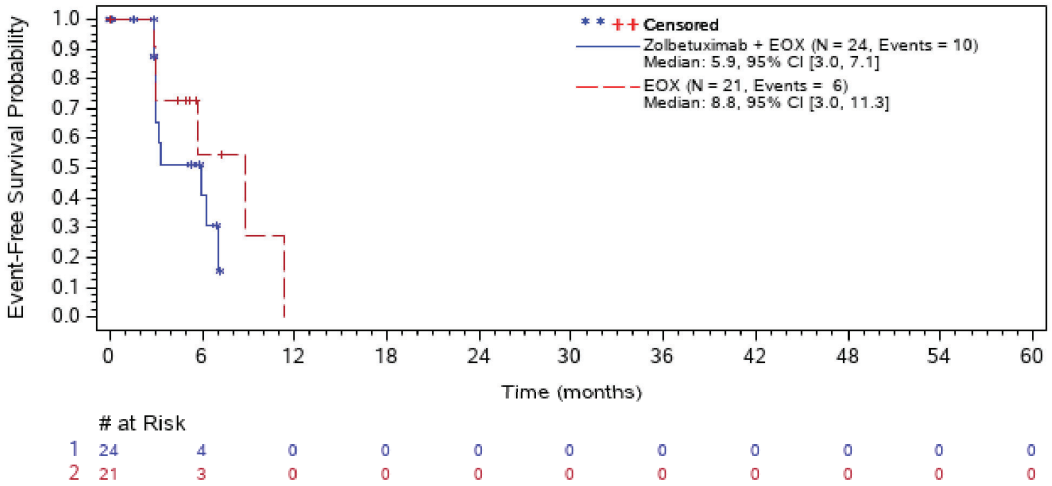
Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.19.2: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - mITT Analysis Set

Sex: Female



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

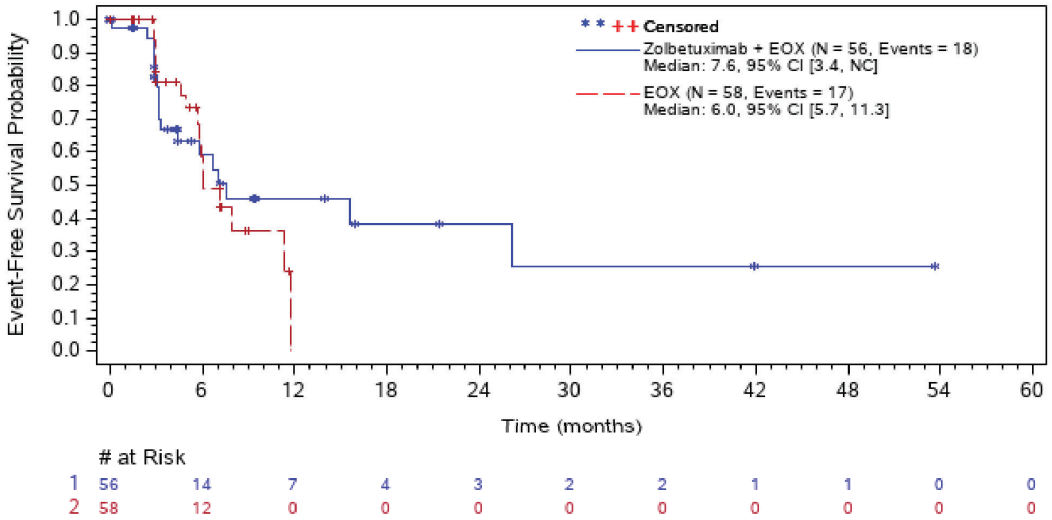
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.20: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Pain (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

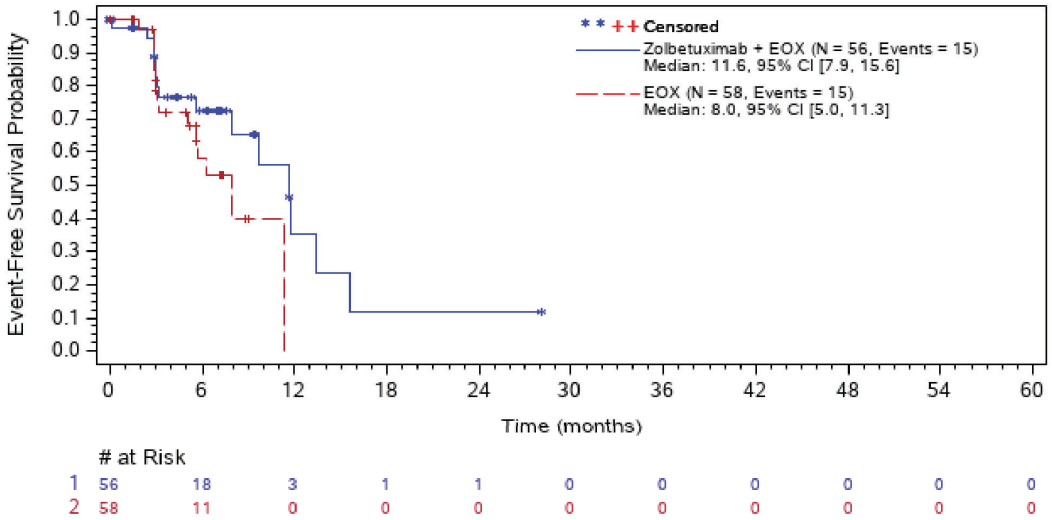
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.21: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Reflux Symptoms (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

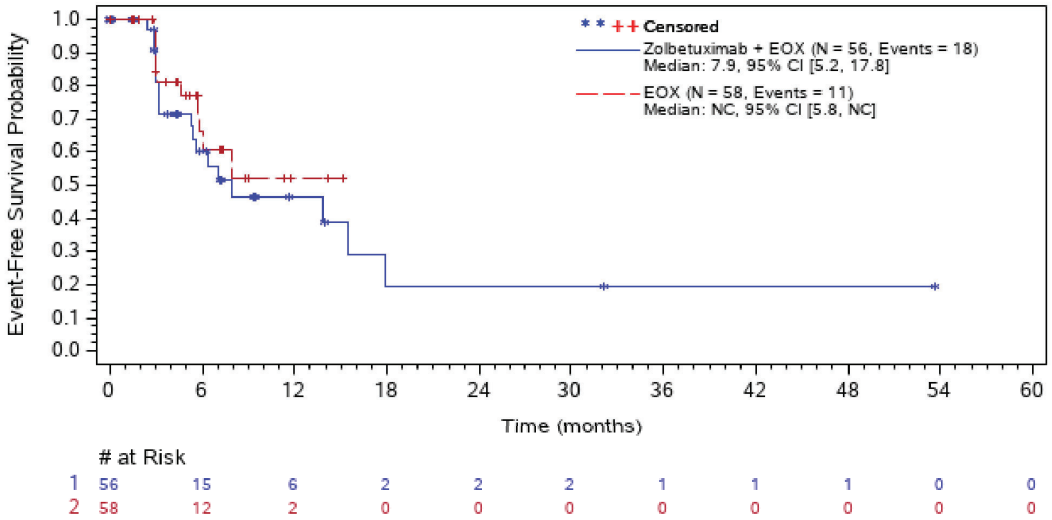
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.22: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Eating Symptoms (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

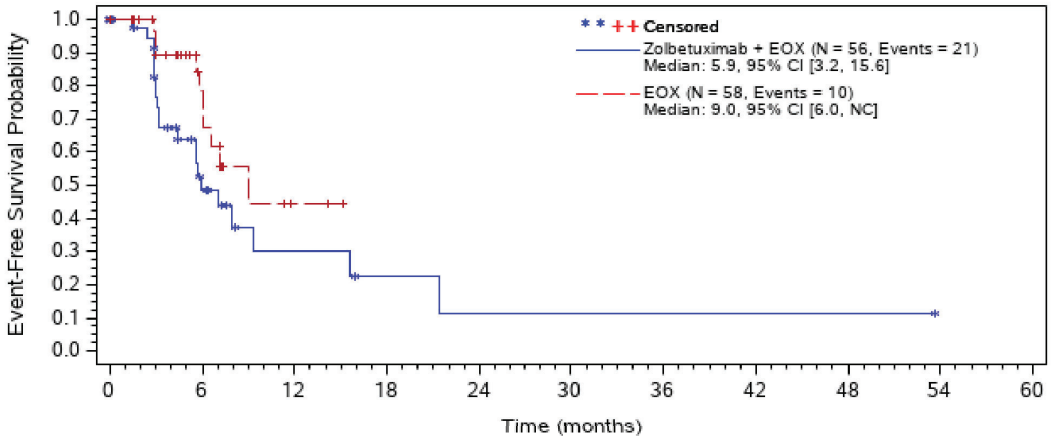
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.23: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety (MID=10) - mITT Analysis Set



# at Risk											
1	56	12	4	2	1	1	1	1	1	0	0
2	58	14	2	0	0	0	0	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

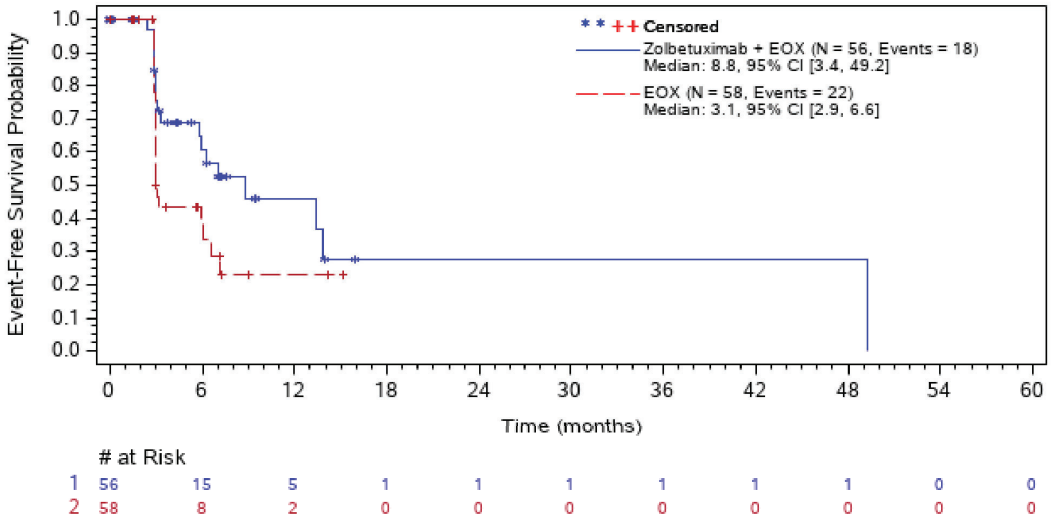
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.24: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Dry Mouth (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

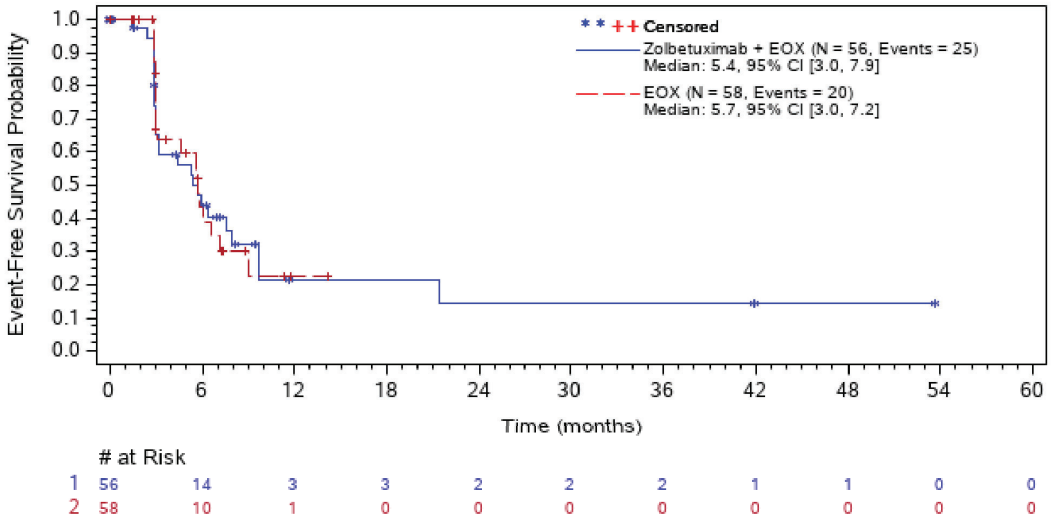
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.25: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Taste (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

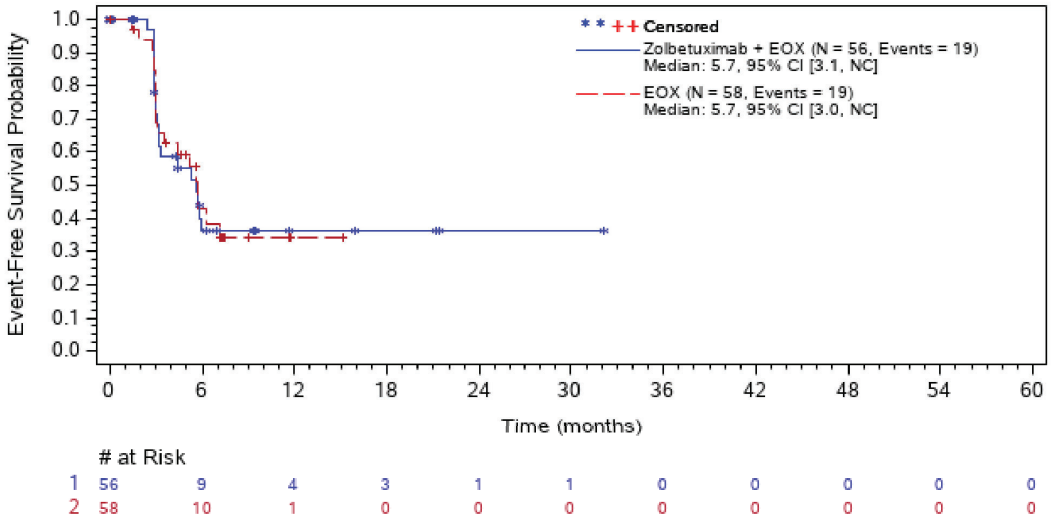
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.26: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Symptom - Body Image (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

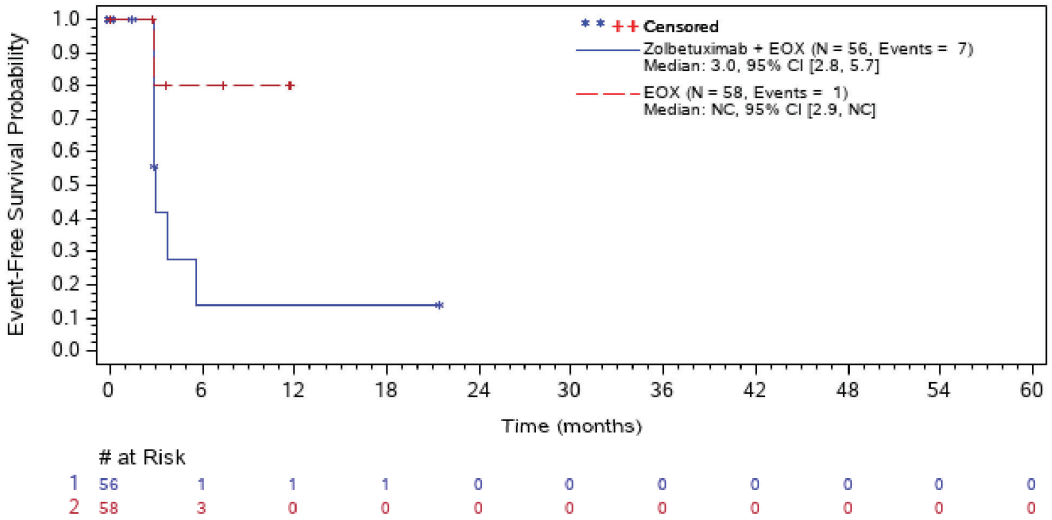
Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.3003.27: EORTC QLQ-STO22 - Kaplan-Meier Plot of Time to First Deterioration of Hair Loss (MID=10) - mITT Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; MID=minimally important difference; mITT=modified intention to treat; N=number of patients; NC=not calculated; PRO=patient-reported outcome.

Note: Time to deterioration is defined as the time from randomization to the first observation with a >=10 point increase.

Censoring date is date of last available assessment of the parameter.

Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse

1. Time-to Event-Analysen

Table GM03.1.2001.1.1: Summary and Results of TEAEs - 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	55 (100.0%)	57 (100.0%)	
Number of patients censored	0 (0.0%)	0 (0.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.0 [0.0, 0.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.420 [0.951, 2.120]
Log-rank test			
Two-sided stratified log-rank p-value			0.1226

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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 GM03.1.2001.1.2: Summary and Results of TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	44 (100.0)	0.0 [NC, NC]	48	48 (100.0)	0.0 [0.0, 0.1]	1.484 [0.958, 2.299]	0.1161	0.4778
>65 years	11	11 (100.0)	0.0 [0.0, 0.1]	9	9 (100.0)	0.0 [0.0, 0.2]	1.141 [0.443, 2.936]	0.9524	
Sex									
Male	31	31 (100.0)	0.0 [NC, NC]	36	36 (100.0)	0.0 [0.0, 0.1]	1.340 [0.804, 2.232]	0.2195	0.5926
Female	24	24 (100.0)	0.0 [NC, NC]	21	21 (100.0)	0.0 [0.0, 0.1]	1.384 [0.727, 2.635]	0.7181	
Number of Organs with Metastatic Sites									
0-2	17	17 (100.0)	0.0 [0.0, 0.1]	17	17 (100.0)	0.0 [0.0, 0.7]	1.680 [0.776, 3.637]	0.1380	0.4567
>=3	38	38 (100.0)	0.0 [NC, NC]	40	40 (100.0)	0.0 [0.0, 0.1]	1.247 [0.777, 2.003]	0.7585	

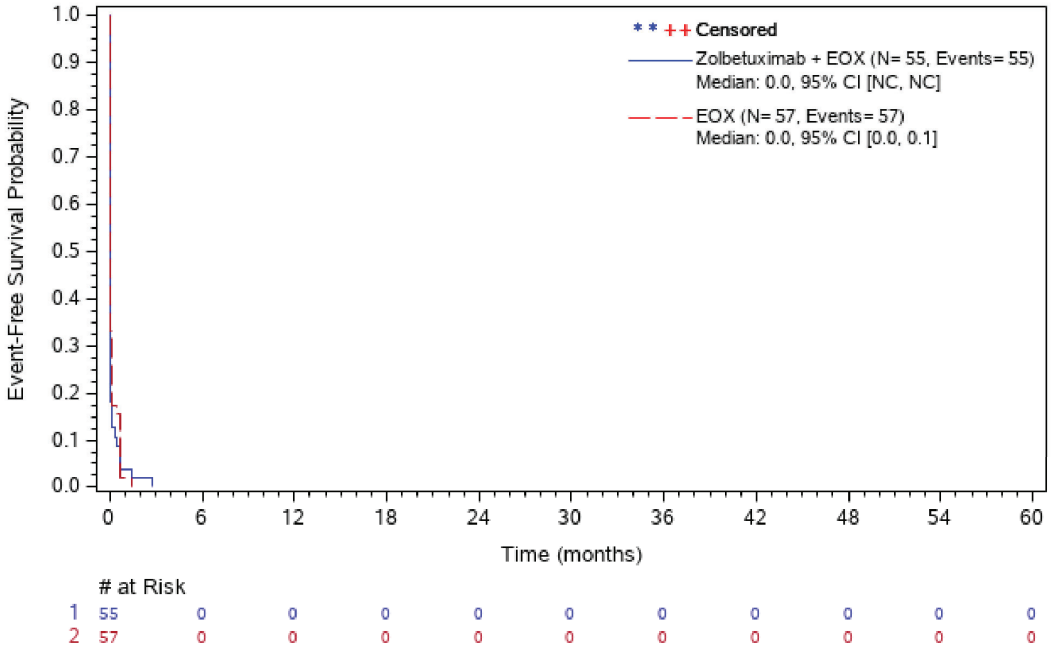
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment 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, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure GM03.1.2001.1: Kaplan-Meier Plot of Time to first TEAE - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwere unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table GM03.1.2001.3.1: Summary and Results of Severe TEAEs - 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	41 (74.5%)	34 (59.6%)	
Number of patients censored	14 (25.5%)	23 (40.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.9 [1.4, 4.8]	3.4 [2.0, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.182 [0.741, 1.884]
Log-rank test			
Two-sided stratified log-rank p-value			0.4835

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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 GM03.1.2001.3.2: Summary and Results of Severe TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	32 (72.7)	2.3 [1.1, 4.9]	48	30 (62.5)	2.9 [1.4, 7.7]	1.061 [0.634, 1.778]	0.8279	0.3975
>65 years	11	9 (81.8)	3.0 [0.3, 4.9]	9	4 (44.4)	NC [0.7, NC]	2.318 [0.708, 7.596]	0.1632	
Sex									
Male	31	23 (74.2)	2.3 [0.7, 4.1]	36	21 (58.3)	3.4 [1.4, 7.4]	1.245 [0.676, 2.292]	0.4841	0.9492
Female	24	18 (75.0)	4.6 [0.8, 4.9]	21	13 (61.9)	2.9 [0.8, 7.7]	1.175 [0.569, 2.430]	0.6948	
Number of Organs with Metastatic Sites									
0-2	17	12 (70.6)	4.1 [0.7, 9.0]	17	9 (52.9)	4.1 [1.5, NC]	1.419 [0.588, 3.429]	0.4360	0.7224
>=3	38	29 (76.3)	2.3 [1.1, 4.6]	40	25 (62.5)	2.9 [1.0, 7.7]	1.136 [0.656, 1.966]	0.6561	

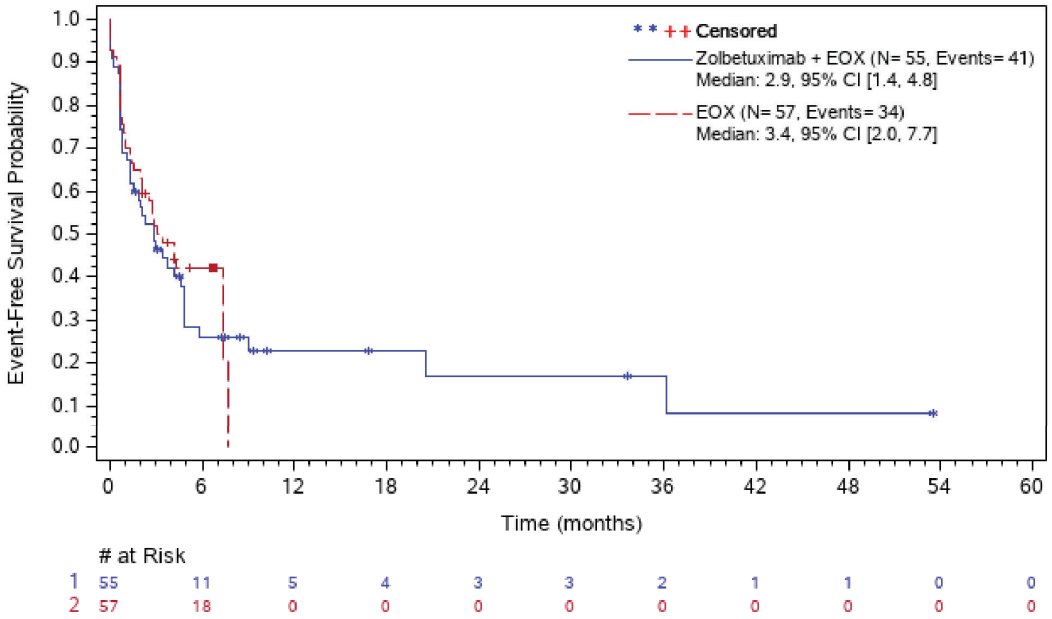
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment 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, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwere unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure GM03.1.2001.3: Kaplan-Meier Plot of Time to first Severe TEAE (CTCAE Grade >= 3) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwerwiegende unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table GM03.1.2001.4.1: Summary and Results of TESAEs - 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	16 (29.1%)	14 (24.6%)	
Number of patients censored	39 (70.9%)	43 (75.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [6.0, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.241 [0.605, 2.546]
Log-rank test			
Two-sided stratified log-rank p-value			0.5524

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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 GM03.1.2001.4.2: Summary and Results of TESAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	12 (27.3)	NC [NC, NC]	48	12 (25.0)	NC [NC, NC]	1.176 [0.528, 2.620]	0.6889	0.6365
>65 years	11	4 (36.4)	NC [0.2, NC]	9	2 (22.2)	NC [0.9, NC]	1.902 [0.348, 10.397]	0.4503	
Sex									
Male	31	9 (29.0)	NC [4.8, NC]	36	8 (22.2)	NC [NC, NC]	1.373 [0.530, 3.562]	0.5091	0.7798
Female	24	7 (29.2)	NC [4.9, NC]	21	6 (28.6)	NC [5.5, NC]	1.143 [0.384, 3.404]	0.8103	
Number of Organs with Metastatic Sites									
0-2	17	5 (29.4)	NC [1.9, NC]	17	1 (5.9)	NC [NC, NC]	5.946 [0.694, 50.969]	0.0645	0.0915
>=3	38	11 (28.9)	NC [4.9, NC]	40	13 (32.5)	NC [5.5, NC]	0.902 [0.404, 2.013]	0.8044	

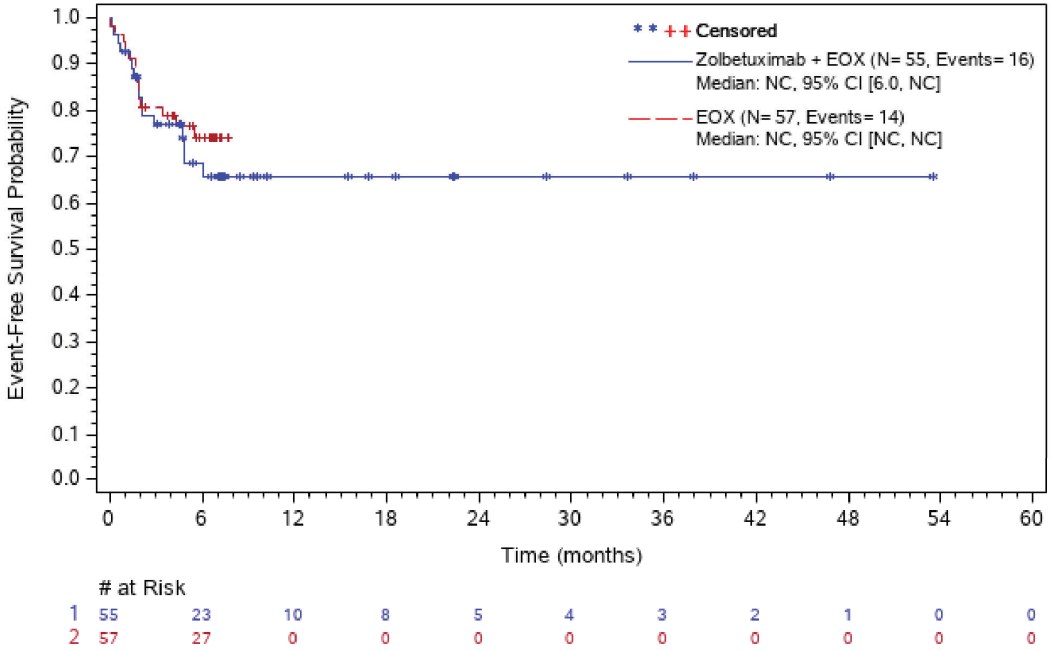
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment 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, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwerwiegende unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure GM03.1.2001.4: Kaplan-Meier Plot of Time to first TESAE - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

1. Time-to-Event-Analysen

Table GM03.1.2001.5.1: Summary and Results of Permanent Treatment Discontinuation due to TEAEs - 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	11 (20.0%)	11 (19.3%)	
Number of patients censored	44 (80.0%)	46 (80.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [37.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.965 [0.409, 2.274]
Log-rank test			
Two-sided stratified log-rank p-value			0.9320

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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 GM03.1.2001.5.2: Summary and Results of Permanent Treatment Discontinuation due to TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	10 (22.7)	NC [37.6, NC]	48	8 (16.7)	NC [NC, NC]	1.293 [0.499, 3.353]	0.5995	0.1676
>65 years	11	1 (9.1)	NC [1.4, NC]	9	3 (33.3)	NC [0.9, NC]	0.254 [0.026, 2.445]	0.2003	
Sex									
Male	31	8 (25.8)	NC [37.6, NC]	36	7 (19.4)	NC [NC, NC]	1.236 [0.433, 3.525]	0.6951	0.5152
Female	24	3 (12.5)	NC [NC, NC]	21	4 (19.0)	NC [NC, NC]	0.674 [0.151, 3.015]	0.6035	
Number of Organs with Metastatic Sites									
0-2	17	4 (23.5)	NC [2.9, NC]	17	2 (11.8)	NC [NC, NC]	2.320 [0.425, 12.671]	0.3171	0.2474
>=3	38	7 (18.4)	NC [37.6, NC]	40	9 (22.5)	NC [NC, NC]	0.710 [0.252, 1.994]	0.5106	

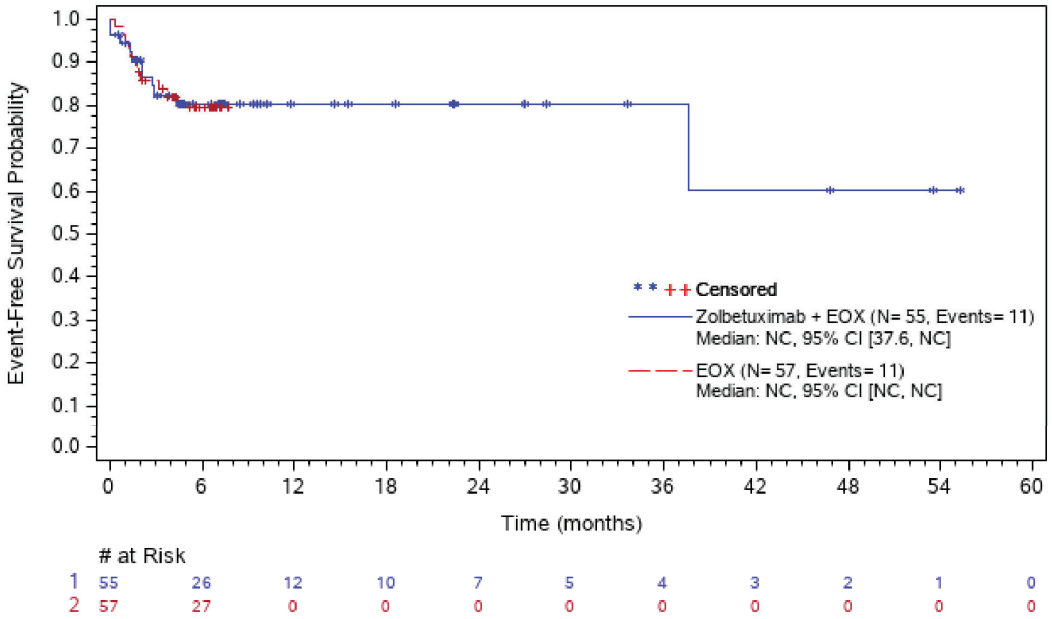
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment 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, [b] Calculated from unstratified Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

2. Kaplan-Meier-Plots

Figure GM03.1.2001.5: Kaplan-Meier Plot of Time to Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table GM03.1.2001.6.1: Summary and Results of TEAEs - Blood and Lymphatic System Disorders (SOC) - 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	39 (70.9%)	35 (61.4%)	
Number of patients censored	16 (29.1%)	22 (38.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.1 [1.4, 3.4]	3.5 [1.4, 4.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.235 [0.778, 1.961]
Log-rank test			
Two-sided stratified log-rank p-value			0.3572

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.7.1: Summary and Results of TEAEs - Anaemia (PT)
- 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	26 (47.3%)	24 (42.1%)	
Number of patients censored	29 (52.7%)	33 (57.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.7 [2.9, NC]	11.5 [4.1, 11.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.100 [0.623, 1.941]
Log-rank test			
Two-sided stratified log-rank p-value			0.7373

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.8.1: Summary and Results of TEAEs - Leukopenia (PT)
- 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%)	7 (12.3%)	
Number of patients censored	45 (81.8%)	50 (87.7%)	
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			1.430 [0.544, 3.758]
Log-rank test			
Two-sided stratified log-rank p-value			0.4619

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.9.1: Summary and Results of TEAEs - Neutropenia (PT)
- 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	26 (47.3%)	19 (33.3%)	
Number of patients censored	29 (52.7%)	38 (66.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [2.1, NC]	NC [4.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.496 [0.826, 2.708]
Log-rank test			
Two-sided stratified log-rank p-value			0.1867

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.10.1: Summary and Results of TEAEs - Thrombocytopenia (PT)
- 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%)	8 (14.0%)	
Number of patients censored	46 (83.6%)	49 (86.0%)	
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			1.065 [0.399, 2.843]
Log-rank test			
Two-sided stratified log-rank p-value			0.8997

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.11.1: Summary and Results of TEAEs - Cardiac Disorders (SOC)
- 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	5 (9.1%)	7 (12.3%)	
Number of patients censored	50 (90.9%)	50 (87.7%)	
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			0.559 [0.163, 1.917]
Log-rank test			
Two-sided stratified log-rank p-value			0.3483

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.12.1: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC) - 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	52 (94.5%)	51 (89.5%)	
Number of patients censored	3 (5.5%)	6 (10.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.1 [0.0, 0.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.674 [1.120, 2.502]
Log-rank test			
Two-sided stratified log-rank p-value			0.0379

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.12.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	42 (95.5)	0.0 [NC, NC]	48	42 (87.5)	0.1 [0.0, 0.1]	1.835 [1.178, 2.856]	0.0163	0.3583
>65 years	11	10 (90.9)	0.0 [0.0, 0.2]	9	9 (100.0)	0.1 [0.0, 0.2]	0.996 [0.382, 2.594]	0.6829	
Sex									
Male	31	29 (93.5)	0.0 [NC, NC]	36	31 (86.1)	0.1 [0.0, 0.1]	1.630 [0.970, 2.739]	0.0830	0.7420
Female	24	23 (95.8)	0.0 [NC, NC]	21	20 (95.2)	0.1 [0.0, 0.1]	1.648 [0.874, 3.105]	0.2908	
Number of Organs with Metastatic Sites									
0-2	17	16 (94.1)	0.0 [0.0, 0.1]	17	14 (82.4)	0.1 [0.0, 0.7]	1.730 [0.820, 3.650]	0.1667	0.6674
>=3	38	36 (94.7)	0.0 [NC, NC]	40	37 (92.5)	0.1 [0.0, 0.1]	1.611 [1.004, 2.587]	0.1176	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.13.1: Summary and Results of TEAEs - Abdominal Pain (PT)
- 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%)	7 (12.3%)	
Number of patients censored	45 (81.8%)	50 (87.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [39.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.332 [0.496, 3.581]
Log-rank test			
Two-sided stratified log-rank p-value			0.5697

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.14.1: Summary and Results of TEAEs - Abdominal Pain Upper (PT)
- 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	5 (9.1%)	12 (21.1%)	
Number of patients censored	50 (90.9%)	45 (78.9%)	
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			0.307 [0.099, 0.957]
Log-rank test			
Two-sided stratified log-rank p-value			0.0307

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.14.2: Summary and Results of TEAEs by Subgroups - Abdominal Pain Upper (PT) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	4 (9.1)	NC [16.1, NC]	48	12 (25.0)	NC [NC, NC]	0.239 [0.067, 0.849]	0.0161	0.9929
>65 years	11	1 (9.1)	NC [NC, NC]	9	0 (0.0)	NC [NC, NC]	6.68E7 [0.000, NC]	0.3657	
Sex									
Male	31	3 (9.7)		36	5 (13.9)				
Female	24	2 (8.3)		21	7 (33.3)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)	NC [NC, NC]	17	4 (23.5)	NC [1.7, NC]	0.000 [0.000, NC]	0.0388	0.9934
>=3	38	5 (13.2)	NC [16.1, NC]	40	8 (20.0)	NC [NC, NC]	0.486 [0.146, 1.618]	0.2265	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.15.1: Summary and Results of TEAEs - Diarrhoea (PT)
- 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%)	20 (35.1%)	
Number of patients censored	46 (83.6%)	37 (64.9%)	
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			0.387 [0.176, 0.850]
Log-rank test			
Two-sided stratified log-rank p-value			0.0145

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.15.2: Summary and Results of TEAEs by Subgroups - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	7 (15.9)	NC [NC, NC]	48	16 (33.3)	NC [NC, NC]	0.400 [0.165, 0.974]	0.0373	0.8736
>65 years	11	2 (18.2)	NC [1.7, NC]	9	4 (44.4)	NC [0.9, NC]	0.278 [0.050, 1.538]	0.1178	
Sex									
Male	31	5 (16.1)	NC [NC, NC]	36	8 (22.2)	NC [NC, NC]	0.660 [0.216, 2.019]	0.4635	0.1252
Female	24	4 (16.7)	NC [NC, NC]	21	12 (57.1)	1.4 [0.2, NC]	0.204 [0.065, 0.636]	0.0025	
Number of Organs with Metastatic Sites									
0-2	17	5 (29.4)	NC [1.7, NC]	17	6 (35.3)	NC [0.9, NC]	0.739 [0.225, 2.423]	0.6147	0.1834
>=3	38	4 (10.5)	NC [NC, NC]	40	14 (35.0)	NC [1.6, NC]	0.244 [0.080, 0.742]	0.0072	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.16.1: Summary and Results of TEAEs - Dysphagia (PT)
- 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%)	6 (10.5%)	
Number of patients censored	54 (98.2%)	51 (89.5%)	
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			0.161 [0.019, 1.342]
Log-rank test			
Two-sided stratified log-rank p-value			0.0535

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.17.1: Summary and Results of TEAEs - Nausea (PT)
- 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	46 (83.6%)	44 (77.2%)	
Number of patients censored	9 (16.4%)	13 (22.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	0.1 [0.1, 0.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.364 [0.898, 2.074]
Log-rank test			
Two-sided stratified log-rank p-value			0.1934

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.18.1: Summary and Results of TEAEs - Vomiting (PT)
- 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	42 (76.4%)	34 (59.6%)	
Number of patients censored	13 (23.6%)	23 (40.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.7]	1.7 [0.7, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.861 [1.173, 2.952]
Log-rank test			
Two-sided stratified log-rank p-value			0.0169

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.18.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	35 (79.5)	0.0 [0.0, 0.7]	48	28 (58.3)	2.2 [0.7, 8.1]	1.978 [1.197, 3.270]	0.0139	0.3884
>65 years	11	7 (63.6)	0.0 [0.0, NC]	9	6 (66.7)	0.8 [0.0, NC]	1.353 [0.451, 4.062]	0.7356	
Sex									
Male	31	23 (74.2)	0.7 [0.0, 2.1]	36	21 (58.3)	1.5 [0.6, NC]	1.607 [0.888, 2.909]	0.1525	0.6177
Female	24	19 (79.2)	0.0 [0.0, 0.2]	21	13 (61.9)	1.7 [0.1, 8.1]	2.186 [1.062, 4.498]	0.0627	
Number of Organs with Metastatic Sites									
0-2	17	13 (76.5)	0.0 [0.0, 1.7]	17	9 (52.9)	1.2 [0.0, NC]	2.160 [0.912, 5.118]	0.0987	0.5697
>=3	38	29 (76.3)	0.1 [0.0, 0.8]	40	25 (62.5)	1.7 [0.6, 8.1]	1.639 [0.954, 2.815]	0.1206	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.19.1: Summary and Results of TEAEs - General Disorders and Administration Site Conditions (SOC) - 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	41 (74.5%)	39 (68.4%)	
Number of patients censored	14 (25.5%)	18 (31.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [1.0, 3.7]	2.0 [0.7, 4.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.959 [0.614, 1.499]
Log-rank test			
Two-sided stratified log-rank p-value			0.8666

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.20.1: Summary and Results of TEAEs - Asthenia (PT)
- 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	14 (25.5%)	13 (22.8%)	
Number of patients censored	41 (74.5%)	44 (77.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	29.8 [12.1, NC]	7.4 [7.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.806 [0.355, 1.829]
Log-rank test			
Two-sided stratified log-rank p-value			0.6074

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.21.1: Summary and Results of TEAEs - Fatigue (PT)
- 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	16 (29.1%)	11 (19.3%)	
Number of patients censored	39 (70.9%)	46 (80.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	7.2 [7.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.414 [0.651, 3.072]
Log-rank test			
Two-sided stratified log-rank p-value			0.3800

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.22.1: Summary and Results of TEAEs - Oedema Peripheral (PT)
- 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	8 (14.5%)	6 (10.5%)	
Number of patients censored	47 (85.5%)	51 (89.5%)	
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			1.311 [0.454, 3.781]
Log-rank test			
Two-sided stratified log-rank p-value			0.6157

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.23.1: Summary and Results of TEAEs - Pyrexia (PT)
- 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	8 (14.5%)	12 (21.1%)	
Number of patients censored	47 (85.5%)	45 (78.9%)	
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			0.652 [0.266, 1.597]
Log-rank test			
Two-sided stratified log-rank p-value			0.3491

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.24.1: Summary and Results of TEAEs - Infections and Infestations (SOC) - 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%)	7 (12.3%)	
Number of patients censored	46 (83.6%)	50 (87.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [24.8, NC]	NC [7.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.574 [0.175, 1.884]
Log-rank test			
Two-sided stratified log-rank p-value			0.3544

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.25.1: Summary and Results of TEAEs - Investigations (SOC)
- 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	31 (56.4%)	33 (57.9%)	
Number of patients censored	24 (43.6%)	24 (42.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.2 [2.8, 14.5]	3.5 [1.8, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.791 [0.477, 1.313]
Log-rank test			
Two-sided stratified log-rank p-value			0.3806

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.26.1: Summary and Results of TEAEs - Alanine Aminotransferase Increased (PT) - 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%)	6 (10.5%)	
Number of patients censored	51 (92.7%)	51 (89.5%)	
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			0.545 [0.136, 2.191]
Log-rank test			
Two-sided stratified log-rank p-value			0.3870

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.27.1: Summary and Results of TEAEs - Aspartate Aminotransferase Increased (PT) - 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	6 (10.9%)	7 (12.3%)	
Number of patients censored	49 (89.1%)	50 (87.7%)	
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			0.624 [0.187, 2.081]
Log-rank test			
Two-sided stratified log-rank p-value			0.4392

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.28.1: Summary and Results of TEAEs - Gamma-Glutamyltransferase Increased (PT) - 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	7 (12.7%)	5 (8.8%)	
Number of patients censored	48 (87.3%)	52 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [17.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.165 [0.352, 3.856]
Log-rank test			
Two-sided stratified log-rank p-value			0.7998

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.29.1: Summary and Results of TEAEs - Weight Decreased (PT)
- 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	20 (36.4%)	16 (28.1%)	
Number of patients censored	35 (63.6%)	41 (71.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	28.0 [5.6, NC]	NC [6.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.102 [0.556, 2.183]
Log-rank test			
Two-sided stratified log-rank p-value			0.7764

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.30.1: Summary and Results of TEAEs - Metabolism and Nutrition Disorders (SOC) - 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	16 (29.1%)	15 (26.3%)	
Number of patients censored	39 (70.9%)	42 (73.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	26.7 [10.0, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.791 [0.370, 1.693]
Log-rank test			
Two-sided stratified log-rank p-value			0.5467

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.31.1: Summary and Results of TEAEs - Decreased Appetite (PT)
- 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	7 (12.7%)	11 (19.3%)	
Number of patients censored	48 (87.3%)	46 (80.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [35.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.527 [0.195, 1.428]
Log-rank test			
Two-sided stratified log-rank p-value			0.2010

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.32.1: Summary and Results of TEAEs - Musculoskeletal and Connective Tissue Disorders (SOC) - 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	6 (10.9%)	11 (19.3%)	
Number of patients censored	49 (89.1%)	46 (80.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.0, NC]	NC [6.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.400 [0.135, 1.185]
Log-rank test			
Two-sided stratified log-rank p-value			0.0873

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.33.1: Summary and Results of TEAEs - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - 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%)	6 (10.5%)	
Number of patients censored	51 (92.7%)	51 (89.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [37.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.504 [0.126, 2.022]
Log-rank test			
Two-sided stratified log-rank p-value			0.3260

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.34.1: Summary and Results of TEAEs - Nervous System Disorders (SOC) - 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	28 (50.9%)	28 (49.1%)	
Number of patients censored	27 (49.1%)	29 (50.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.2 [1.2, NC]	4.4 [0.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.911 [0.536, 1.546]
Log-rank test			
Two-sided stratified log-rank p-value			0.7477

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.35.1: Summary and Results of TEAEs - Dizziness (PT)
- 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%)	7 (12.3%)	
Number of patients censored	53 (96.4%)	50 (87.7%)	
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			0.289 [0.060, 1.394]
Log-rank test			
Two-sided stratified log-rank p-value			0.1001

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.36.1: Summary and Results of TEAEs - Headache (PT)
- 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	12 (21.8%)	14 (24.6%)	
Number of patients censored	43 (78.2%)	43 (75.4%)	
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			0.882 [0.408, 1.907]
Log-rank test			
Two-sided stratified log-rank p-value			0.7501

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.37.1: Summary and Results of TEAEs - Paraesthesia (PT)
- 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	7 (12.7%)	8 (14.0%)	
Number of patients censored	48 (87.3%)	49 (86.0%)	
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			0.777 [0.279, 2.166]
Log-rank test			
Two-sided stratified log-rank p-value			0.6291

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.38.1: Summary and Results of TEAEs - Respiratory, Thoracic and Mediastinal Disorders (SOC) - 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	14 (25.5%)	15 (26.3%)	
Number of patients censored	41 (74.5%)	42 (73.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [13.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.834 [0.396, 1.753]
Log-rank test			
Two-sided stratified log-rank p-value			0.6276

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.39.1: Summary and Results of TEAEs - Skin and Subcutaneous Tissue Disorders (SOC) - 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	24 (43.6%)	17 (29.8%)	
Number of patients censored	31 (56.4%)	40 (70.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [2.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.592 [0.855, 2.965]
Log-rank test			
Two-sided stratified log-rank p-value			0.1400

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.40.1: Summary and Results of TEAEs - Alopecia (PT)
- 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	16 (29.1%)	13 (22.8%)	
Number of patients censored	39 (70.9%)	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			1.293 [0.622, 2.689]
Log-rank test			
Two-sided stratified log-rank p-value			0.4927

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
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Table GM03.1.2001.41.1: Summary and Results of TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - 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%)	5 (8.8%)	
Number of patients censored	45 (81.8%)	52 (91.2%)	
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			2.274 [0.775, 6.672]
Log-rank test			
Two-sided stratified log-rank p-value			0.1240

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.42.1: Summary and Results of TEAEs - Vascular Disorders (SOC) - 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%)	5 (8.8%)	
Number of patients censored	46 (83.6%)	52 (91.2%)	
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			1.708 [0.558, 5.227]
Log-rank test			
Two-sided stratified log-rank p-value			0.3459

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.43.1: Summary and Results of TEAEs - Hypertension (PT)
- 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	6 (10.9%)	2 (3.5%)	
Number of patients censored	49 (89.1%)	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			2.666 [0.516, 13.763]
Log-rank test			
Two-sided stratified log-rank p-value			0.2262

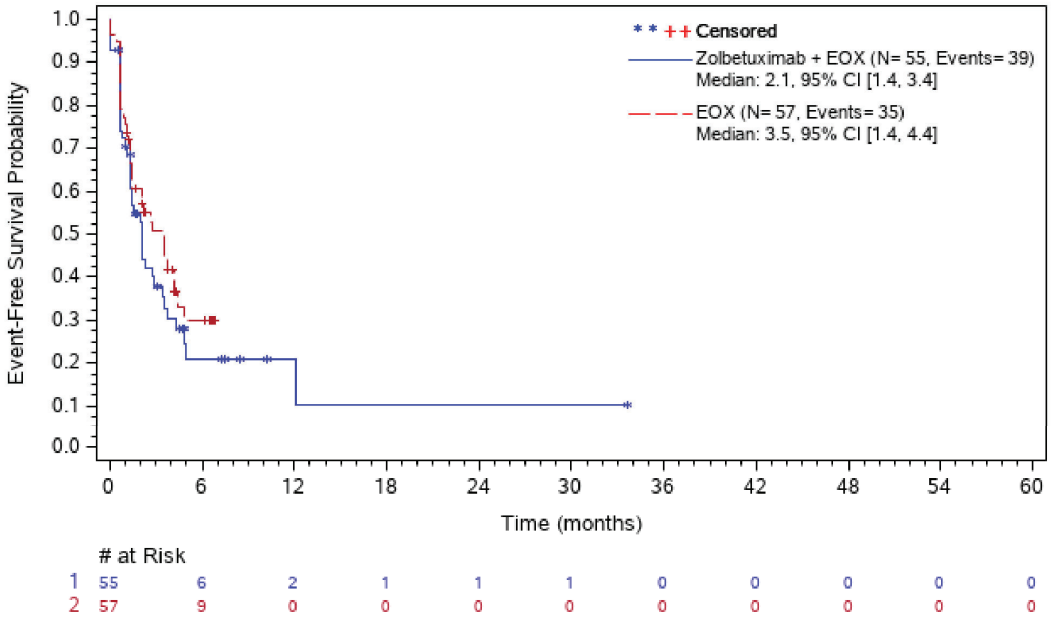
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse - SOC und PT

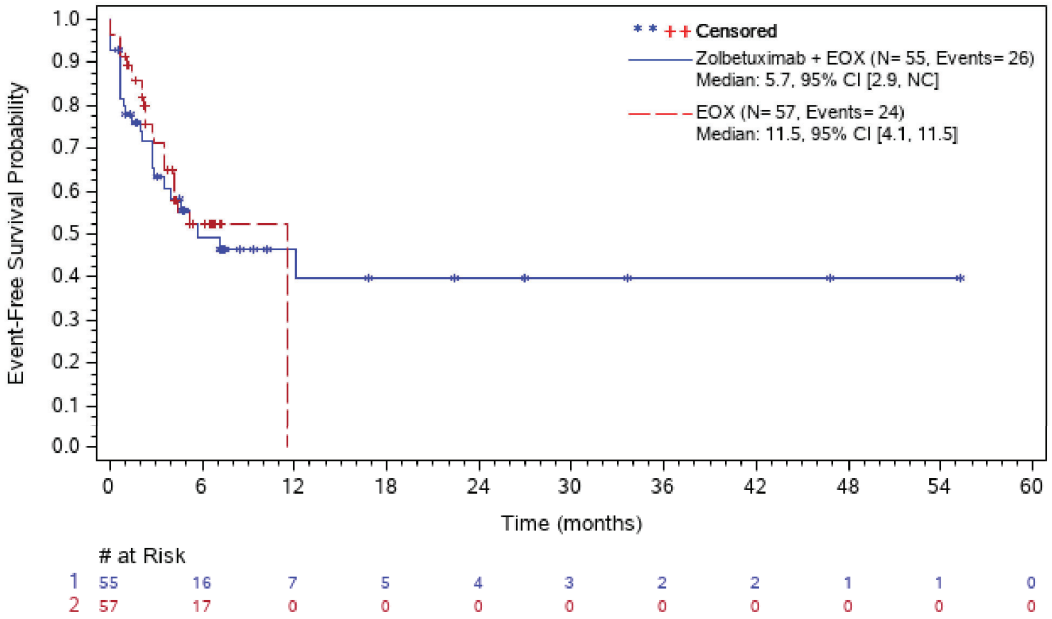
2. Kaplan-Meier-Plots

Figure GM03.1.2001.6: Kaplan-Meier Plot of Time to first TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



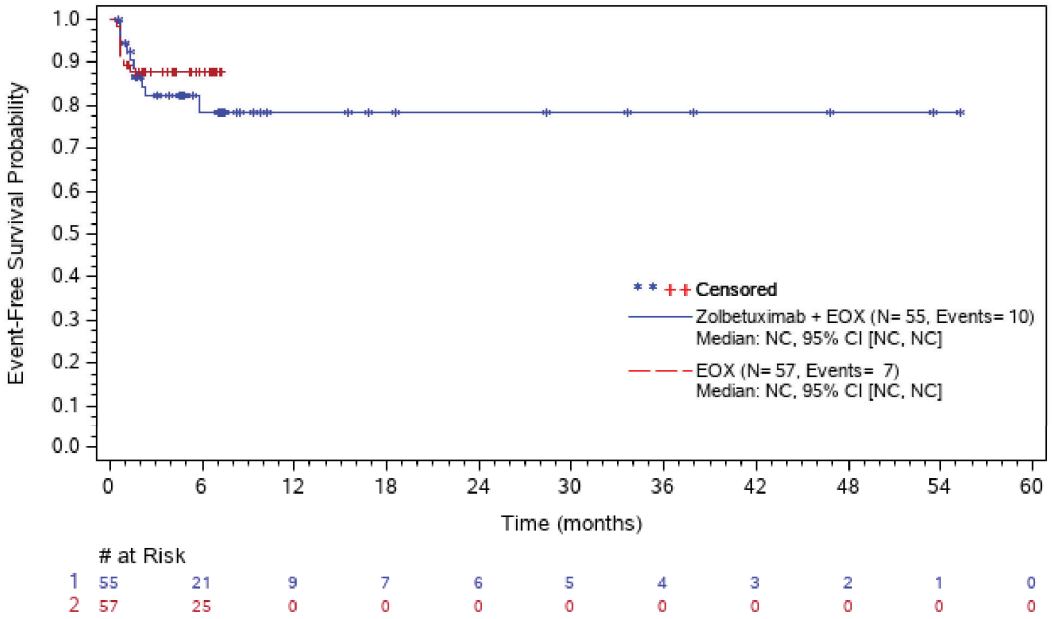
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.7: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Safety Analysis Set



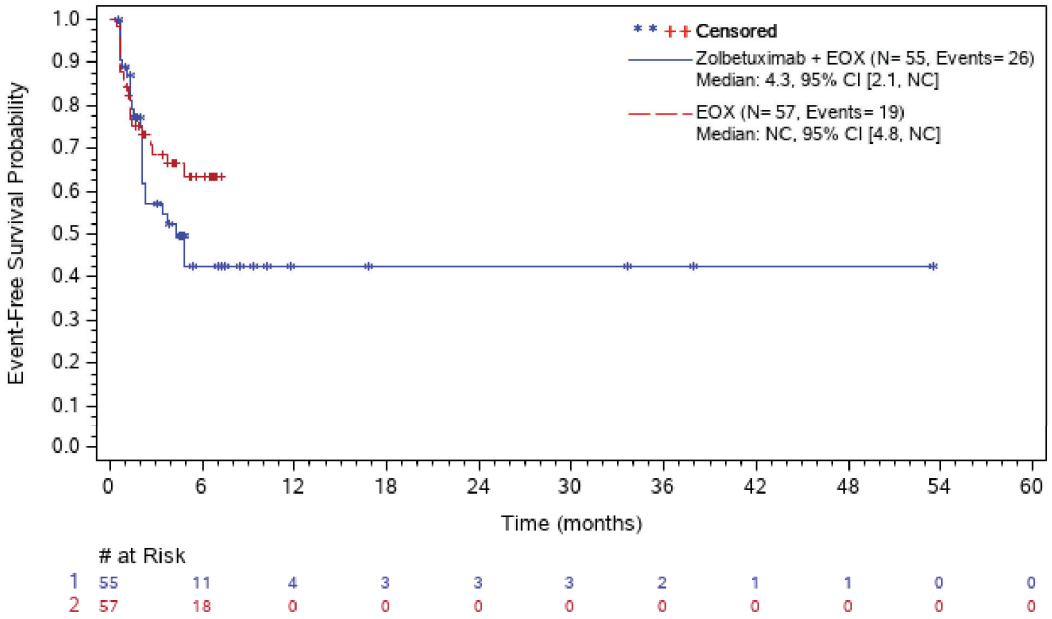
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.8: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Safety Analysis Set



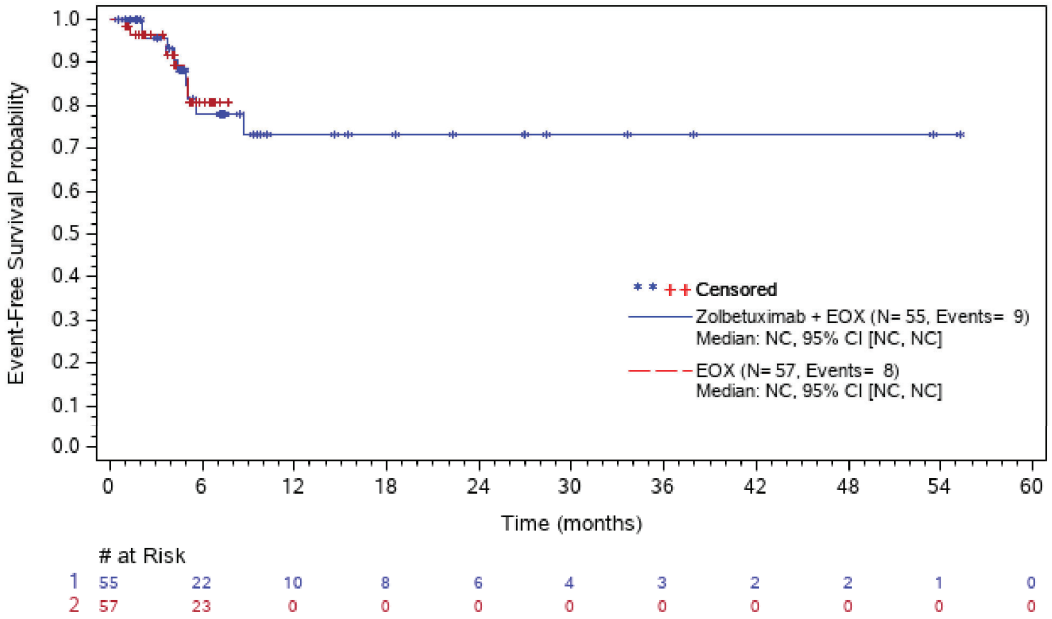
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.9: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Safety Analysis Set



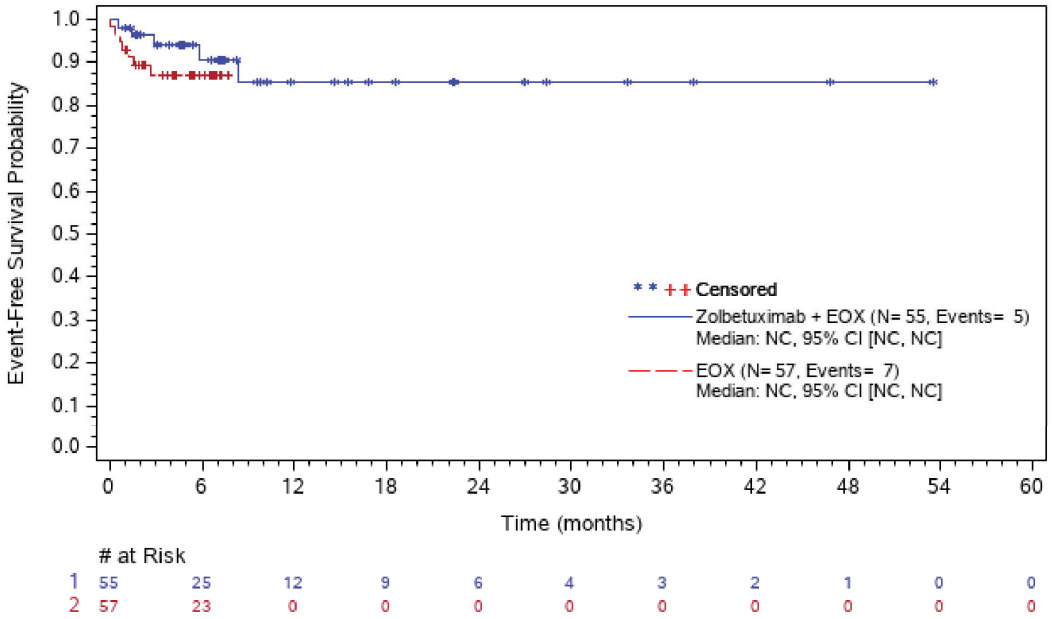
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.10: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Safety Analysis Set



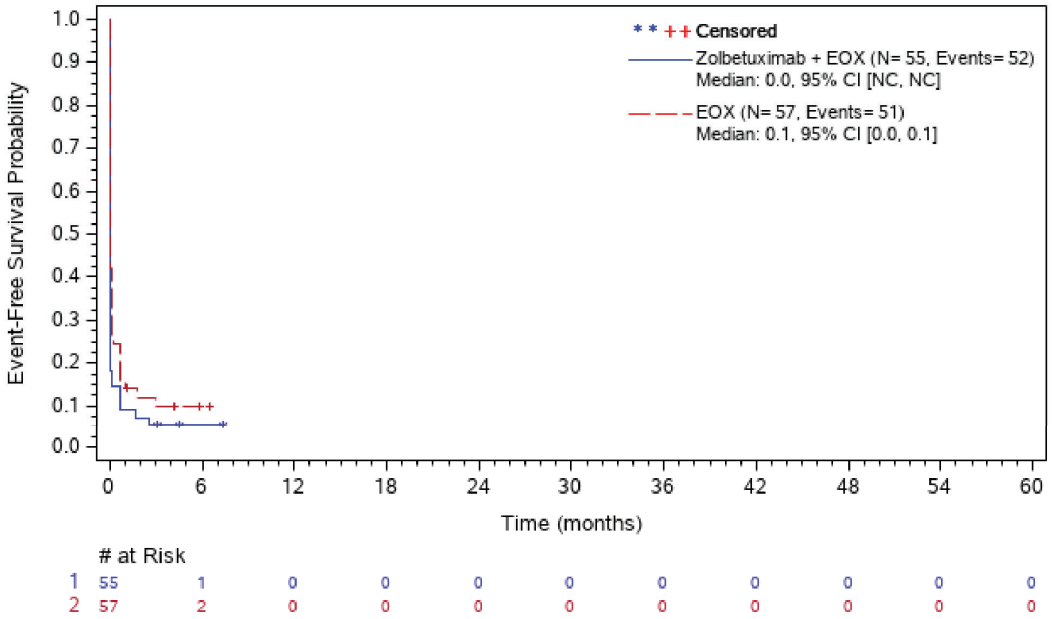
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.11: Kaplan-Meier Plot of Time to first TEAE - Cardiac Disorders (SOC) - Safety Analysis Set



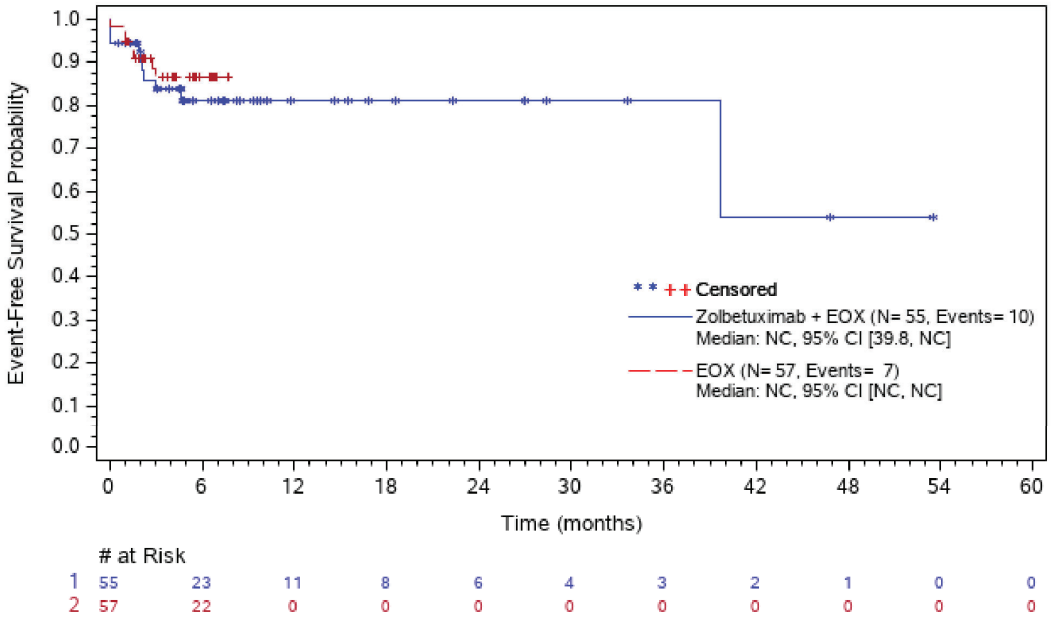
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.12: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



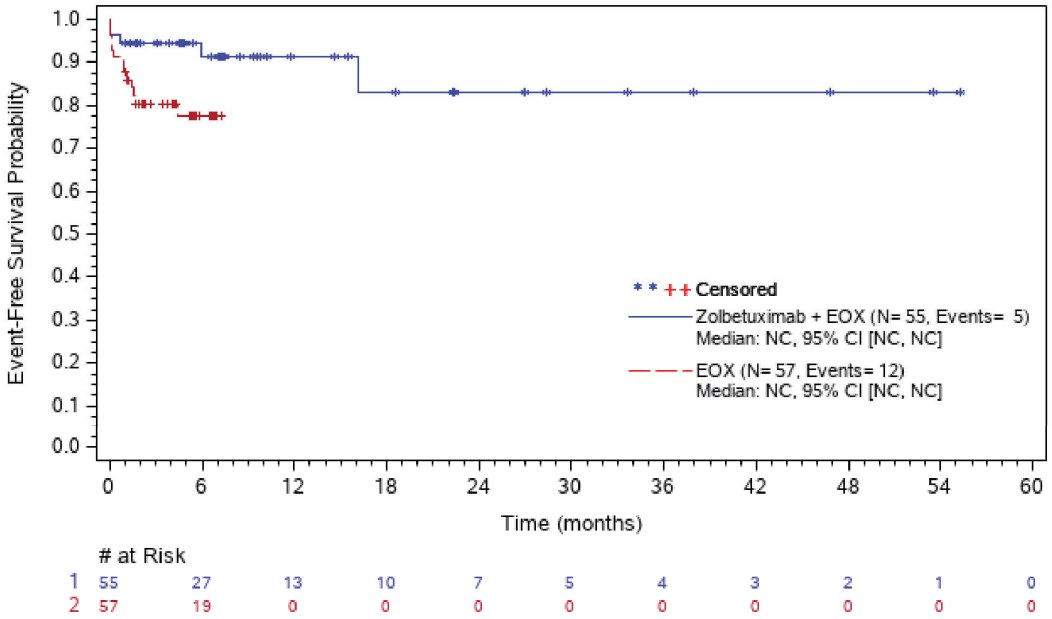
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.13: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (PT) - Safety Analysis Set



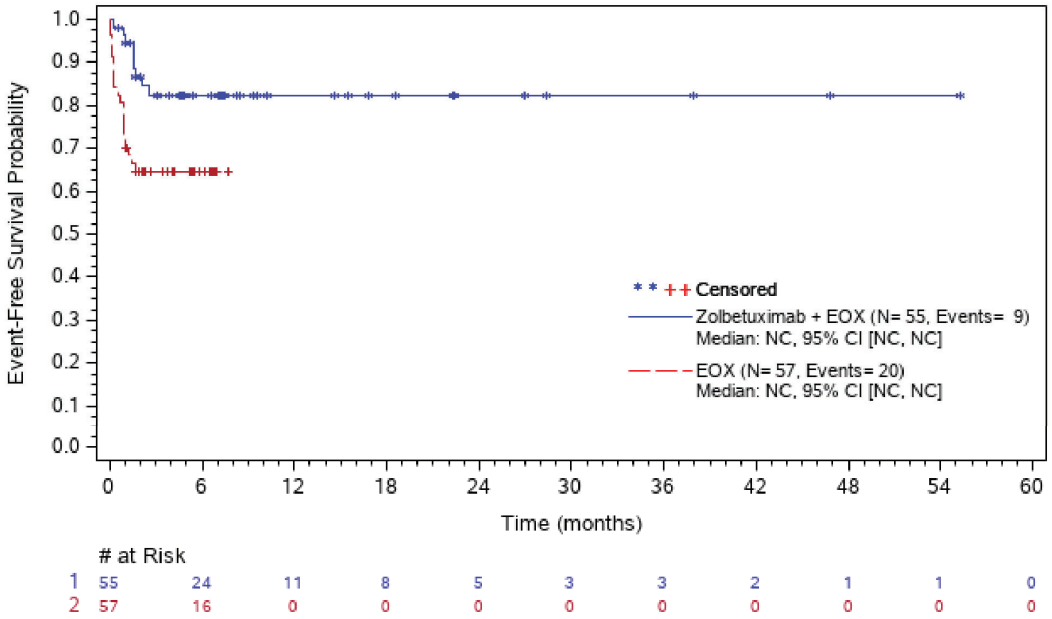
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.14: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain Upper (PT) - Safety Analysis Set



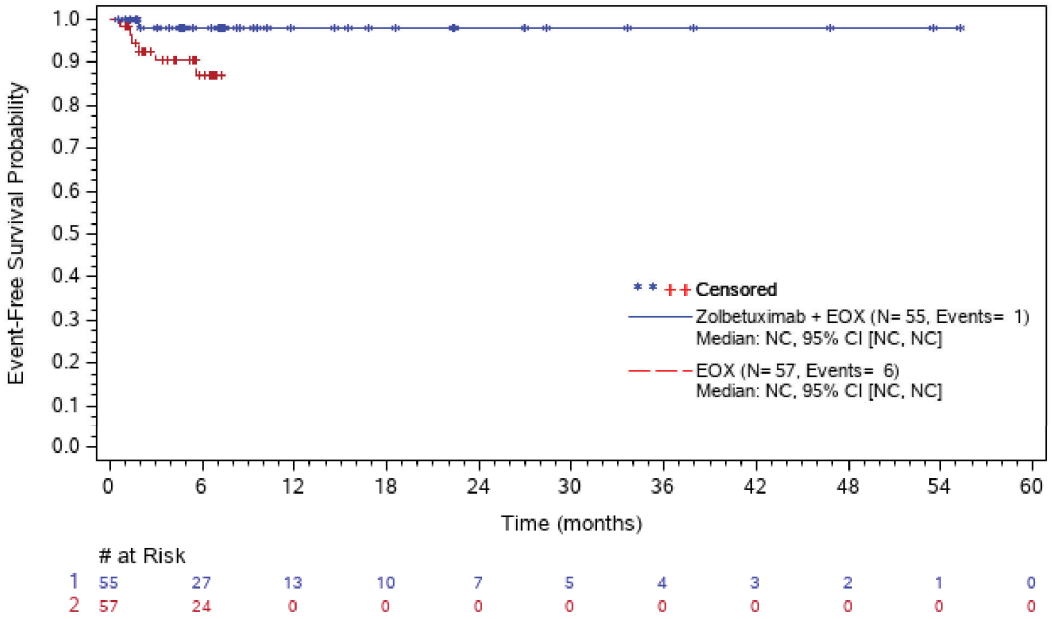
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.15: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Safety Analysis Set



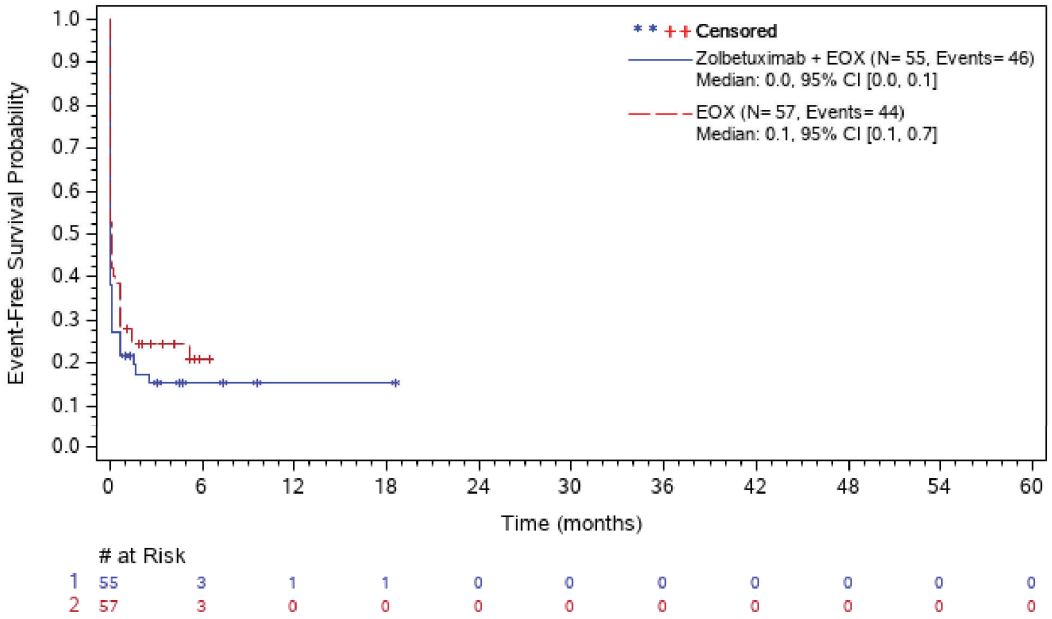
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.16: Kaplan-Meier Plot of Time to first TEAE - Dysphagia (PT) - Safety Analysis Set



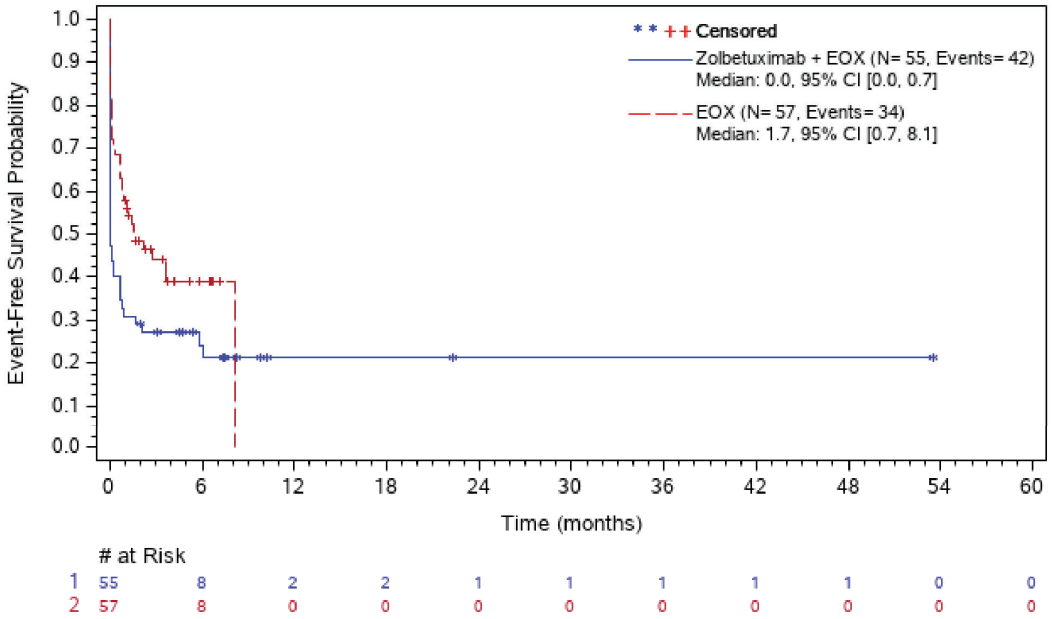
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.17: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Safety Analysis Set



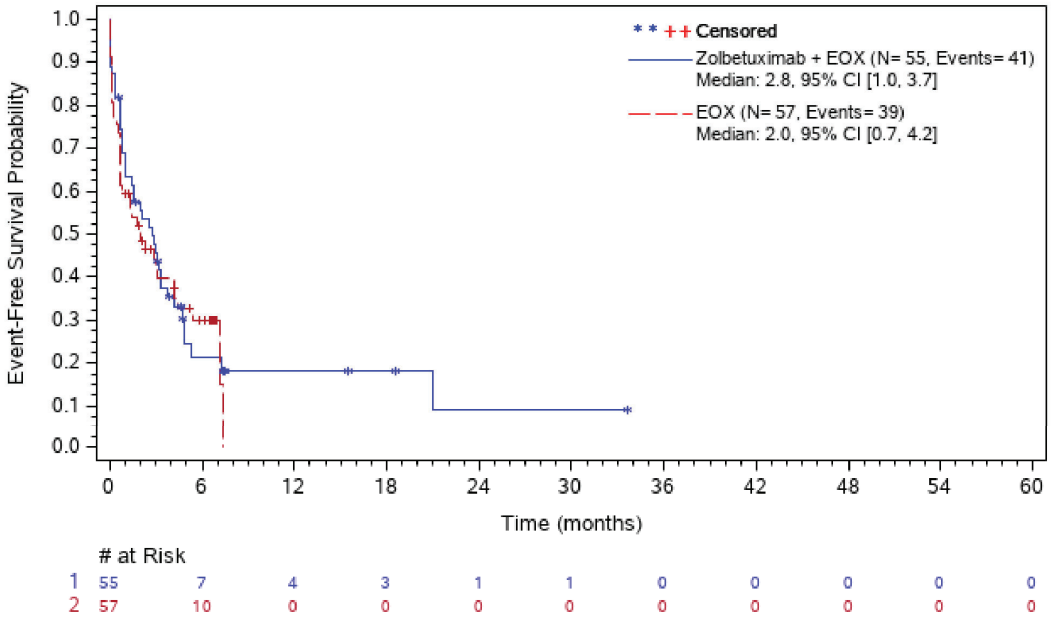
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.18: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Safety Analysis Set



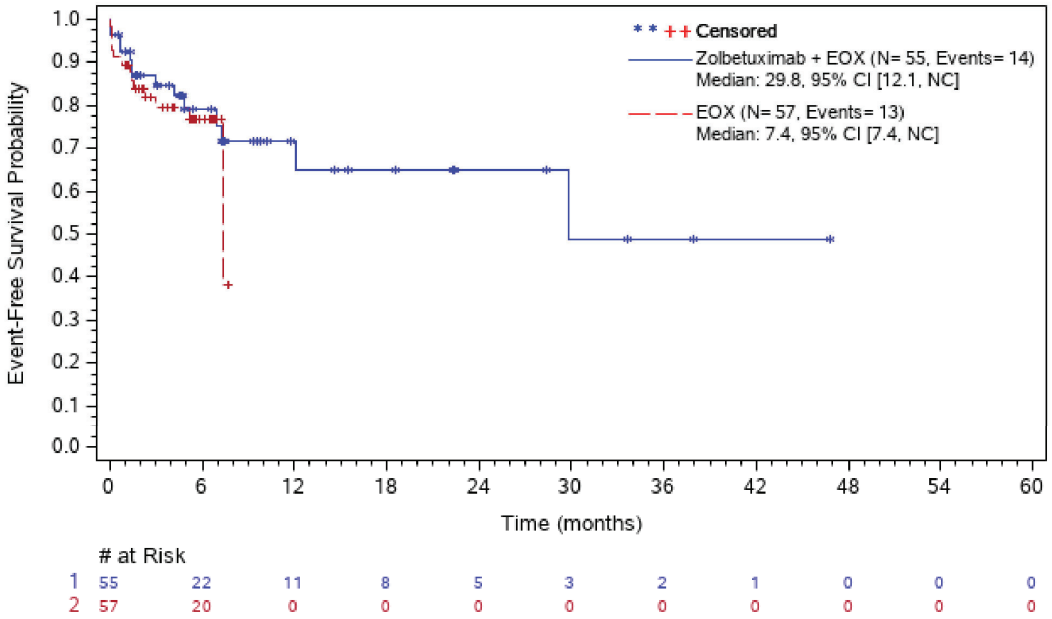
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.19: Kaplan-Meier Plot of Time to first TEAE - General Disorders and Administration Site Conditions (SOC) - Safety Analysis Set



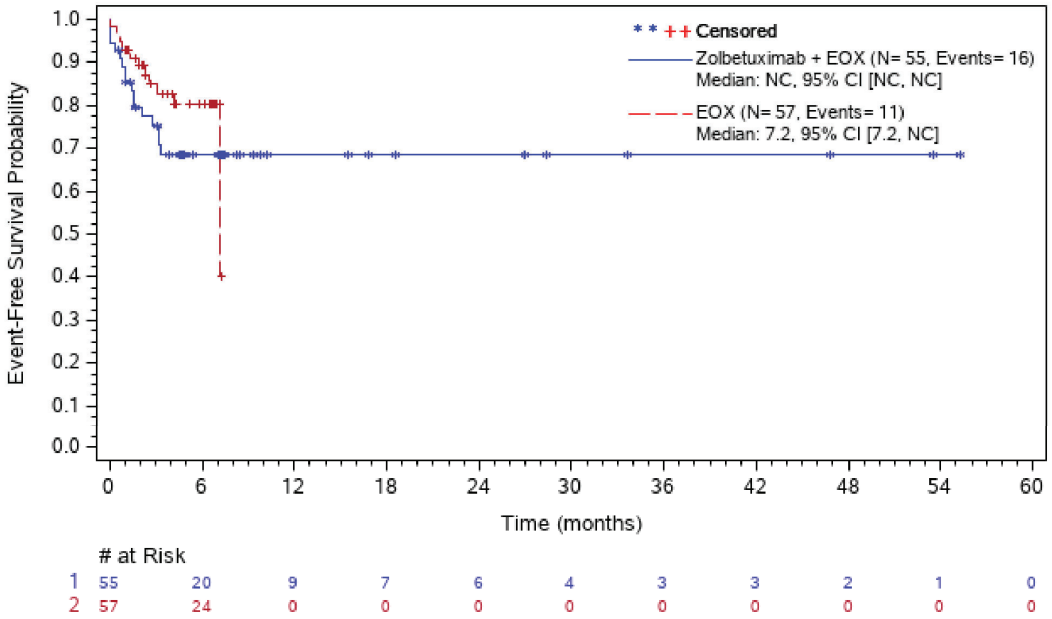
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.20: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Safety Analysis Set



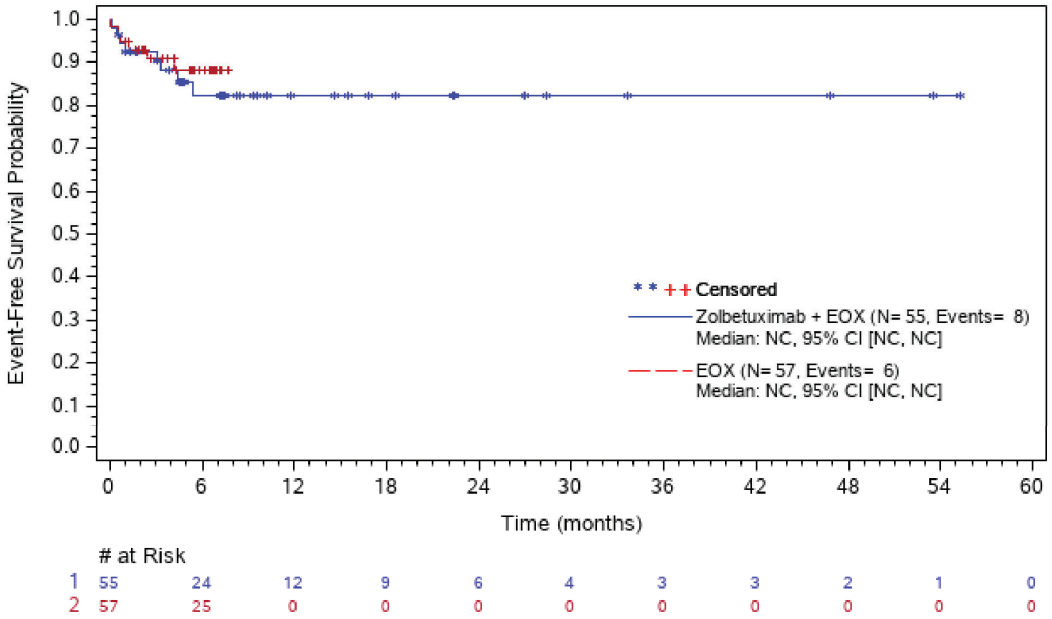
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.21: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Safety Analysis Set



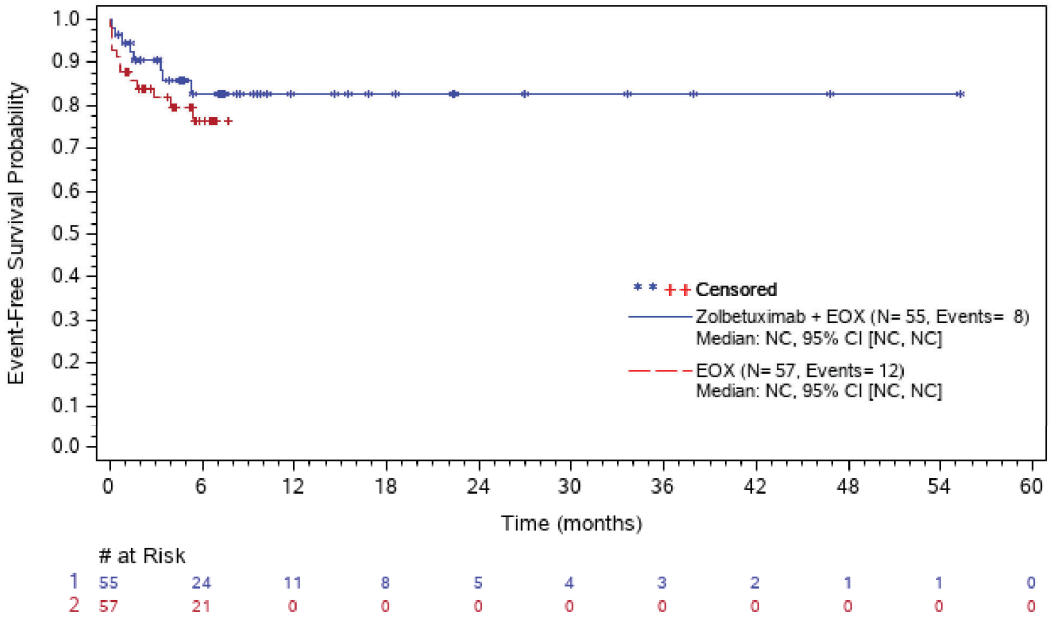
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.22: Kaplan-Meier Plot of Time to first TEAE - Oedema Peripheral (PT) - Safety Analysis Set



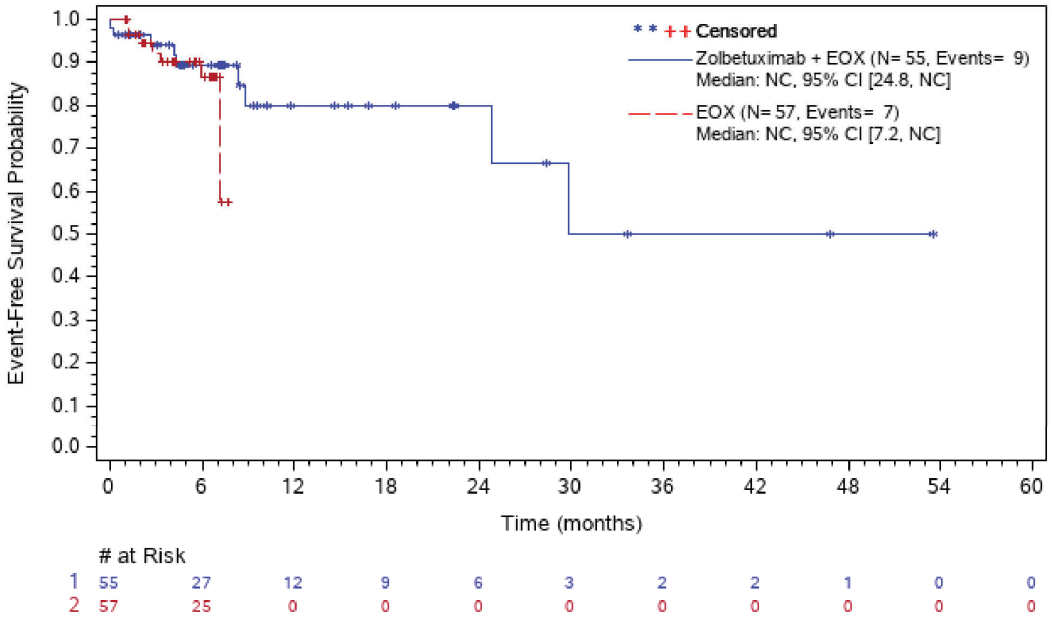
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.23: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Safety Analysis Set



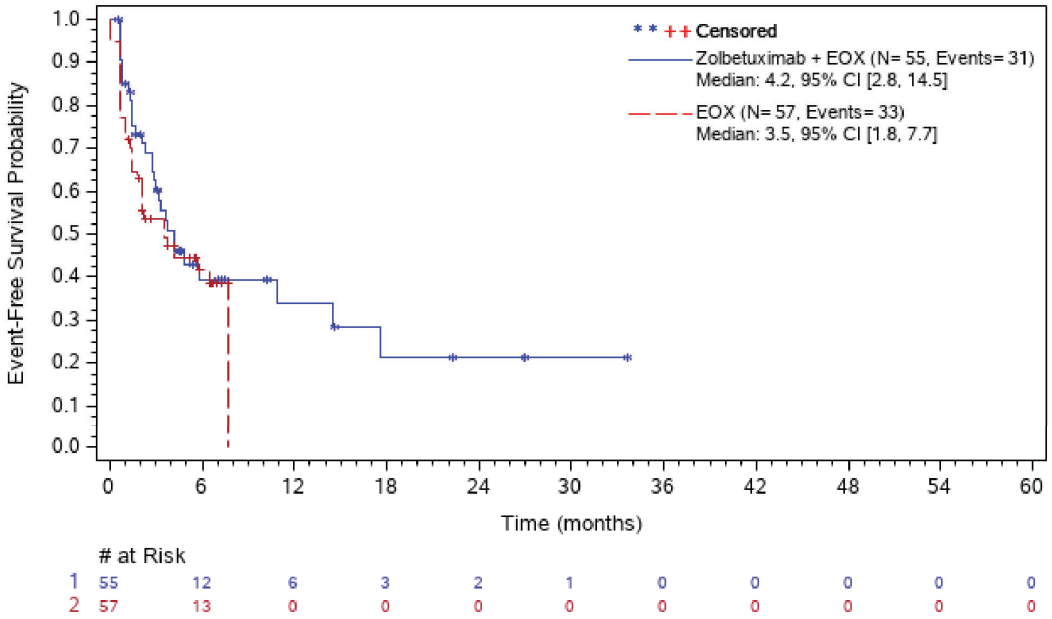
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.24: Kaplan-Meier Plot of Time to first TEAE - Infections and Infestations (SOC) - Safety Analysis Set



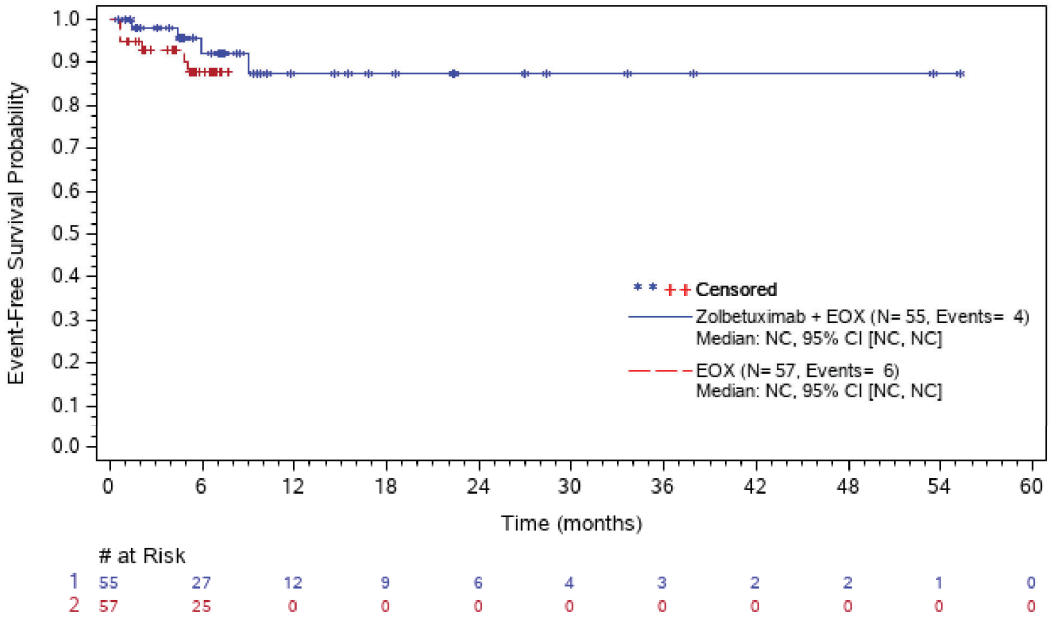
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.25: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Safety Analysis Set



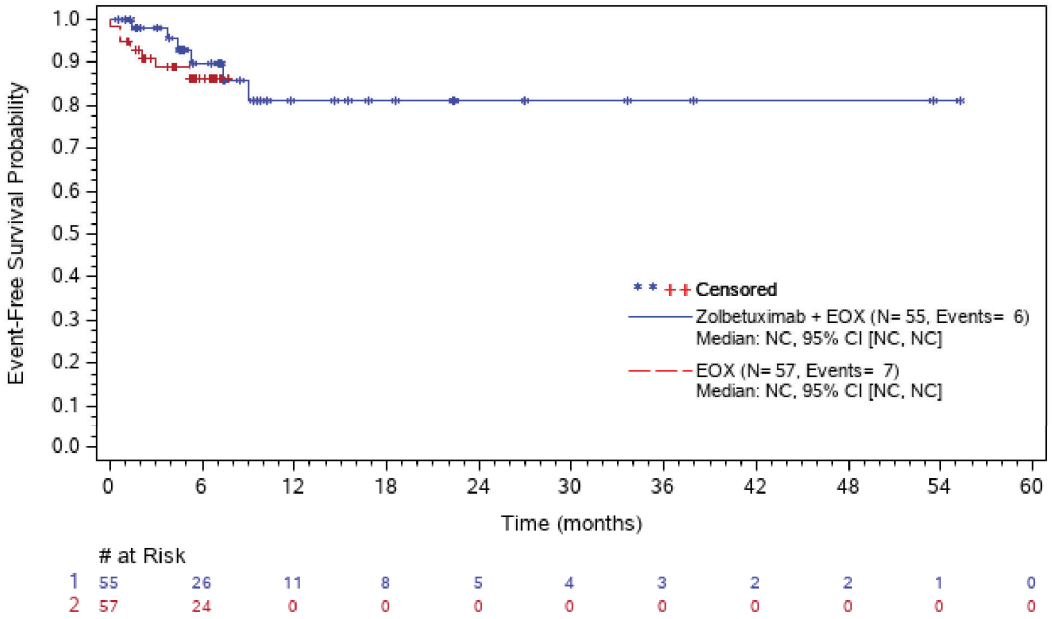
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.26: Kaplan-Meier Plot of Time to first TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set



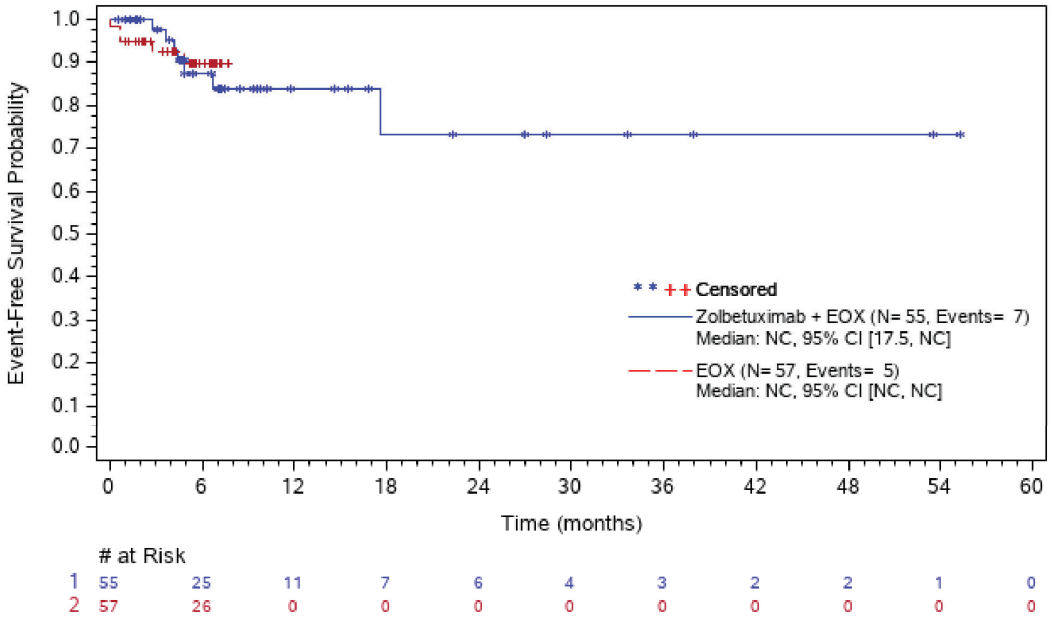
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.27: Kaplan-Meier Plot of Time to first TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



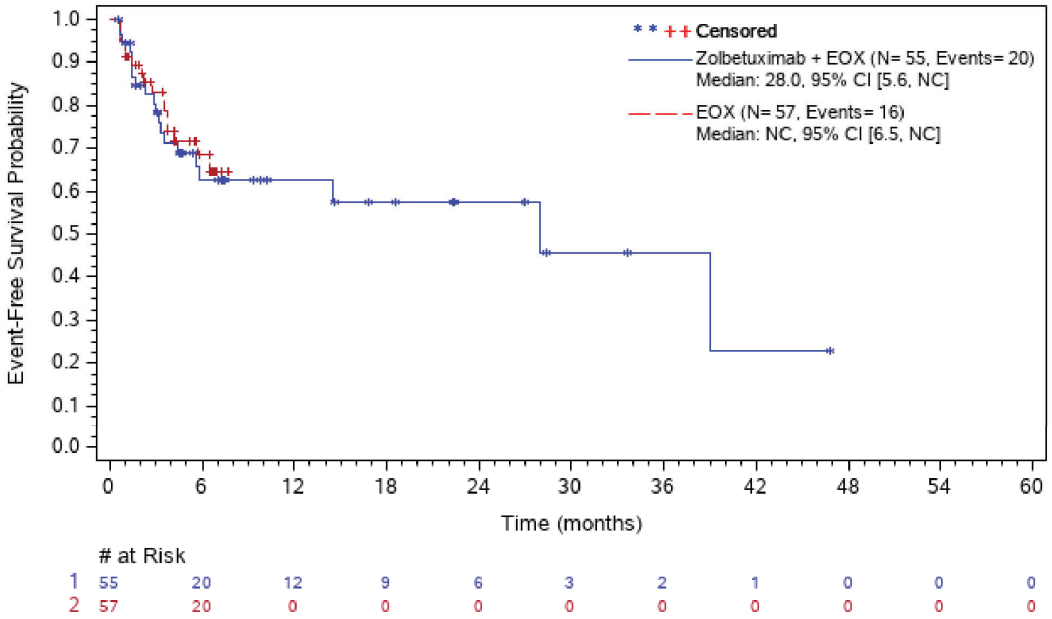
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.28: Kaplan-Meier Plot of Time to first TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



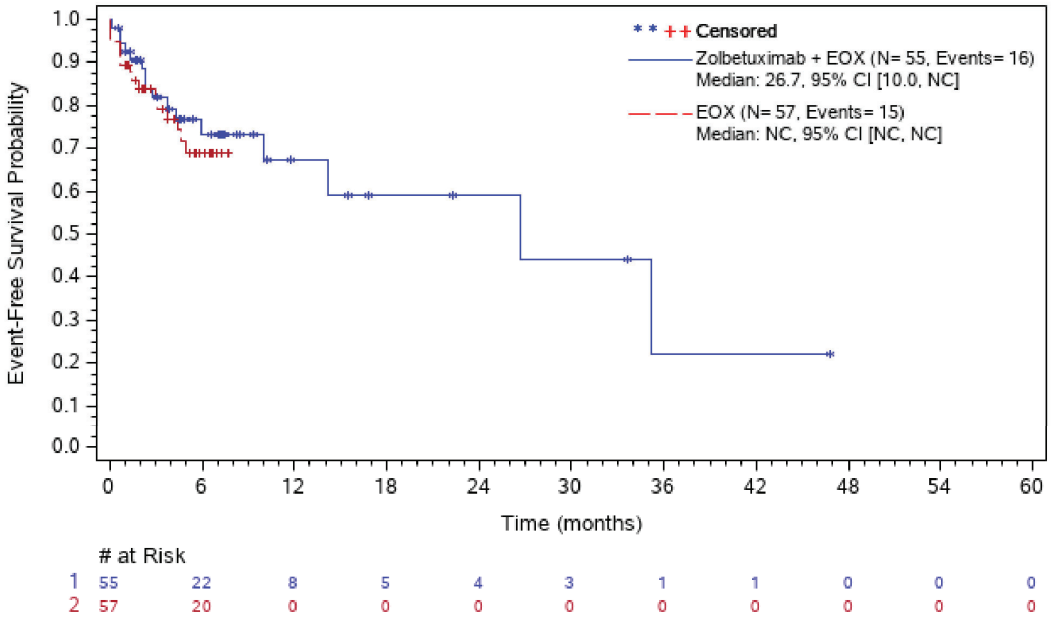
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.29: Kaplan-Meier Plot of Time to first TEAE - Weight Decreased (PT) - Safety Analysis Set



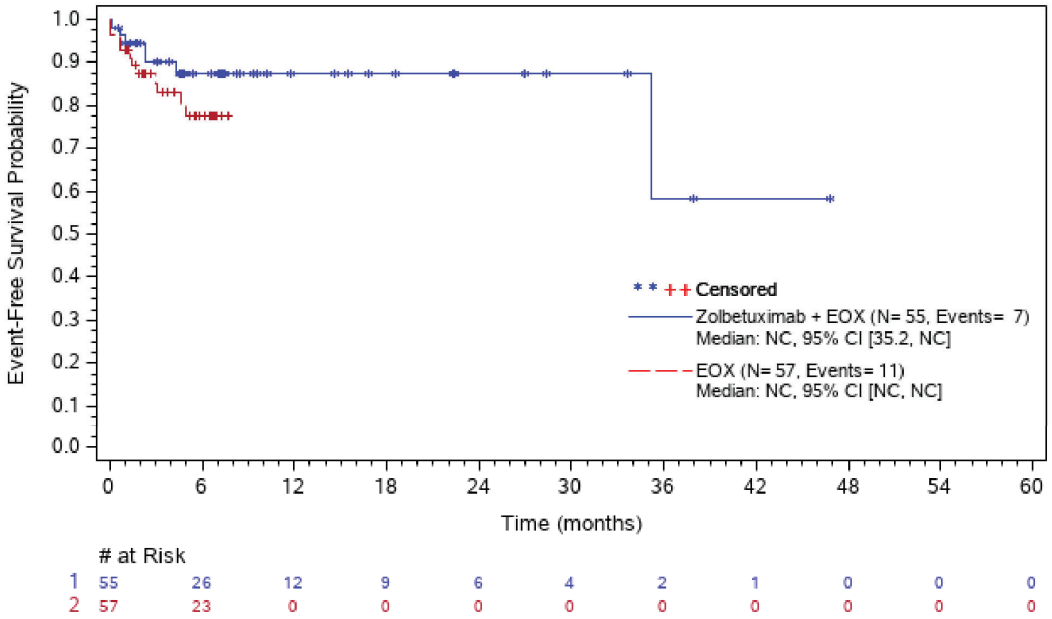
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.30: Kaplan-Meier Plot of Time to first TEAE - Metabolism and Nutrition Disorders (SOC) - Safety Analysis Set



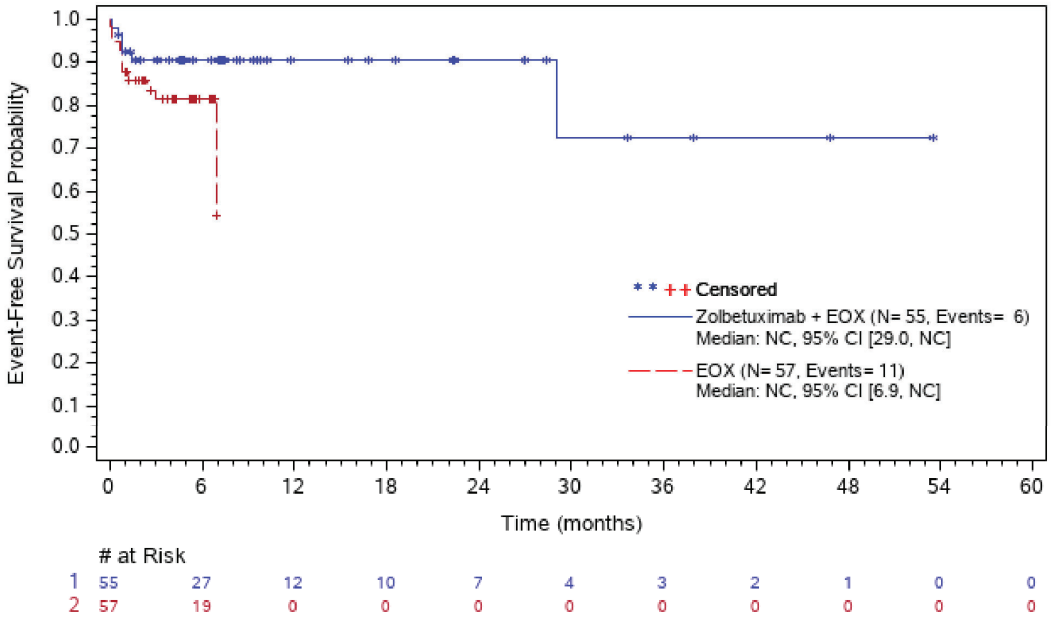
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.31: Kaplan-Meier Plot of Time to first TEAE - Decreased Appetite (PT) - Safety Analysis Set



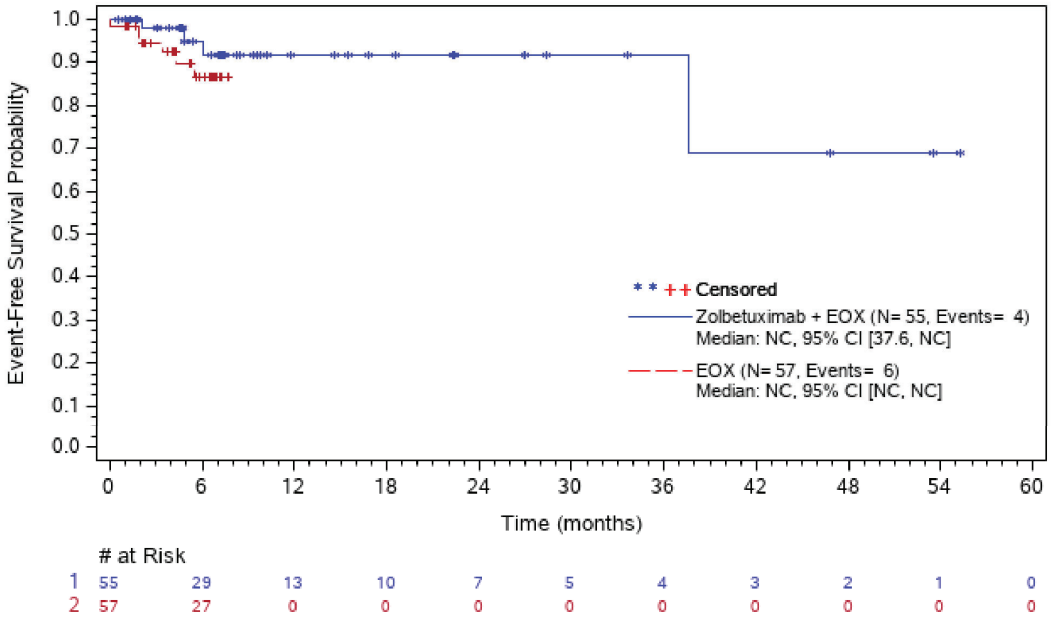
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.32: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal and Connective Tissue Disorders (SOC) - Safety Analysis Set



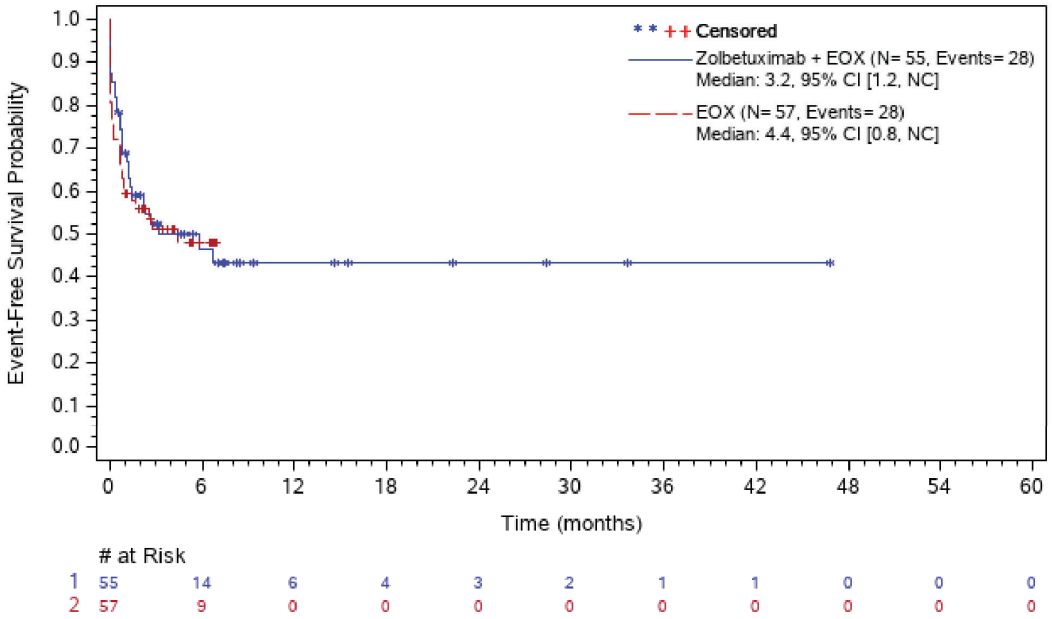
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.33: Kaplan-Meier Plot of Time to first TEAE - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - Safety Analysis Set



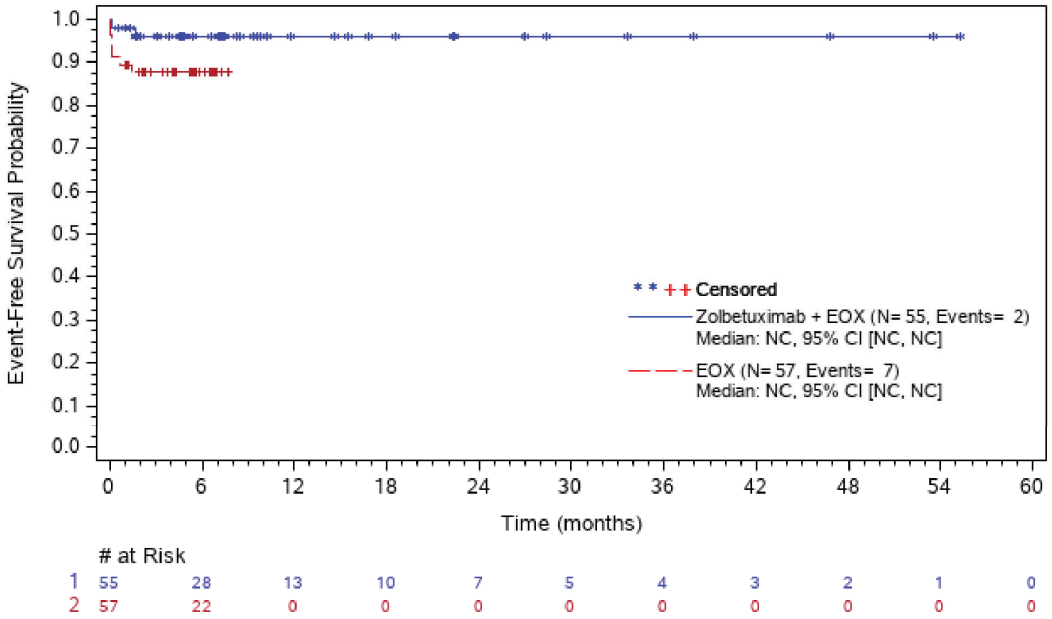
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.34: Kaplan-Meier Plot of Time to first TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



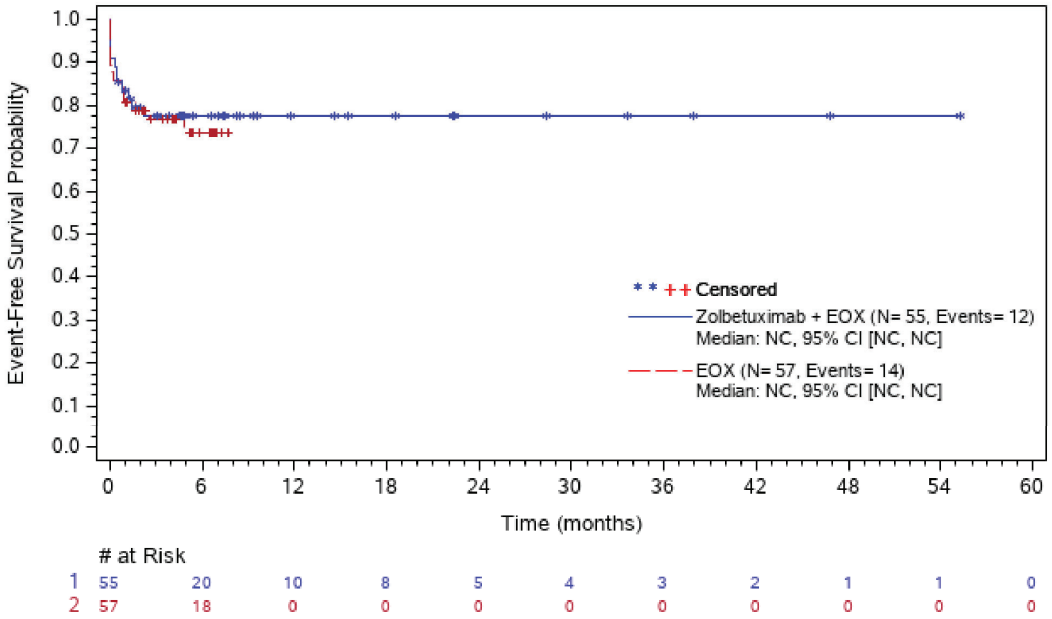
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.35: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Safety Analysis Set



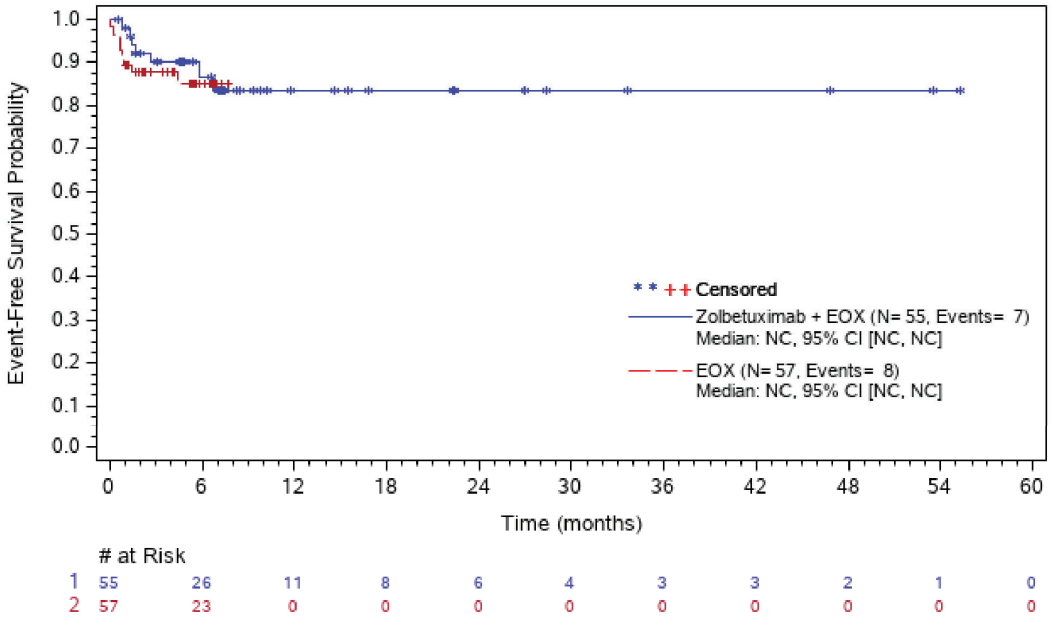
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.36: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Safety Analysis Set



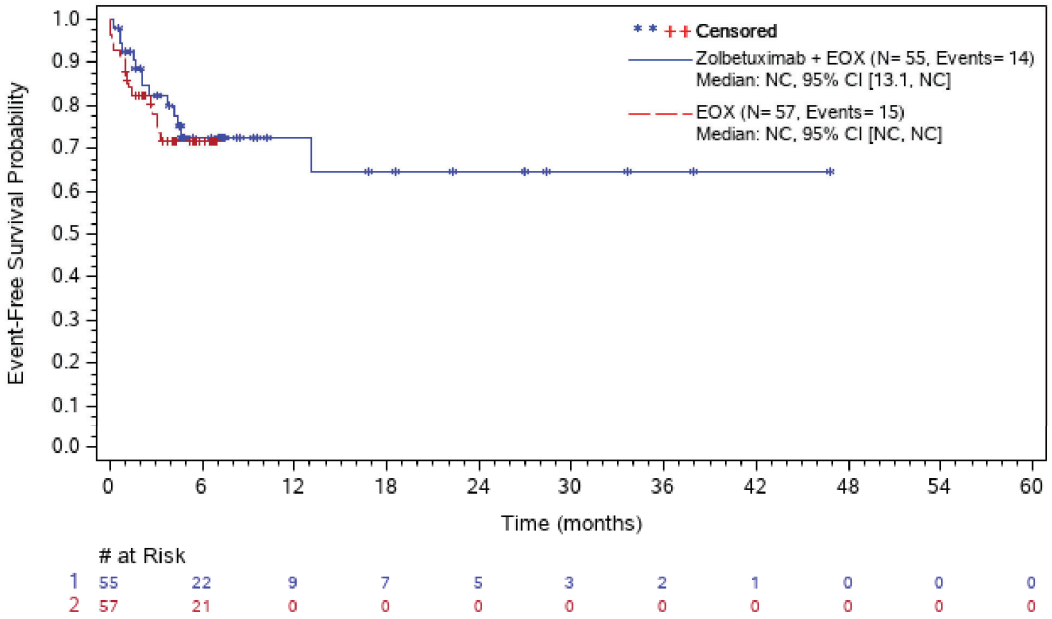
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.37: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Safety Analysis Set



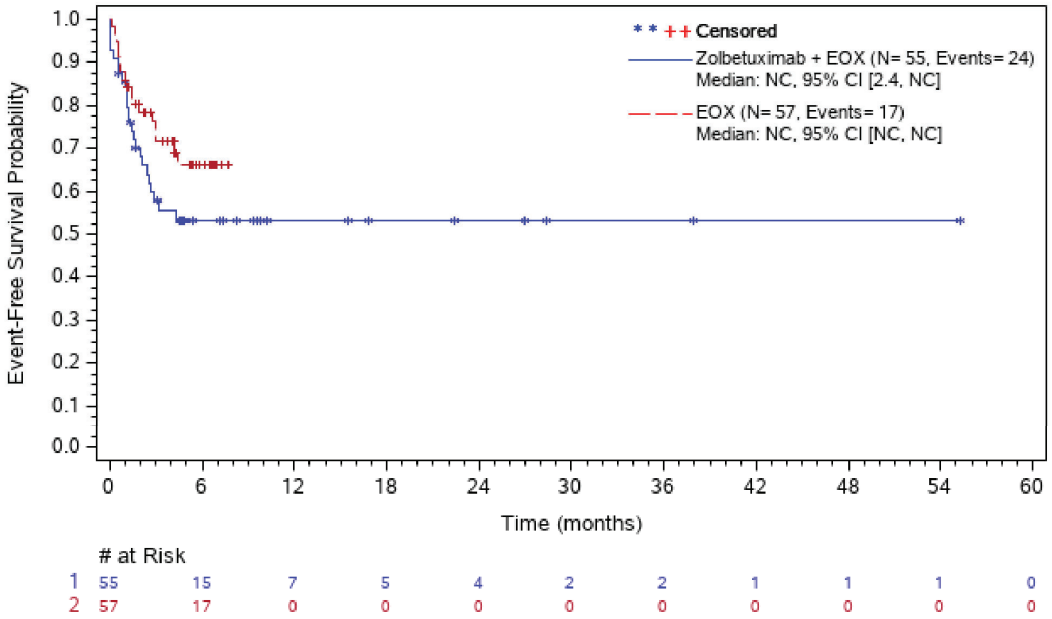
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.38: Kaplan-Meier Plot of Time to first TEAE - Respiratory, Thoracic and Mediastinal Disorders (SOC) - Safety Analysis Set



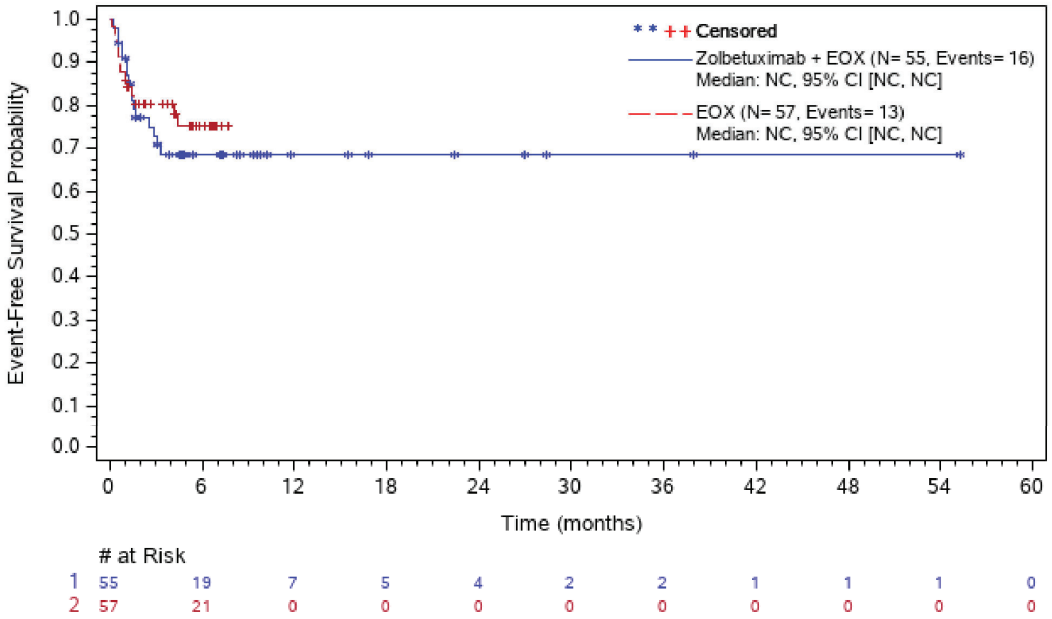
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.39: Kaplan-Meier Plot of Time to first TEAE - Skin and Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



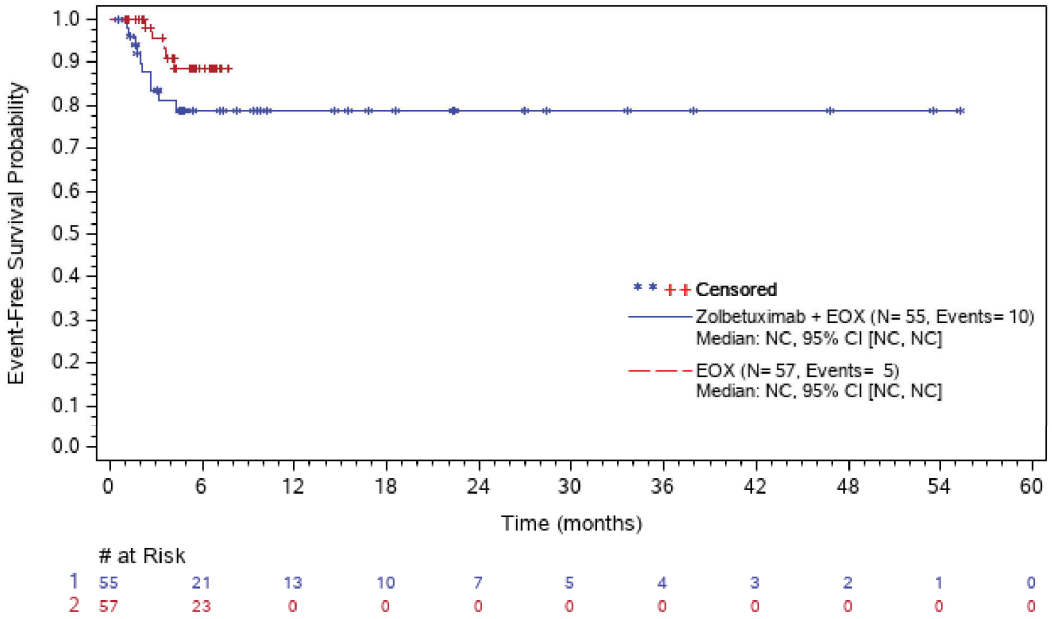
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.40: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Safety Analysis Set



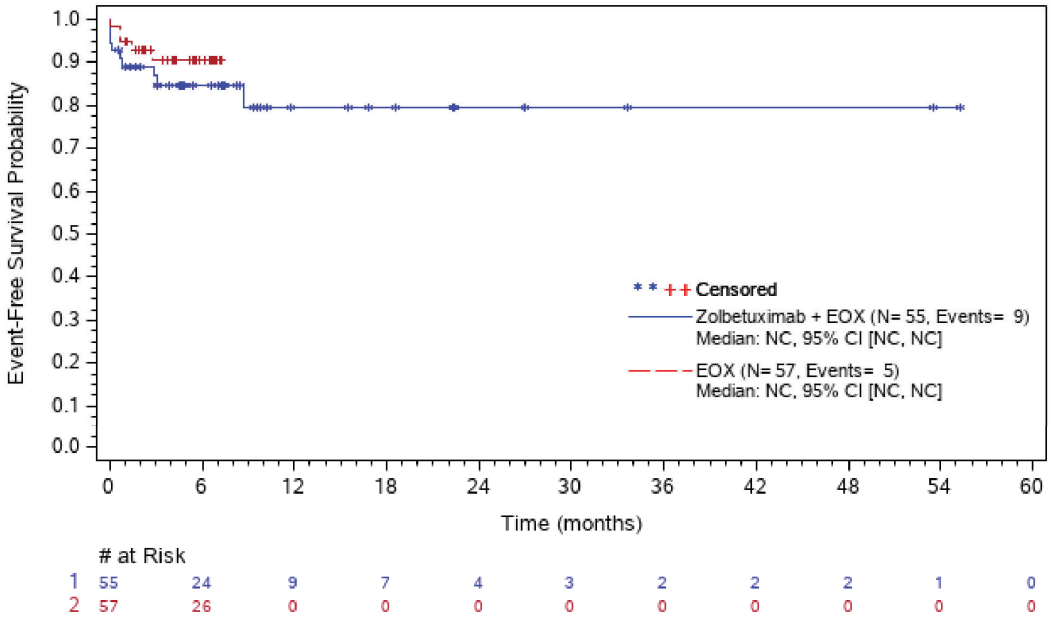
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.41: Kaplan-Meier Plot of Time to first TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set



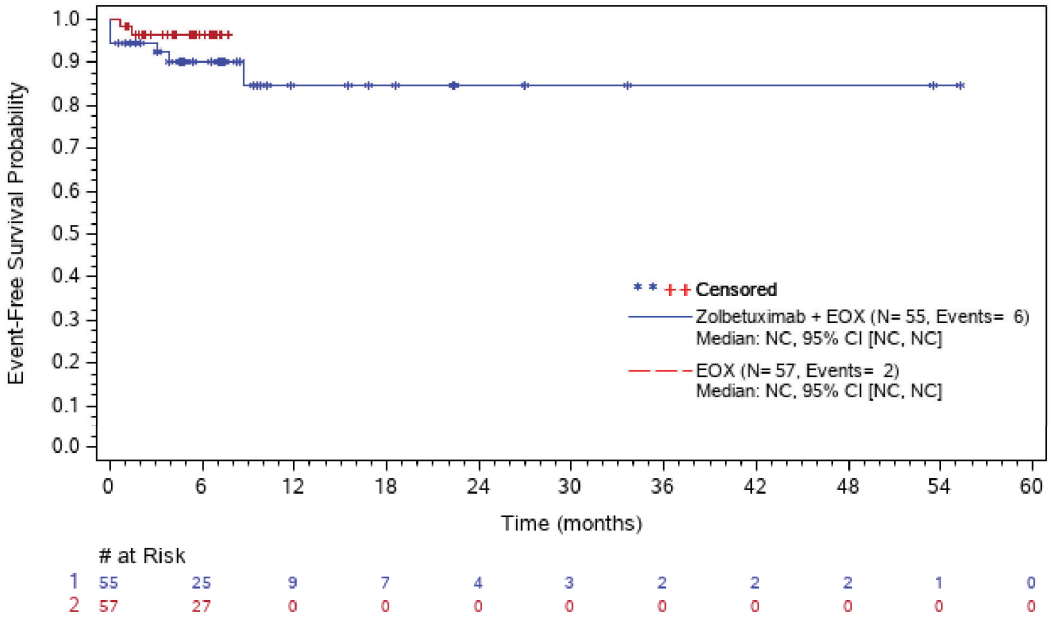
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.42: Kaplan-Meier Plot of Time to first TEAE - Vascular Disorders (SOC) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.43: Kaplan-Meier Plot of Time to first TEAE - Hypertension (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwere unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table GM03.1.2001.49.1: Summary and Results of Severe TEAEs - Blood and Lymphatic System Disorders (SOC) - 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	25 (45.5%)	16 (28.1%)	
Number of patients censored	30 (54.5%)	41 (71.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.7, NC]	7.4 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.736 [0.917, 3.287]
Log-rank test			
Two-sided stratified log-rank p-value			0.0882

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.50.1: Summary and Results of Severe TEAEs - Anaemia (PT)
- 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	8 (14.5%)	6 (10.5%)	
Number of patients censored	47 (85.5%)	51 (89.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [20.5, NC]	7.4 [7.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.751 [0.220, 2.559]
Log-rank test			
Two-sided stratified log-rank p-value			0.6487

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.51.1: Summary and Results of Severe TEAEs - Leukopenia (PT)
- 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	5 (9.1%)	3 (5.3%)	
Number of patients censored	50 (90.9%)	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			1.733 [0.414, 7.255]
Log-rank test			
Two-sided stratified log-rank p-value			0.4459

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.52.1: Summary and Results of Severe TEAEs - Lymphopenia (PT)
- 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%)	2 (3.5%)	
Number of patients censored	52 (94.5%)	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			1.487 [0.248, 8.898]
Log-rank test			
Two-sided stratified log-rank p-value			0.6608

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.53.1: Summary and Results of Severe TEAEs - Neutropenia (PT)
- 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	19 (34.5%)	11 (19.3%)	
Number of patients censored	36 (65.5%)	46 (80.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [4.9, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.955 [0.928, 4.116]
Log-rank test			
Two-sided stratified log-rank p-value			0.0741

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.54.1: Summary and Results of Severe TEAEs - Gastrointestinal Disorders (SOC) - 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	12 (21.8%)	14 (24.6%)	
Number of patients censored	43 (78.2%)	43 (75.4%)	
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			0.757 [0.339, 1.690]
Log-rank test			
Two-sided stratified log-rank p-value			0.4946

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.55.1: Summary and Results of Severe TEAEs - Ascites (PT)
- 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%)	3 (5.3%)	
Number of patients censored	55 (100.0%)	54 (94.7%)	
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			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0123

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.55.2: Summary and Results of Severe TEAEs by Subgroups - Ascites (PT) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	3 (6.3)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	3 (8.3)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	3 (7.5)				

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.56.1: Summary and Results of Severe TEAEs - Diarrhoea (PT)
- 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%)	3 (5.3%)	
Number of patients censored	54 (98.2%)	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			0.330 [0.034, 3.174]
Log-rank test			
Two-sided stratified log-rank p-value			0.3126

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.57.1: Summary and Results of Severe TEAEs - Nausea (PT)
- 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			1.396 [0.312, 6.238]
Log-rank test			
Two-sided stratified log-rank p-value			0.6608

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.58.1: Summary and Results of Severe TEAEs - Vomiting (PT)
- 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	6 (10.9%)	2 (3.5%)	
Number of patients censored	49 (89.1%)	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			3.225 [0.650, 16.013]
Log-rank test			
Two-sided stratified log-rank p-value			0.1298

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.59.1: Summary and Results of Severe TEAEs - General Disorders and Administration Site Conditions (SOC) - 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	8 (14.5%)	4 (7.0%)	
Number of patients censored	47 (85.5%)	53 (93.0%)	
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			2.106 [0.634, 7.003]
Log-rank test			
Two-sided stratified log-rank p-value			0.2136

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.60.1: Summary and Results of Severe TEAEs - Fatigue (PT)
- 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			2.029 [0.371, 11.097]
Log-rank test			
Two-sided stratified log-rank p-value			0.4048

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.61.1: Summary and Results of Severe TEAEs - Investigations (SOC)
- 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	12 (21.8%)	10 (17.5%)	
Number of patients censored	43 (78.2%)	47 (82.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	36.2 [17.5, NC]	7.7 [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.798 [0.320, 1.992]
Log-rank test			
Two-sided stratified log-rank p-value			0.6297

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.62.1: Summary and Results of Severe TEAEs - C-Reactive Protein Increased (PT) - 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%)	3 (5.3%)	
Number of patients censored	55 (100.0%)	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			NC [NC, NC]
Log-rank test			
Two-sided stratified log-rank p-value			0.0842

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.63.1: Summary and Results of Severe TEAEs - Gamma-Glutamyltransferase Increased (PT) - 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 [17.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.841 [0.167, 4.226]
Log-rank test			
Two-sided stratified log-rank p-value			0.8332

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.64.1: Summary and Results of Severe TEAEs - Weight Decreased (PT)
- 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	8 (14.5%)	2 (3.5%)	
Number of patients censored	47 (85.5%)	55 (96.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [36.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.605 [0.747, 17.384]
Log-rank test			
Two-sided stratified log-rank p-value			0.0876

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.65.1: Summary and Results of Severe TEAEs - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - 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%)	5 (8.8%)	
Number of patients censored	51 (92.7%)	52 (91.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [37.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.616 [0.147, 2.588]
Log-rank test			
Two-sided stratified log-rank p-value			0.5065

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.66.1: Summary and Results of Severe TEAEs - Neoplasm Malignant (PT) - 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%)	4 (7.0%)	
Number of patients censored	51 (92.7%)	53 (93.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [37.6, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.732 [0.164, 3.275]
Log-rank test			
Two-sided stratified log-rank p-value			0.6852

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.67.1: Summary and Results of Severe TEAEs - Nervous System Disorders (SOC) - 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%)	3 (5.3%)	
Number of patients censored	54 (98.2%)	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			0.350 [0.036, 3.369]
Log-rank test			
Two-sided stratified log-rank p-value			0.3405

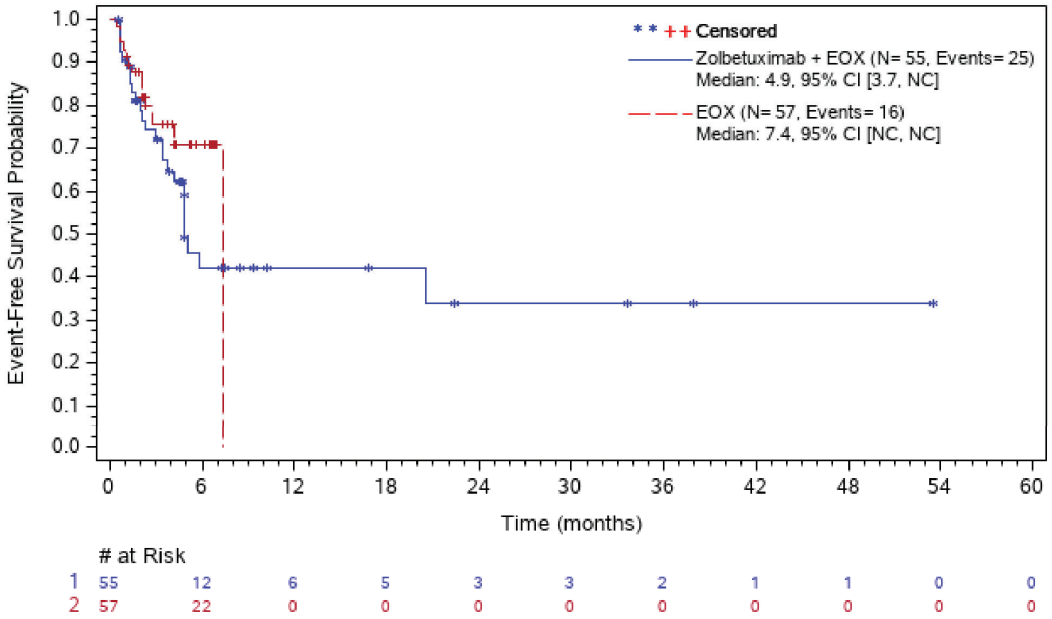
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwere unerwünschte Ereignisse - SOC und PT

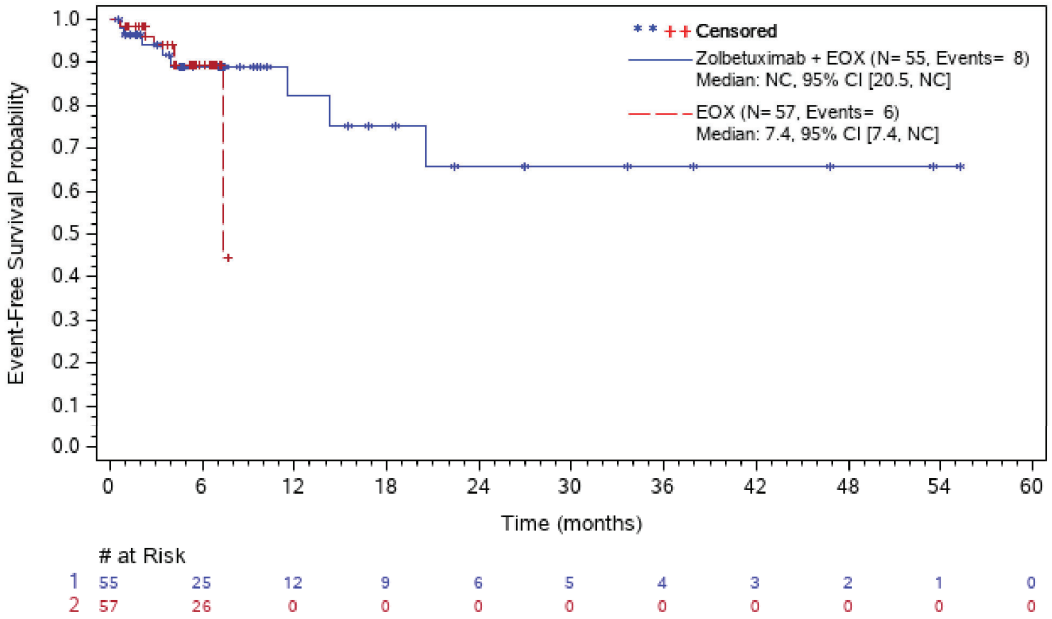
2. Kaplan-Meier-Plots

Figure GM03.1.2001.49: Kaplan-Meier Plot of Time to first Severe TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



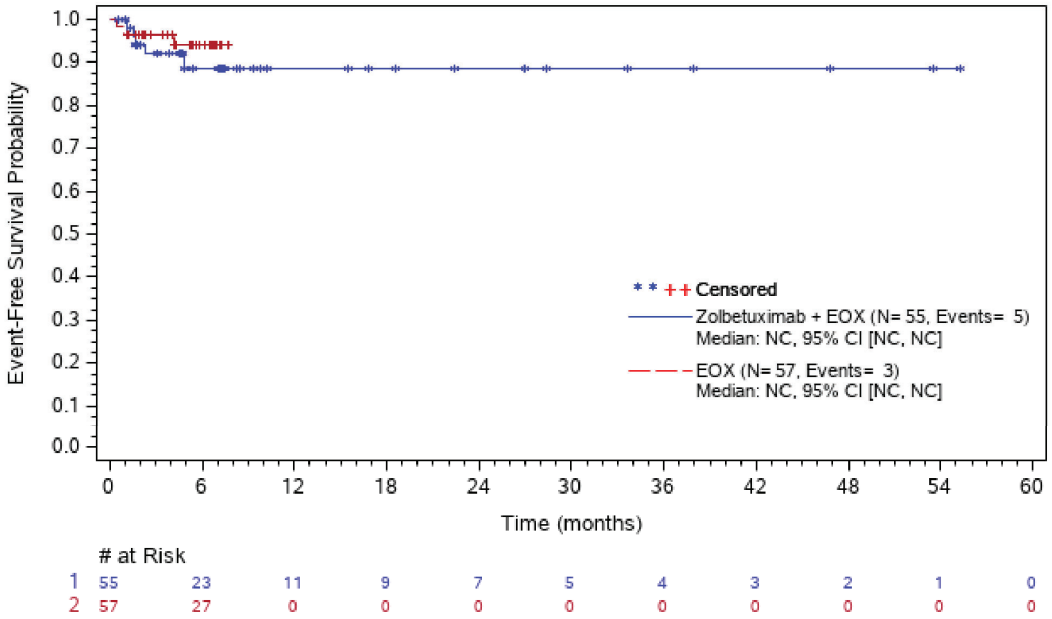
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.50: Kaplan-Meier Plot of Time to first Severe TEAE - Anaemia (PT) - Safety Analysis Set



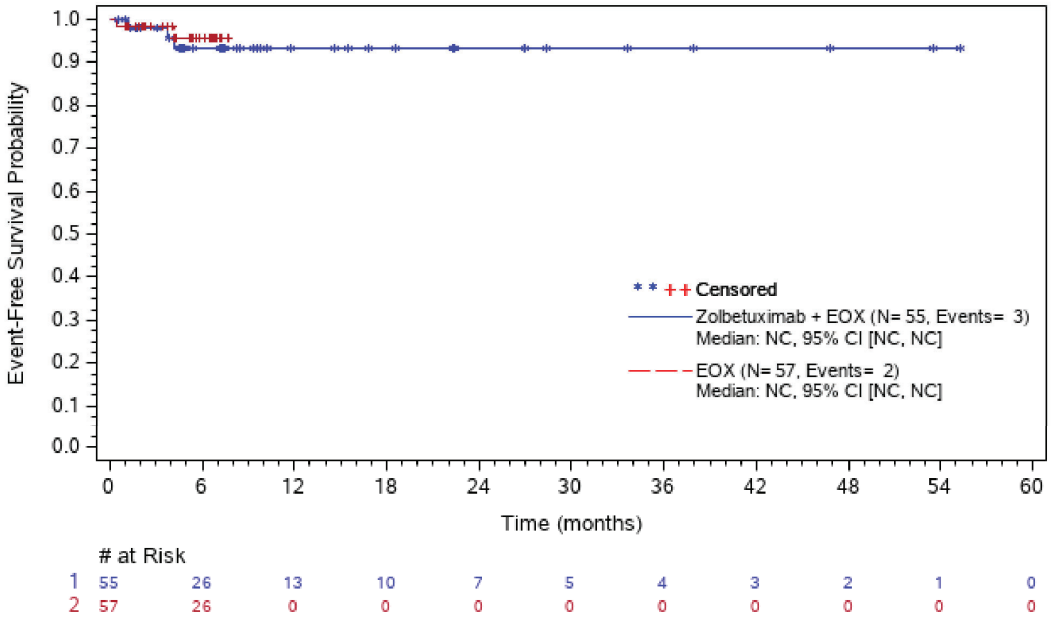
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.51: Kaplan-Meier Plot of Time to first Severe TEAE - Leukopenia (PT) - Safety Analysis Set



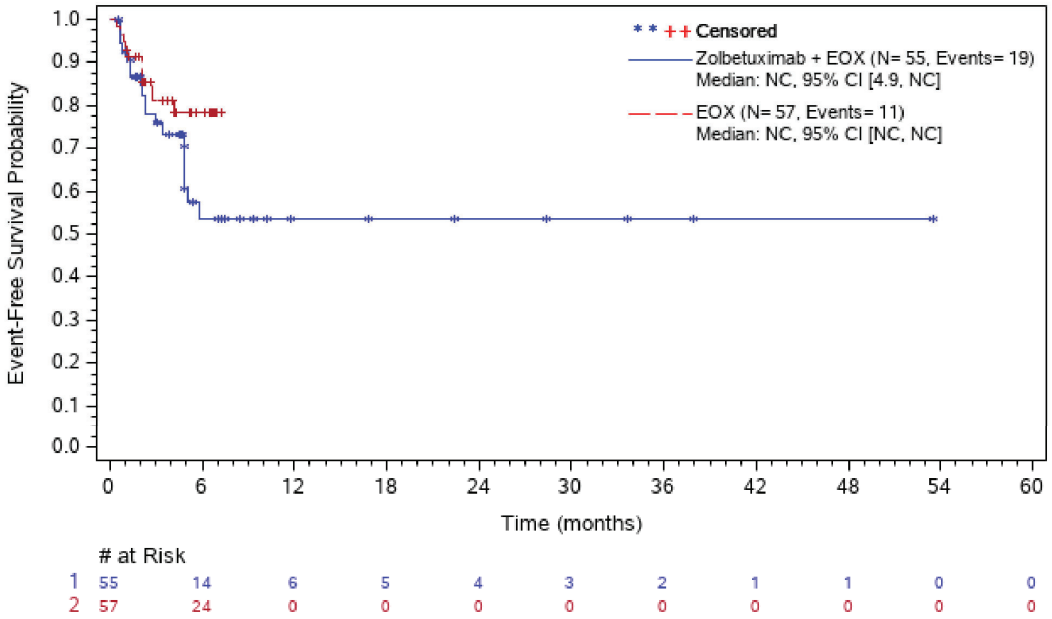
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.52: Kaplan-Meier Plot of Time to first Severe TEAE - Lymphopenia (PT) - Safety Analysis Set



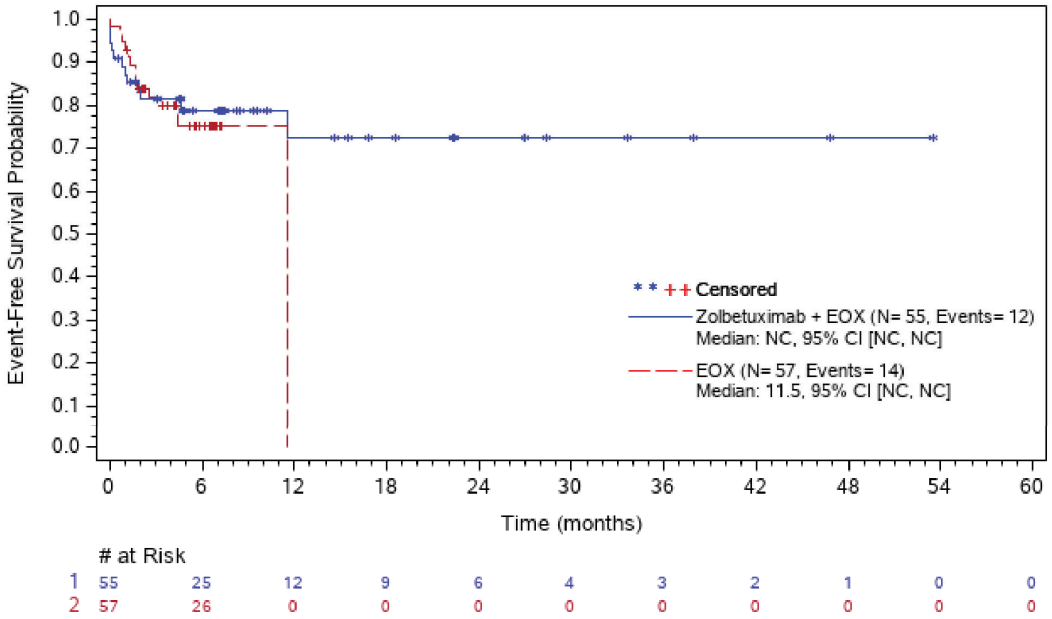
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.53: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (PT) - Safety Analysis Set



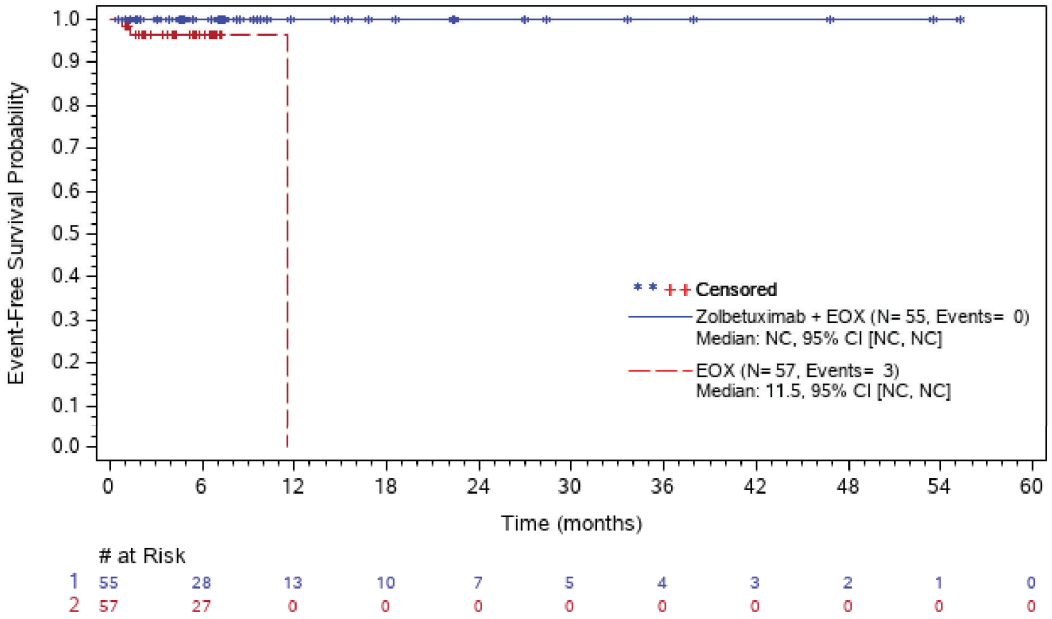
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.54: Kaplan-Meier Plot of Time to first Severe TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



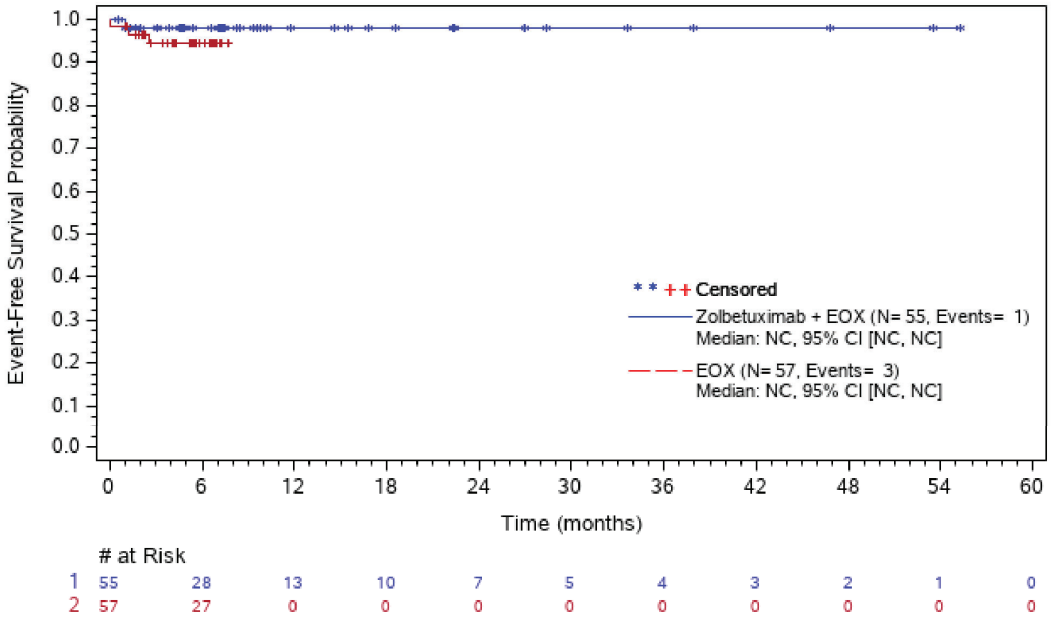
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.55: Kaplan-Meier Plot of Time to first Severe TEAE - Ascites (PT) - Safety Analysis Set



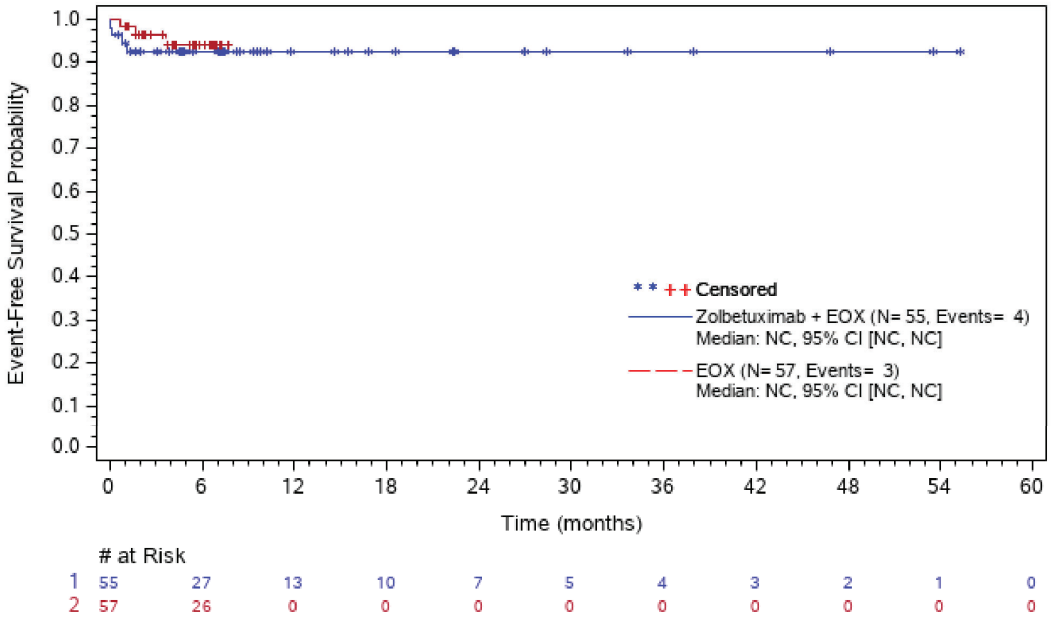
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.56: Kaplan-Meier Plot of Time to first Severe TEAE - Diarrhoea (PT) - Safety Analysis Set



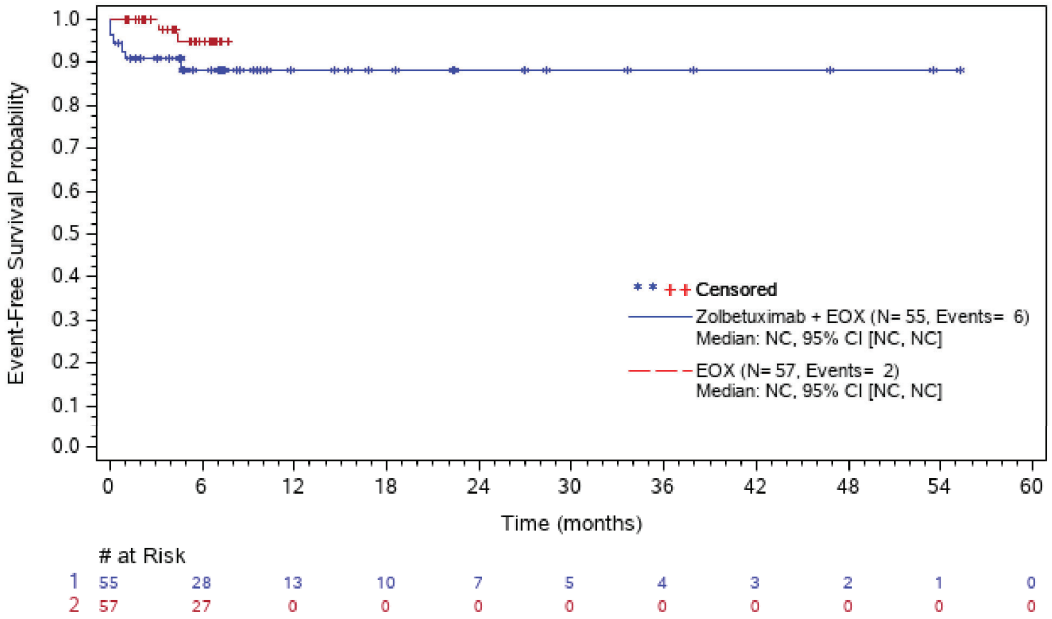
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.57: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (PT) - Safety Analysis Set



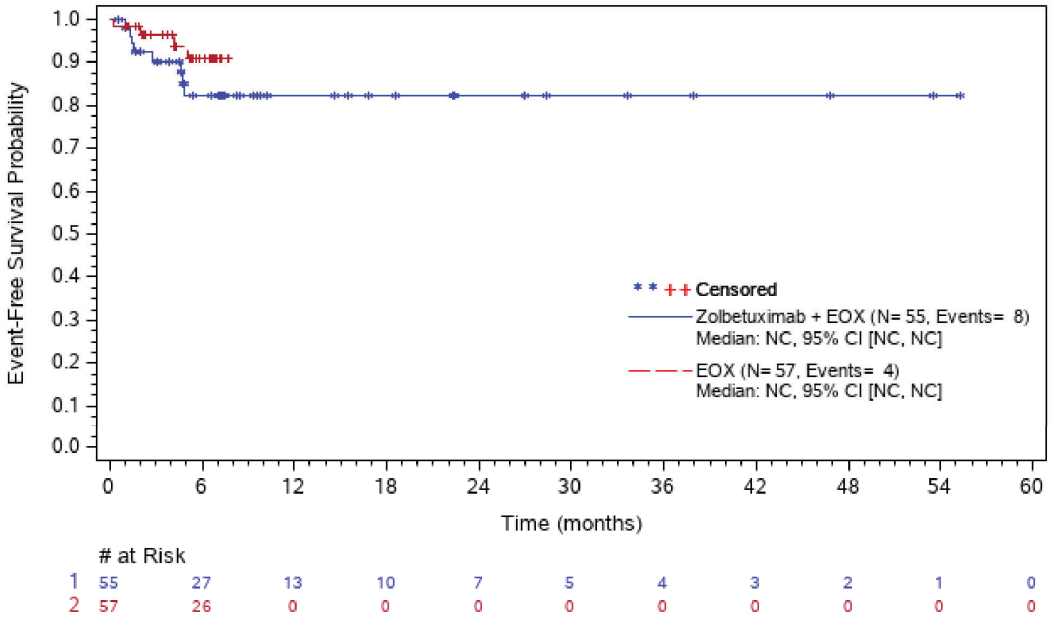
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.58: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (PT) - Safety Analysis Set



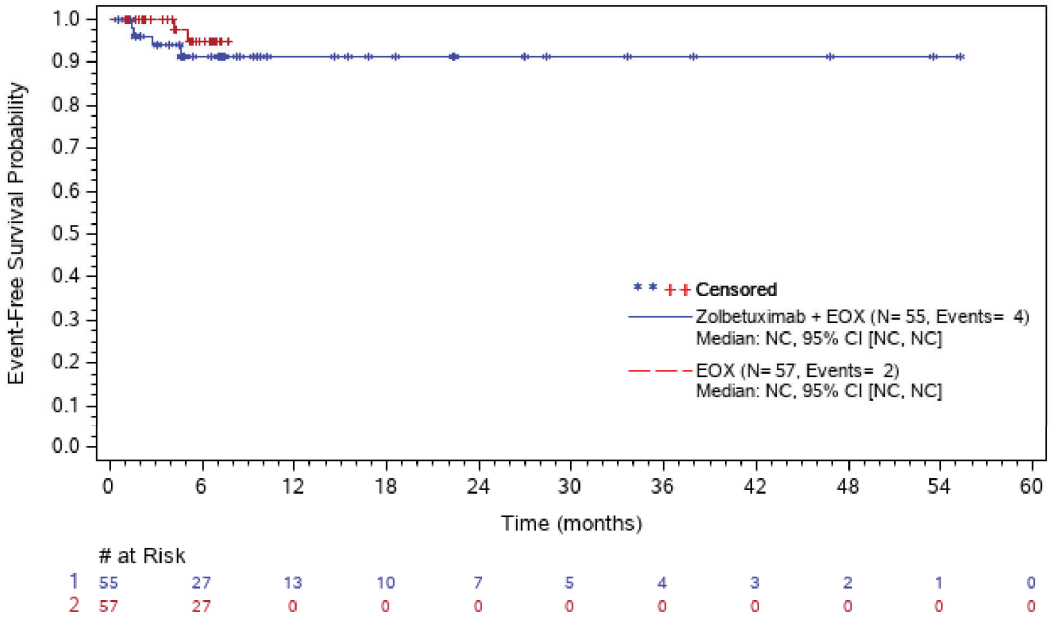
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.59: Kaplan-Meier Plot of Time to first Severe TEAE - General Disorders and Administration Site Conditions (SOC) - Safety Analysis Set



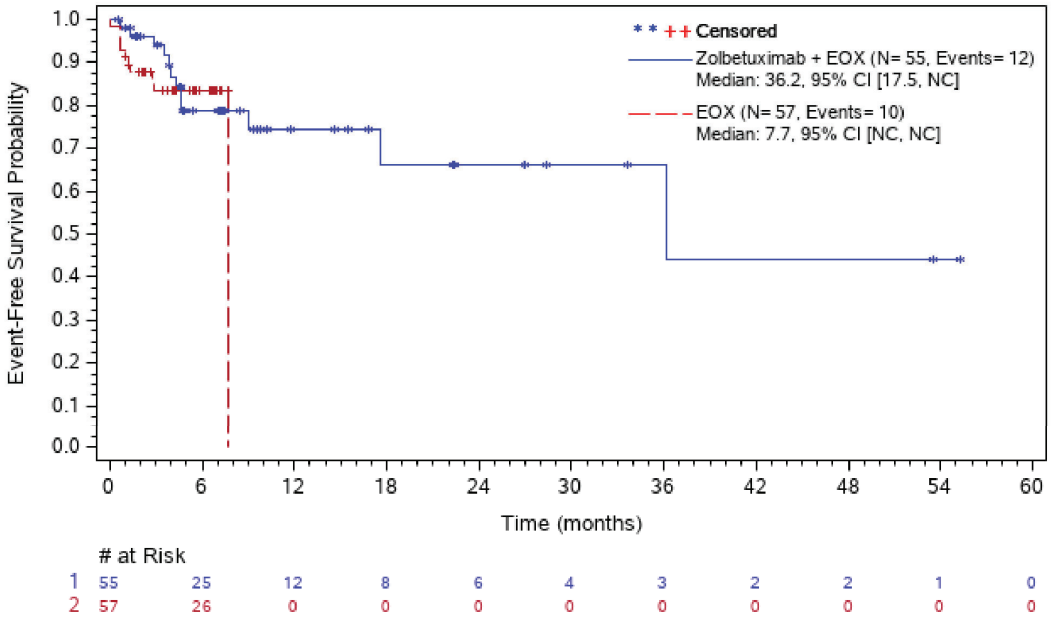
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.60: Kaplan-Meier Plot of Time to first Severe TEAE - Fatigue (PT) - Safety Analysis Set



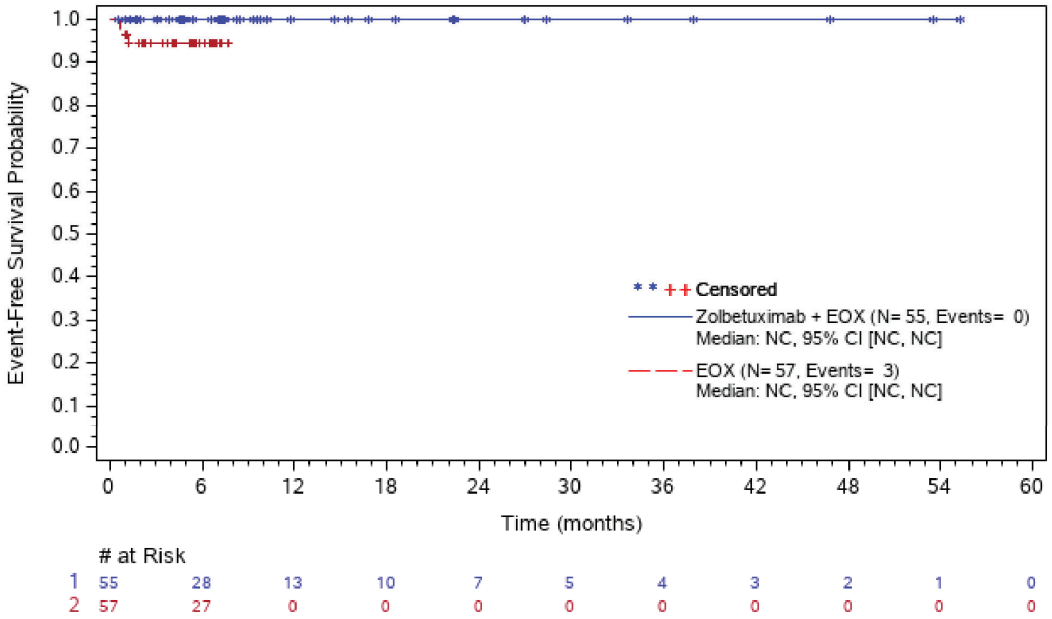
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.61: Kaplan-Meier Plot of Time to first Severe TEAE - Investigations (SOC) - Safety Analysis Set



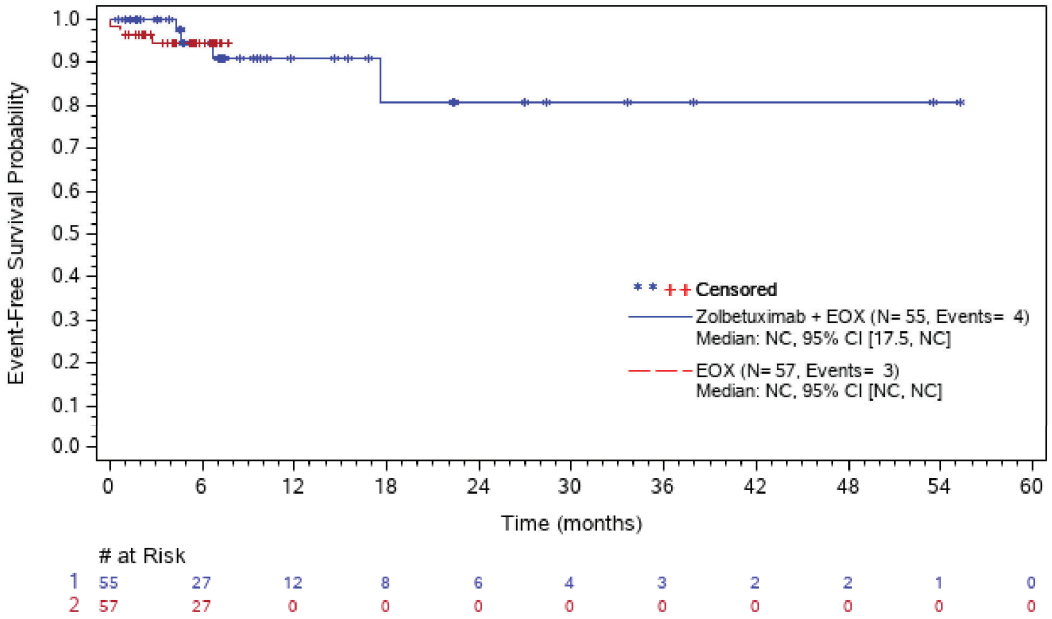
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.62: Kaplan-Meier Plot of Time to first Severe TEAE - C-Reactive Protein Increased (PT) - Safety Analysis Set



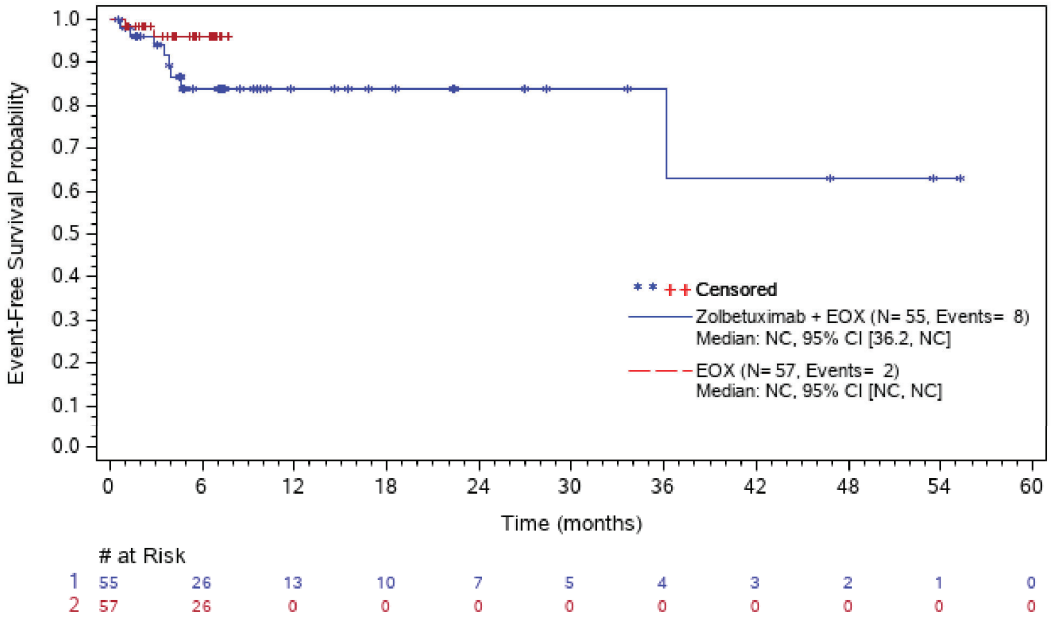
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.63: Kaplan-Meier Plot of Time to first Severe TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



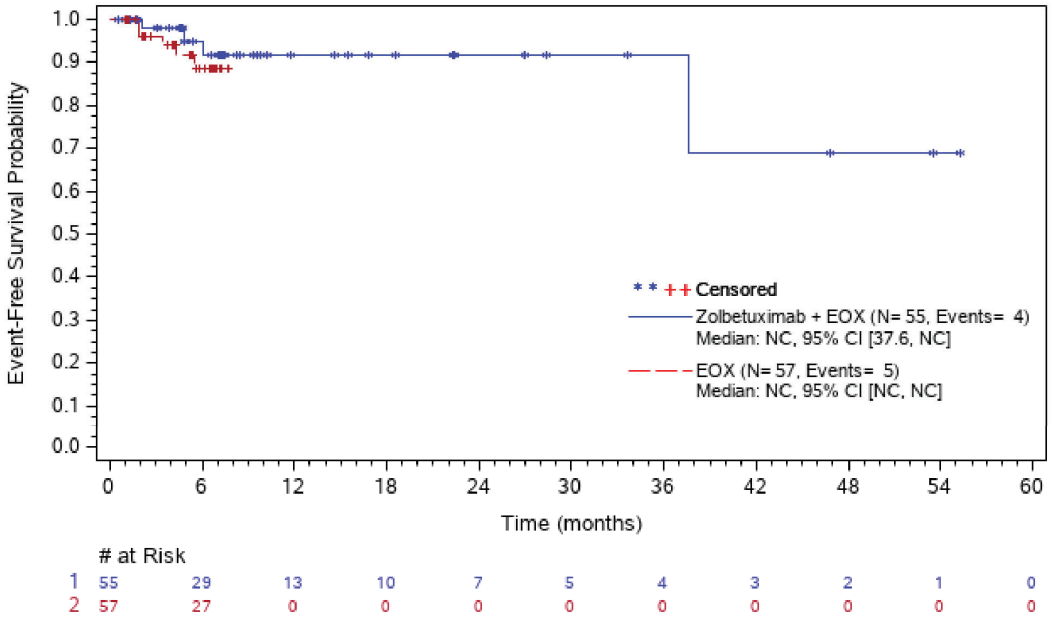
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.64: Kaplan-Meier Plot of Time to first Severe TEAE - Weight Decreased (PT) - Safety Analysis Set



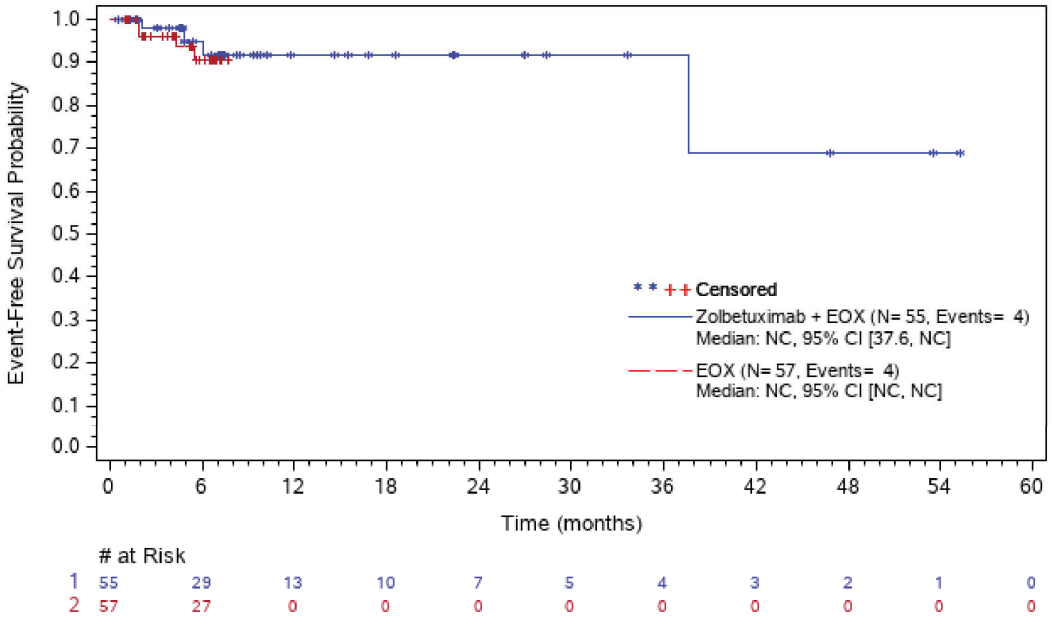
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.65: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - Safety Analysis Set



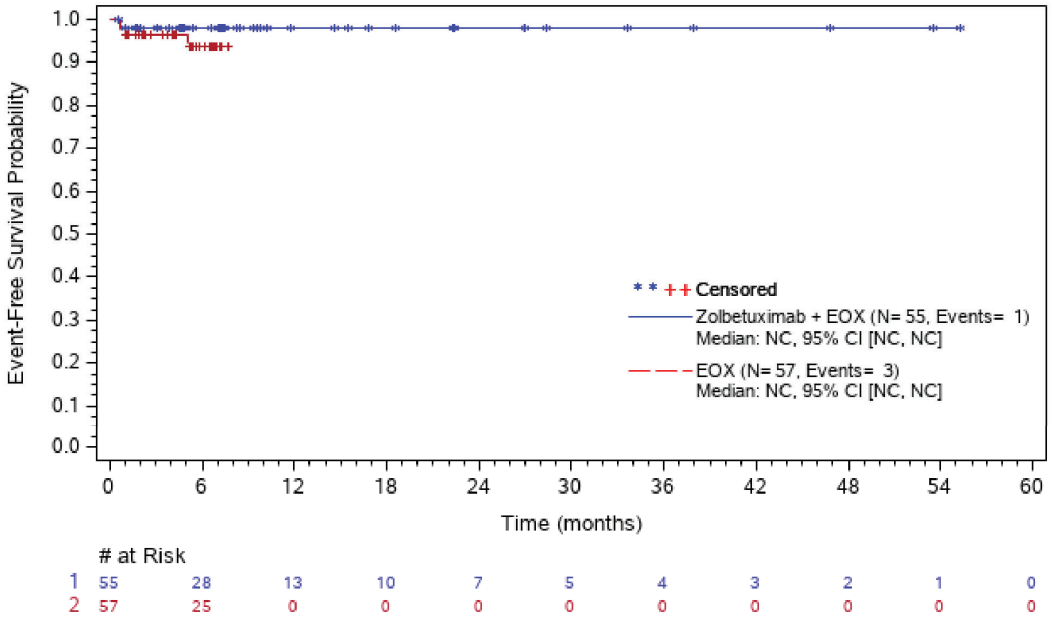
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.66: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasm Malignant (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.67: Kaplan-Meier Plot of Time to first Severe TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwerwiegende unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table GM03.1.2001.44.1: Summary and Results of TESAEs - Blood and Lymphatic System Disorders (SOC) - 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%)	1 (1.8%)	
Number of patients censored	52 (94.5%)	56 (98.2%)	
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			3.024 [0.314, 29.076]
Log-rank test			
Two-sided stratified log-rank p-value			0.3135

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.45.1: Summary and Results of TESAEs - Gastrointestinal Disorders (SOC) - 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	5 (9.1%)	5 (8.8%)	
Number of patients censored	50 (90.9%)	52 (91.2%)	
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			1.025 [0.297, 3.540]
Log-rank test			
Two-sided stratified log-rank p-value			0.9659

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.46.1: Summary and Results of TESAEs - General Disorders and Administration Site Conditions (SOC) - 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%)	1 (1.8%)	
Number of patients censored	52 (94.5%)	56 (98.2%)	
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			3.426 [0.356, 32.991]
Log-rank test			
Two-sided stratified log-rank p-value			0.2567

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.47.1: Summary and Results of TESAEs - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - 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%)	5 (8.8%)	
Number of patients censored	52 (94.5%)	52 (91.2%)	
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			0.616 [0.147, 2.588]
Log-rank test			
Two-sided stratified log-rank p-value			0.5065

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.48.1: Summary and Results of TESAEs - Neoplasm Malignant (PT)
- 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%)	4 (7.0%)	
Number of patients censored	52 (94.5%)	53 (93.0%)	
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			0.732 [0.164, 3.275]
Log-rank test			
Two-sided stratified log-rank p-value			0.6852

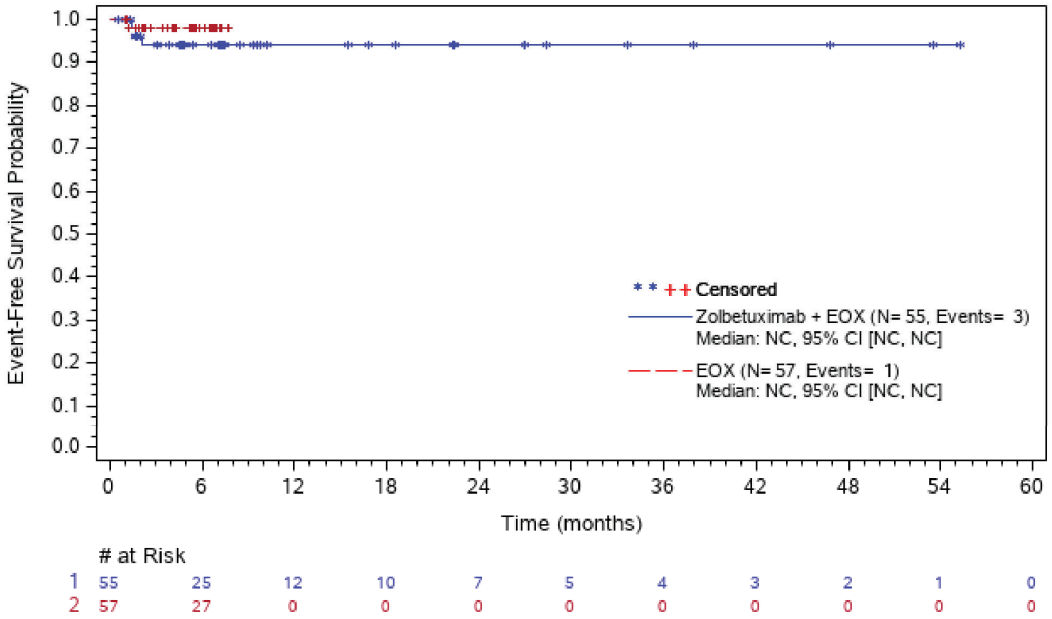
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Schwerwiegende unerwünschte Ereignisse - SOC und PT

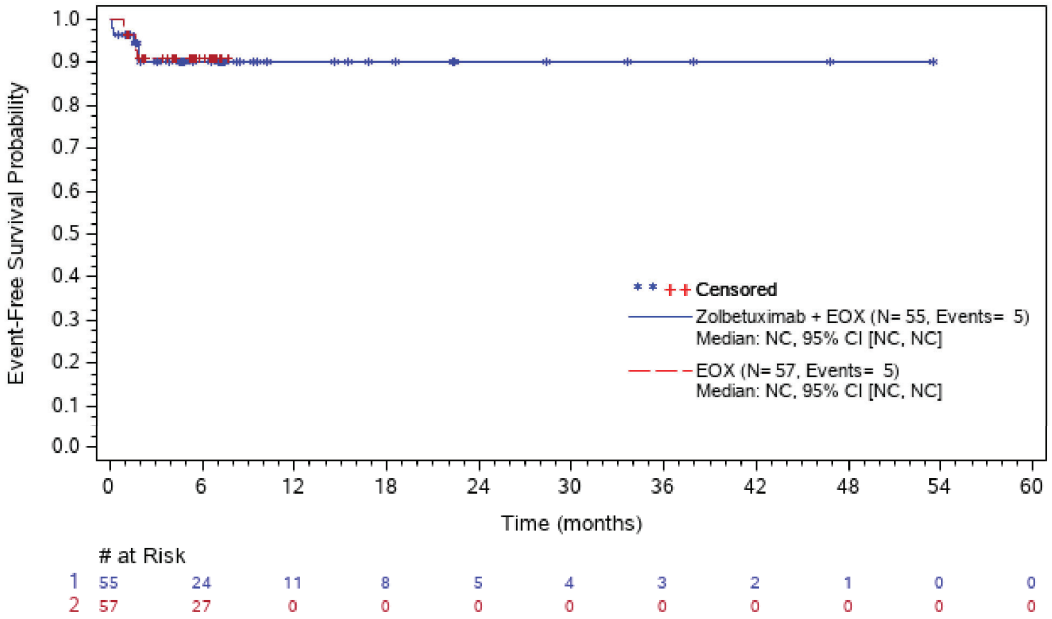
2. Kaplan-Meier-Plots

Figure GM03.1.2001.44: Kaplan-Meier Plot of Time to first TESAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



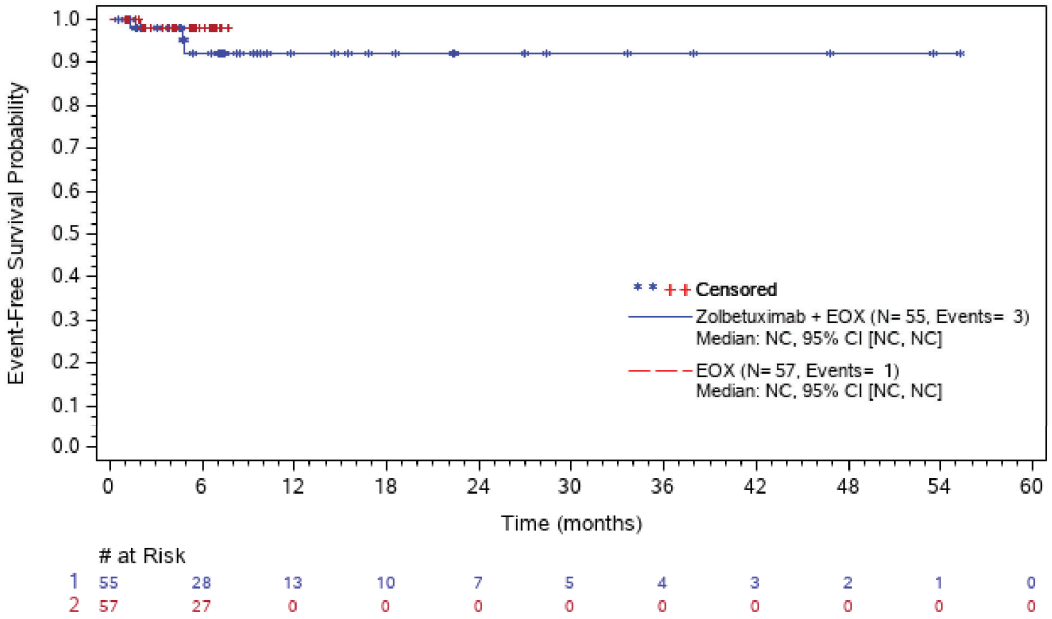
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.45: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



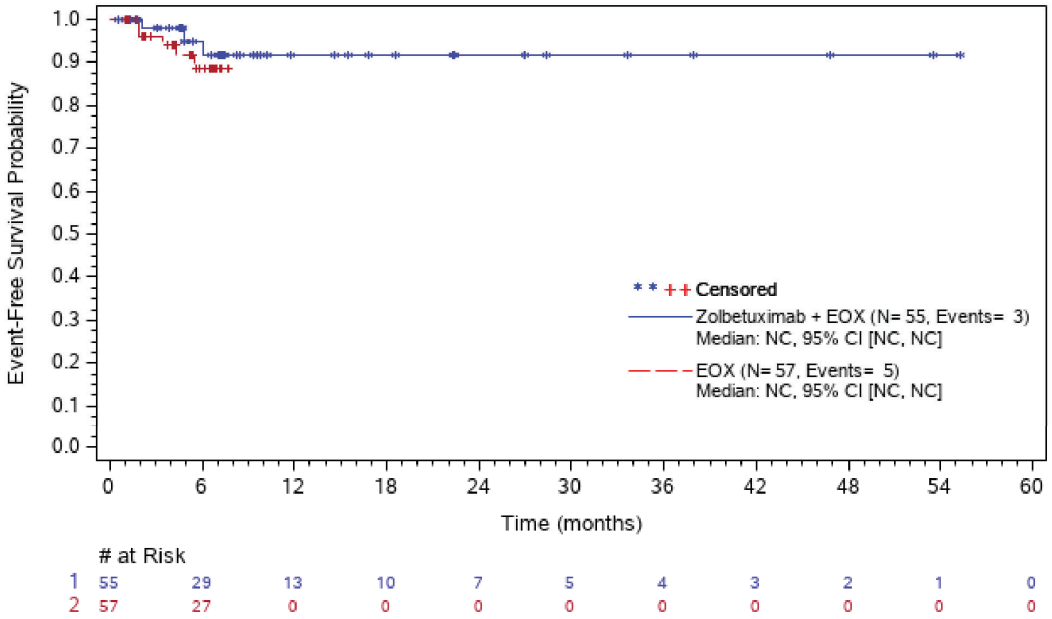
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.46: Kaplan-Meier Plot of Time to first TESAE - General Disorders and Administration Site Conditions (SOC) - Safety Analysis Set



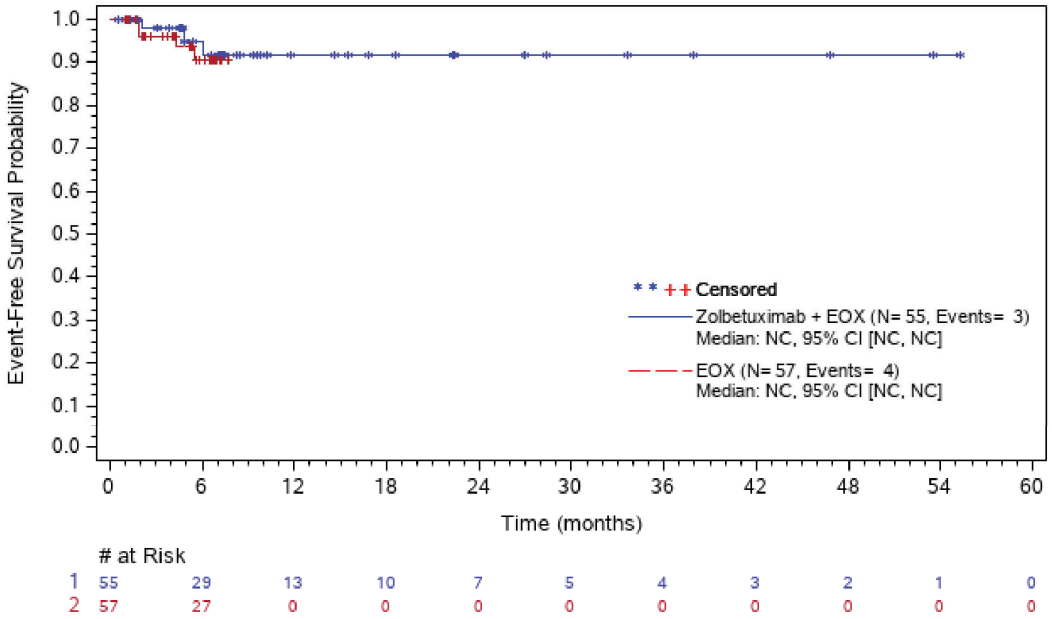
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.47: Kaplan-Meier Plot of Time to first TESAE - Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps) (SOC) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.48: Kaplan-Meier Plot of Time to first TESAE - Neoplasm Malignant (PT) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Abbruchgründe - SOC und PT

Table GM03.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Overall	11 (20.0%)	11 (19.3%)	22 (19.6%)
Gastrointestinal Disorders	2 (3.6%)	7 (12.3%)	9 (8.0%)
Vomiting	2 (3.6%)	2 (3.5%)	4 (3.6%)
Gastric Haemorrhage	0	2 (3.5%)	2 (1.8%)
Abdominal Pain	1 (1.8%)	0	1 (0.9%)
Diarrhoea	0	1 (1.8%)	1 (0.9%)
Ileus	0	1 (1.8%)	1 (0.9%)
Intestinal Fistula	0	1 (1.8%)	1 (0.9%)
Nausea	1 (1.8%)	0	1 (0.9%)
Obstruction Gastric	0	1 (1.8%)	1 (0.9%)
General Disorders And Administration Site Conditions	4 (7.3%)	1 (1.8%)	5 (4.5%)
Asthenia	2 (3.6%)	0	2 (1.8%)
Fatigue	1 (1.8%)	0	1 (0.9%)
General Physical Health Deterioration	0	1 (1.8%)	1 (0.9%)
Multi-Organ Failure	1 (1.8%)	0	1 (0.9%)
Investigations	4 (7.3%)	0	4 (3.6%)
Weight Decreased	2 (3.6%)	0	2 (1.8%)
Alanine Aminotransferase Increased	1 (1.8%)	0	1 (0.9%)
Aspartate Aminotransferase Increased	1 (1.8%)	0	1 (0.9%)
Blood Alkaline Phosphatase Increased	1 (1.8%)	0	1 (0.9%)
Ejection Fraction Decreased	1 (1.8%)	0	1 (0.9%)
Gamma-Glutamyltransferase Increased	1 (1.8%)	0	1 (0.9%)
Blood And Lymphatic System Disorders	1 (1.8%)	1 (1.8%)	2 (1.8%)
Neutropenia	1 (1.8%)	1 (1.8%)	2 (1.8%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: descending by the number of subjects in total group by system organ class and preferred term.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Anaemia	1 (1.8%)	0	1 (0.9%)
Thrombocytopenia	1 (1.8%)	0	1 (0.9%)
Hepatobiliary Disorders	0	2 (3.5%)	2 (1.8%)
Hyperbilirubinaemia	0	1 (1.8%)	1 (0.9%)
Jaundice Cholestatic	0	1 (1.8%)	1 (0.9%)
Infections And Infestations	0	1 (1.8%)	1 (0.9%)
Peritonitis	0	1 (1.8%)	1 (0.9%)
Injury, Poisoning And Procedural Complications	1 (1.8%)	0	1 (0.9%)
Infusion Related Reaction	1 (1.8%)	0	1 (0.9%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	1 (1.8%)	0	1 (0.9%)
Neoplasm Malignant	1 (1.8%)	0	1 (0.9%)
Nervous System Disorders	1 (1.8%)	0	1 (0.9%)
Cerebrovascular Accident	1 (1.8%)	0	1 (0.9%)
Renal And Urinary Disorders	0	1 (1.8%)	1 (0.9%)
Renal Failure	0	1 (1.8%)	1 (0.9%)
Respiratory, Thoracic And Mediastinal Disorders	0	1 (1.8%)	1 (0.9%)
Pulmonary Artery Thrombosis	0	1 (1.8%)	1 (0.9%)
Skin And Subcutaneous Tissue Disorders	1 (1.8%)	0	1 (0.9%)
Erythema	1 (1.8%)	0	1 (0.9%)
Vascular Disorders	1 (1.8%)	0	1 (0.9%)
Vena Cava Thrombosis	1 (1.8%)	0	1 (0.9%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: descending by the number of subjects in total group by system organ class and preferred term.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse von besonderem Interesse

1. Time-to-Event-Analysen

Table GM03.1.2001.68.1: Summary and Results of TEAEs - Hypersensitivity Reactions (AESI) - 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	7 (12.7%)	8 (14.0%)	
Number of patients censored	48 (87.3%)	49 (86.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [17.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.784 [0.272, 2.262]
Log-rank test			
Two-sided stratified log-rank p-value			0.6431

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.68.2: Summary and Results of TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	6 (13.6)	NC [17.1, NC]	48	7 (14.6)	NC [NC, NC]	0.807 [0.256, 2.542]	0.6951	0.8499
>65 years	11	1 (9.1)	NC [NC, NC]	9	1 (11.1)	NC [2.8, NC]	0.798 [0.050, 12.756]	0.8728	
Sex									
Male	31	4 (12.9)		36	5 (13.9)				
Female	24	3 (12.5)		21	3 (14.3)				
Number of Organs with Metastatic Sites									
0-2	17	1 (5.9)	NC [NC, NC]	17	2 (11.8)	NC [NC, NC]	0.512 [0.046, 5.654]	0.5776	0.6157
>=3	38	6 (15.8)	NC [17.1, NC]	40	6 (15.0)	NC [NC, NC]	0.904 [0.276, 2.964]	0.8468	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.69.1: Summary and Results of TEAEs - Infusion Related Reaction (AESI) - 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	31 (56.4%)	27 (47.4%)	
Number of patients censored	24 (43.6%)	30 (52.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.0 [1.0, NC]	5.1 [2.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.256 [0.745, 2.116]
Log-rank test			
Two-sided stratified log-rank p-value			0.3965

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; or 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.69.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	26 (59.1)	3.0 [0.8, NC]	48	24 (50.0)	4.9 [1.4, NC]	1.253 [0.715, 2.197]	0.4338	0.8564
>65 years	11	5 (45.5)	NC [0.6, NC]	9	3 (33.3)	NC [0.7, NC]	1.575 [0.376, 6.602]	0.5278	
Sex									
Male	31	15 (48.4)	7.4 [1.0, NC]	36	14 (38.9)	NC [2.1, NC]	1.243 [0.592, 2.609]	0.5621	0.8946
Female	24	16 (66.7)	2.1 [0.0, 3.3]	21	13 (61.9)	2.8 [0.8, NC]	1.228 [0.588, 2.564]	0.5983	
Number of Organs with Metastatic Sites									
0-2	17	11 (64.7)	1.4 [0.1, NC]	17	7 (41.2)	NC [0.7, NC]	2.024 [0.775, 5.286]	0.1339	0.2300
>=3	38	20 (52.6)	3.3 [1.4, NC]	40	20 (50.0)	4.9 [1.4, NC]	1.019 [0.543, 1.913]	0.9797	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.70.1: Summary and Results of TEAEs - Nausea (AESI)
- 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	46 (83.6%)	44 (77.2%)	
Number of patients censored	9 (16.4%)	13 (22.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	0.1 [0.1, 0.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.364 [0.898, 2.074]
Log-rank test			
Two-sided stratified log-rank p-value			0.1934

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.70.2: Summary and Results of TEAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	38 (86.4)	0.0 [0.0, 0.1]	48	35 (72.9)	0.1 [0.1, 0.7]	1.702 [1.067, 2.715]	0.0353	0.0450
>65 years	11	8 (72.7)	0.2 [0.0, NC]	9	9 (100.0)	0.1 [0.0, 0.2]	0.437 [0.160, 1.194]	0.0826	
Sex									
Male	31	25 (80.6)	0.1 [0.0, 0.2]	36	26 (72.2)	0.1 [0.1, 0.7]	1.297 [0.745, 2.257]	0.3262	0.9556
Female	24	21 (87.5)	0.0 [NC, NC]	21	18 (85.7)	0.1 [0.0, 0.2]	1.490 [0.778, 2.855]	0.4267	
Number of Organs with Metastatic Sites									
0-2	17	14 (82.4)	0.1 [0.0, 0.7]	17	13 (76.5)	0.1 [0.0, 0.7]	1.228 [0.571, 2.639]	0.5669	0.9245
>=3	38	32 (84.2)	0.0 [0.0, 0.1]	40	31 (77.5)	0.1 [0.1, 0.7]	1.397 [0.848, 2.300]	0.2531	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.71.1: Summary and Results of TEAEs - Vomiting (AESI)
- 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	42 (76.4%)	34 (59.6%)	
Number of patients censored	13 (23.6%)	23 (40.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.7]	1.7 [0.7, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.861 [1.173, 2.952]
Log-rank test			
Two-sided stratified log-rank p-value			0.0169

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.71.2: Summary and Results of TEAEs by Subgroups - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	35 (79.5)	0.0 [0.0, 0.7]	48	28 (58.3)	2.2 [0.7, 8.1]	1.978 [1.197, 3.270]	0.0139	0.3884
>65 years	11	7 (63.6)	0.0 [0.0, NC]	9	6 (66.7)	0.8 [0.0, NC]	1.353 [0.451, 4.062]	0.7356	
Sex									
Male	31	23 (74.2)	0.7 [0.0, 2.1]	36	21 (58.3)	1.5 [0.6, NC]	1.607 [0.888, 2.909]	0.1525	0.6177
Female	24	19 (79.2)	0.0 [0.0, 0.2]	21	13 (61.9)	1.7 [0.1, 8.1]	2.186 [1.062, 4.498]	0.0627	
Number of Organs with Metastatic Sites									
0-2	17	13 (76.5)	0.0 [0.0, 1.7]	17	9 (52.9)	1.2 [0.0, NC]	2.160 [0.912, 5.118]	0.0987	0.5697
>=3	38	29 (76.3)	0.1 [0.0, 0.8]	40	25 (62.5)	1.7 [0.6, 8.1]	1.639 [0.954, 2.815]	0.1206	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.72.1: Summary and Results of Non-Severe TEAEs - Hypersensitivity Reactions (AESI) - 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	7 (12.7%)	8 (14.0%)	
Number of patients censored	48 (87.3%)	49 (86.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [17.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.784 [0.272, 2.262]
Log-rank test			
Two-sided stratified log-rank p-value			0.6431

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.72.2: Summary and Results of Non-Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	6 (13.6)	NC [17.1, NC]	48	7 (14.6)	NC [NC, NC]	0.807 [0.256, 2.542]	0.6951	0.8499
>65 years	11	1 (9.1)	NC [NC, NC]	9	1 (11.1)	NC [2.8, NC]	0.798 [0.050, 12.756]	0.8728	
Sex									
Male	31	4 (12.9)		36	5 (13.9)				
Female	24	3 (12.5)		21	3 (14.3)				
Number of Organs with Metastatic Sites									
0-2	17	1 (5.9)	NC [NC, NC]	17	2 (11.8)	NC [NC, NC]	0.512 [0.046, 5.654]	0.5776	0.6157
>=3	38	6 (15.8)	NC [17.1, NC]	40	6 (15.0)	NC [NC, NC]	0.904 [0.276, 2.964]	0.8468	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.73.1: Summary and Results of Non-Severe TEAEs - Infusion Related Reaction (AESI) - 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	31 (56.4%)	27 (47.4%)	
Number of patients censored	24 (43.6%)	30 (52.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.0 [1.0, NC]	5.1 [2.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.249 [0.741, 2.105]
Log-rank test			
Two-sided stratified log-rank p-value			0.4039

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.73.2: Summary and Results of Non-Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	26 (59.1)	3.0 [0.8, NC]	48	24 (50.0)	4.9 [1.4, NC]	1.245 [0.710, 2.182]	0.4397	0.8493
>65 years	11	5 (45.5)	NC [0.6, NC]	9	3 (33.3)	NC [0.7, NC]	1.575 [0.376, 6.602]	0.5278	
Sex									
Male	31	15 (48.4)	7.4 [1.0, NC]	36	14 (38.9)	NC [2.1, NC]	1.231 [0.586, 2.584]	0.5809	0.9090
Female	24	16 (66.7)	2.1 [0.0, 3.3]	21	13 (61.9)	2.8 [0.8, NC]	1.228 [0.588, 2.564]	0.5983	
Number of Organs with Metastatic Sites									
0-2	17	11 (64.7)	1.4 [0.1, NC]	17	7 (41.2)	NC [0.7, NC]	2.024 [0.775, 5.286]	0.1339	0.2261
>=3	38	20 (52.6)	3.3 [1.4, NC]	40	20 (50.0)	4.9 [1.4, NC]	1.012 [0.539, 1.899]	0.9865	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.74.1: Summary and Results of Non-Severe TEAEs - Nausea (AESI)
- 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	45 (81.8%)	44 (77.2%)	
Number of patients censored	10 (18.2%)	13 (22.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	0.1 [0.1, 0.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.284 [0.844, 1.955]
Log-rank test			
Two-sided stratified log-rank p-value			0.3104

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.74.2: Summary and Results of Non-Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	37 (84.1)	0.0 [0.0, 0.1]	48	35 (72.9)	0.1 [0.1, 0.7]	1.597 [0.999, 2.552]	0.0673	0.0492
>65 years	11	8 (72.7)	0.2 [0.0, NC]	9	9 (100.0)	0.1 [0.0, 0.2]	0.369 [0.128, 1.062]	0.0469	
Sex									
Male	31	25 (80.6)	0.1 [0.0, 0.7]	36	26 (72.2)	0.1 [0.1, 0.7]	1.279 [0.735, 2.225]	0.3491	0.7913
Female	24	20 (83.3)	0.0 [NC, NC]	21	18 (85.7)	0.1 [0.0, 0.2]	1.304 [0.678, 2.508]	0.6840	
Number of Organs with Metastatic Sites									
0-2	17	14 (82.4)	0.1 [0.0, 1.4]	17	13 (76.5)	0.1 [0.0, 0.7]	1.171 [0.545, 2.515]	0.6656	0.9756
>=3	38	31 (81.6)	0.0 [0.0, 0.1]	40	31 (77.5)	0.1 [0.1, 0.7]	1.299 [0.786, 2.146]	0.3900	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.75.1: Summary and Results of Non-Severe TEAEs - Vomiting (AESI)
- 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	41 (74.5%)	34 (59.6%)	
Number of patients censored	14 (25.5%)	23 (40.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.7]	1.7 [0.7, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.763 [1.110, 2.800]
Log-rank test			
Two-sided stratified log-rank p-value			0.0306

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.75.2: Summary and Results of Non-Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	34 (77.3)	0.1 [0.0, 0.8]	48	28 (58.3)	2.2 [0.7, 8.1]	1.875 [1.131, 3.109]	0.0248	0.4288
>65 years	11	7 (63.6)	0.0 [0.0, NC]	9	6 (66.7)	0.8 [0.0, NC]	1.353 [0.451, 4.062]	0.7356	
Sex									
Male	31	23 (74.2)	0.7 [0.0, 2.1]	36	21 (58.3)	1.5 [0.6, NC]	1.607 [0.888, 2.909]	0.1525	0.7597
Female	24	18 (75.0)	0.0 [0.0, 0.2]	21	13 (61.9)	1.7 [0.1, 8.1]	1.943 [0.939, 4.021]	0.1245	
Number of Organs with Metastatic Sites									
0-2	17	13 (76.5)	0.0 [0.0, 1.7]	17	9 (52.9)	1.2 [0.0, NC]	2.160 [0.912, 5.118]	0.0987	0.5002
>=3	38	28 (73.7)	0.2 [0.0, 0.9]	40	25 (62.5)	1.7 [0.6, 8.1]	1.536 [0.891, 2.648]	0.1860	

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.76.1: Summary and Results of Severe TEAEs - Hypersensitivity Reactions (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.76.2: Summary and Results of Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.77.1: Summary and Results of Severe TEAEs - Infusion Related Reaction (AESI) - 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%)	1 (1.8%)	
Number of patients censored	54 (98.2%)	56 (98.2%)	
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			1.048 [0.066, 16.757]
Log-rank test			
Two-sided stratified log-rank p-value			0.9736

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.77.2: Summary and Results of Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	1 (2.3)		48	1 (2.1)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	1 (3.2)		36	1 (2.8)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	1 (5.9)				
>=3	38	1 (2.6)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.78.1: Summary and Results of Severe TEAEs - Nausea (AESI)
- 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			1.396 [0.312, 6.238]
Log-rank test			
Two-sided stratified log-rank p-value			0.6608

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.78.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	3 (6.8)		48	2 (4.2)				
>65 years	11	1 (9.1)		9	1 (11.1)				
Sex									
Male	31	1 (3.2)		36	1 (2.8)				
Female	24	3 (12.5)		21	2 (9.5)				
Number of Organs with Metastatic Sites									
0-2	17	1 (5.9)		17	0 (0.0)				
>=3	38	3 (7.9)		40	3 (7.5)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.79.1: Summary and Results of Severe TEAEs - Vomiting (AESI)
- 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	6 (10.9%)	2 (3.5%)	
Number of patients censored	49 (89.1%)	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			3.225 [0.650, 16.013]
Log-rank test			
Two-sided stratified log-rank p-value			0.1298

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.79.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	5 (11.4)		48	0 (0.0)				
>65 years	11	1 (9.1)		9	2 (22.2)				
Sex									
Male	31	1 (3.2)		36	1 (2.8)				
Female	24	5 (20.8)		21	1 (4.8)				
Number of Organs with Metastatic Sites									
0-2	17	2 (11.8)		17	1 (5.9)				
>=3	38	4 (10.5)		40	1 (2.5)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.80.1: Summary and Results of TESAEs - Hypersensitivity Reactions (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.80.2: Summary and Results of TESAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.81.1: Summary and Results of TESAEs - Infusion Related Reaction (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.81.2: Summary and Results of TESAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.82.1: Summary and Results of TESAEs - Nausea (AESI)
- 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%)	1 (1.8%)	
Number of patients censored	54 (98.2%)	56 (98.2%)	
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			1.024 [0.064, 16.373]
Log-rank test			
Two-sided stratified log-rank p-value			0.9865

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.82.2: Summary and Results of TESAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	1 (9.1)		9	1 (11.1)				
Sex									
Male	31	1 (3.2)		36	0 (0.0)				
Female	24	0 (0.0)		21	1 (4.8)				
Number of Organs with Metastatic Sites									
0-2	17	1 (5.9)		17	0 (0.0)				
>=3	38	0 (0.0)		40	1 (2.5)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.83.1: Summary and Results of TESAEs - Vomiting (AESI)
- 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			0.2980

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.83.2: Summary and Results of TESAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	1 (9.1)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	1 (4.2)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	1 (5.9)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.84.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - 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			0.2980

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.84.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	1 (2.3)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	1 (4.2)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	1 (2.6)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.85.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - 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%)	0 (0.0%)	
Number of patients censored	53 (96.4%)	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			0.1467

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.85.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	2 (4.5)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	1 (3.2)		36	0 (0.0)				
Female	24	1 (4.2)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	2 (5.3)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.86.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Nausea (AESI) - 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			0.2980

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.86.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	1 (2.3)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	1 (4.2)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	1 (2.6)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.87.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Vomiting (AESI) - 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			1.007 [0.141, 7.171]
Log-rank test			
Two-sided stratified log-rank p-value			0.9944

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.87.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	N	n (%)	KME [95% CI][a]	N	n (%)	KME [95% CI][a]	HR [95% CI][b]	Log-rank p-value[c]	Test for Interaction p-value[d]
Age Group 1									
<=65 years	44	2 (4.5)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	2 (22.2)				
Sex									
Male	31	0 (0.0)		36	1 (2.8)				
Female	24	2 (8.3)		21	1 (4.8)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	1 (5.9)				
>=3	38	2 (5.3)		40	1 (2.5)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.96.1: Summary and Results of TEAEs leading to Death - Hypersensitivity Reactions (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.96.2: Summary and Results of TEAEs leading to Death by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.97.1: Summary and Results of TEAEs leading to Death - Infusion Related Reaction (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.97.2: Summary and Results of TEAEs leading to Death by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.98.1: Summary and Results of TEAEs leading to Death - Nausea (AESI)
- 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.98.2: Summary and Results of TEAEs leading to Death by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.99.1: Summary and Results of TEAEs leading to Death - Vomiting (AESI) - 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: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event .
Note: The stratification factors are CLDN18.2 positivity (>=70% tumor cells stained vs. <70% tumor cells stained) and presence of disease at baseline (non-measurable vs. measurable).
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.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2001.99.2: Summary and Results of TEAEs leading to Death by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + EOX			EOX			Zolbetuximab + EOX vs. EOX		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	44	0 (0.0)		48	0 (0.0)				
>65 years	11	0 (0.0)		9	0 (0.0)				
Sex									
Male	31	0 (0.0)		36	0 (0.0)				
Female	24	0 (0.0)		21	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	17	0 (0.0)		17	0 (0.0)				
>=3	38	0 (0.0)		40	0 (0.0)				

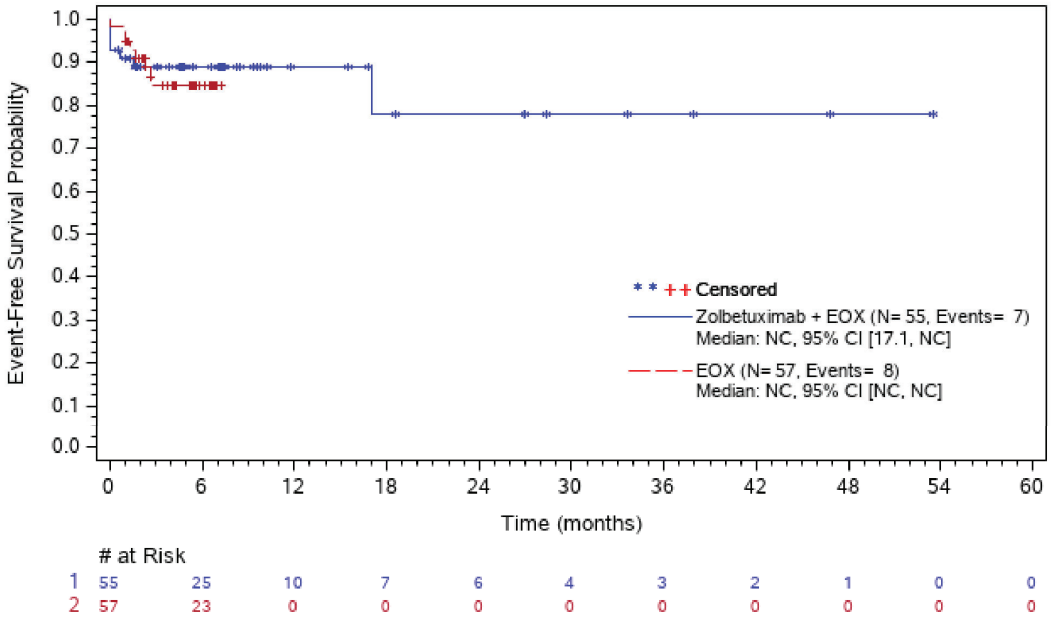
Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
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, [b] Calculated from Cox proportional hazards model and [c] Two-sided unstratified log-rank p-value [d]Two-sided Type 3 Wald test p-value from Cox proportional hazards model including treatment, subgroup, and treatment x subgroup interaction.
SOCs and PTs are reported only if events are either 1) occurring in at least 5% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and occurring in at least 1% of subjects in at least one treatment group.
Subgroup analyses are performed only when the following conditions are fulfilled 1) at least 10 subjects in each subgroup factor/level, and 2) at least 10 subjects with events occurred in at least one of the subgroup factors/levels. Only SOCs and PTs with significant treatment effect (p-value <0.05) in the overall safety analysis set are presented.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Sicherheit

Anhang 4-G2 Unerwünschte Ereignisse von besonderem Interesse

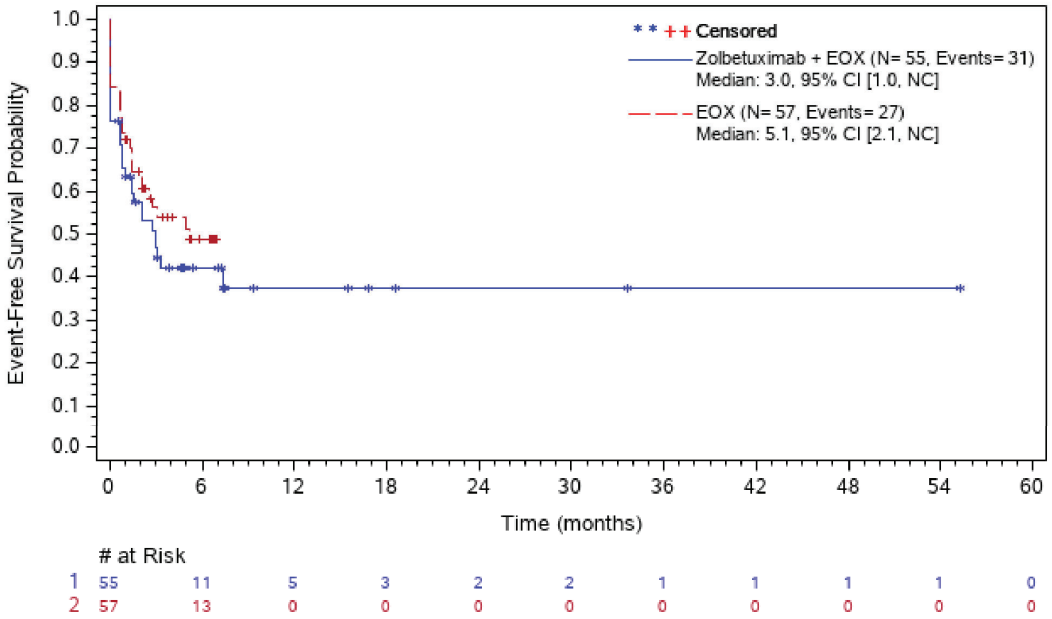
2. Kaplan-Meier-Plots

Figure GM03.1.2001.68: Kaplan-Meier Plot of Time to first TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



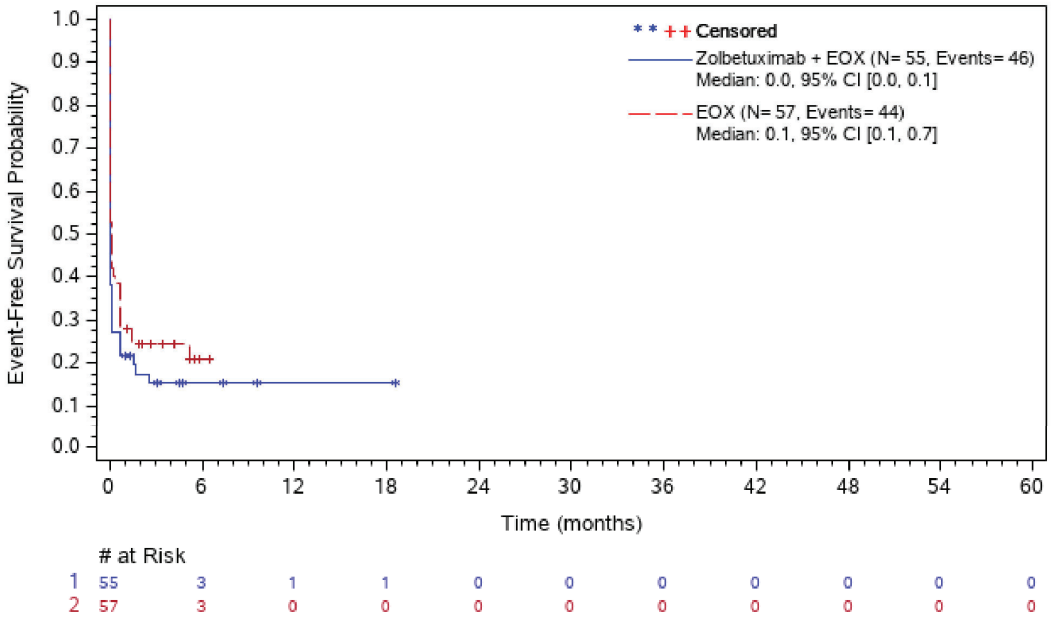
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.69: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



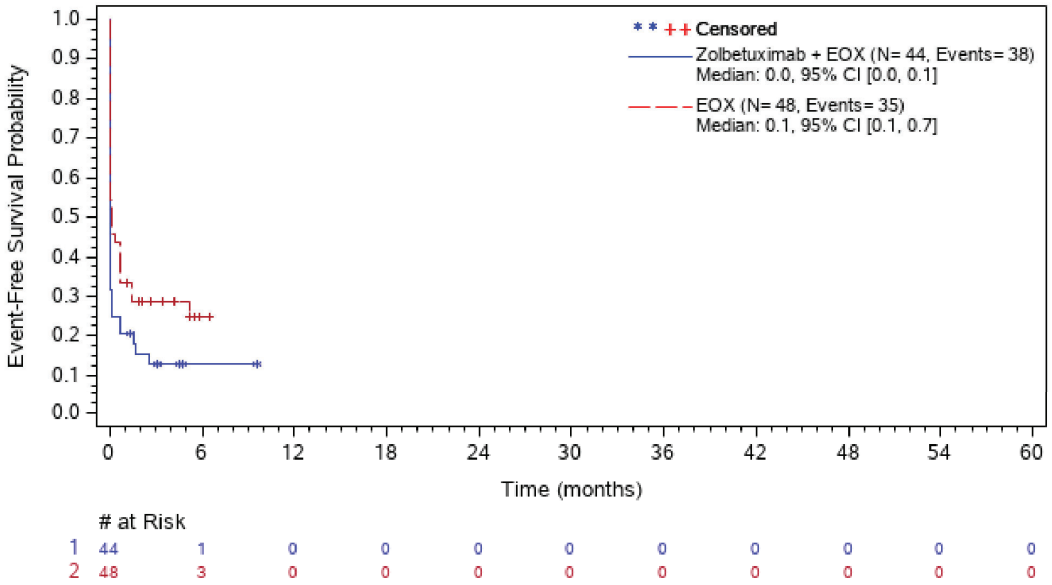
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.70: Kaplan-Meier Plot of Time to first TEAE - Nausea (AESI) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

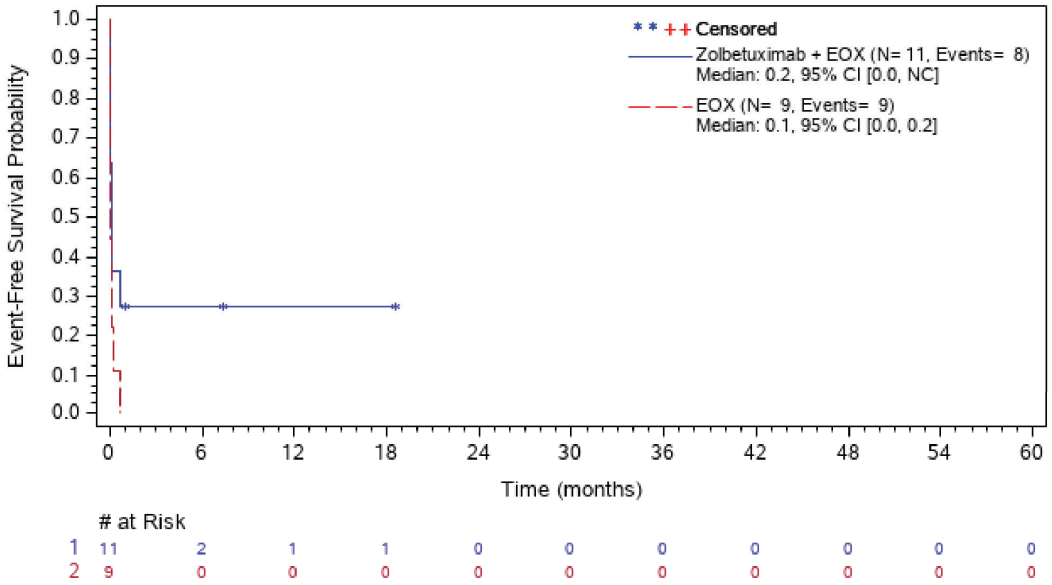
Figure GM03.1.2001.70.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set
Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

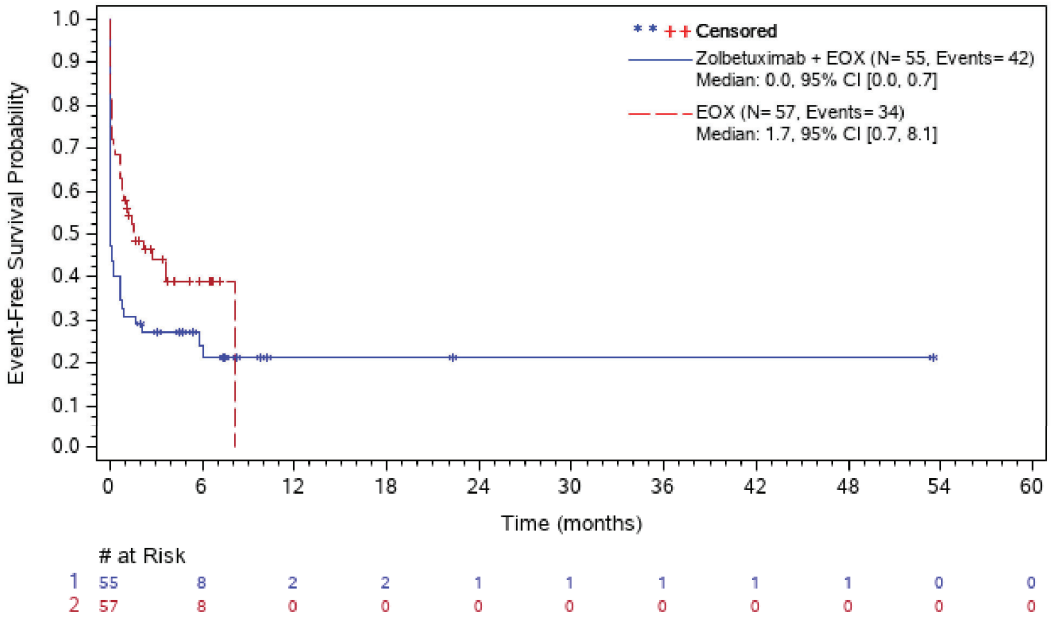
Figure GM03.1.2001.70.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set

Age Group 1: >65 years



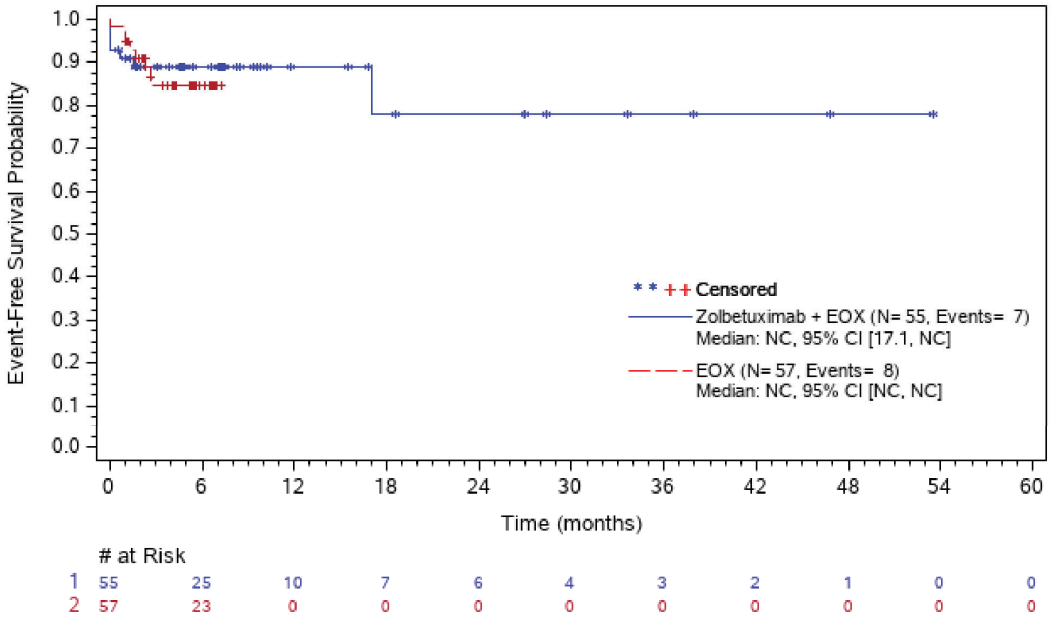
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.71: Kaplan-Meier Plot of Time to first TEAE - Vomiting (AESI) - Safety Analysis Set



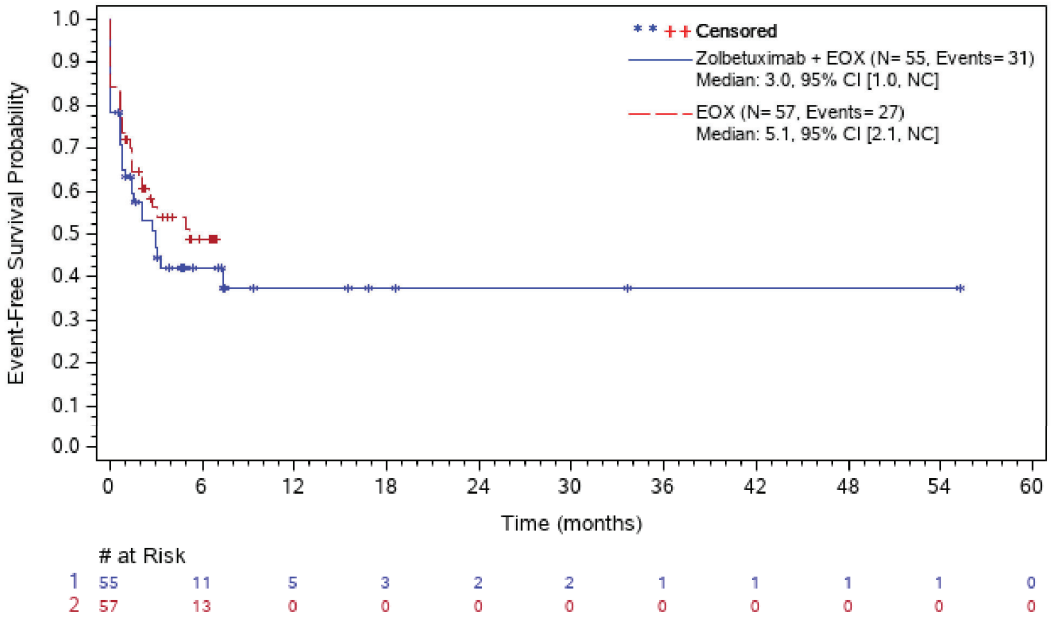
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.72: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



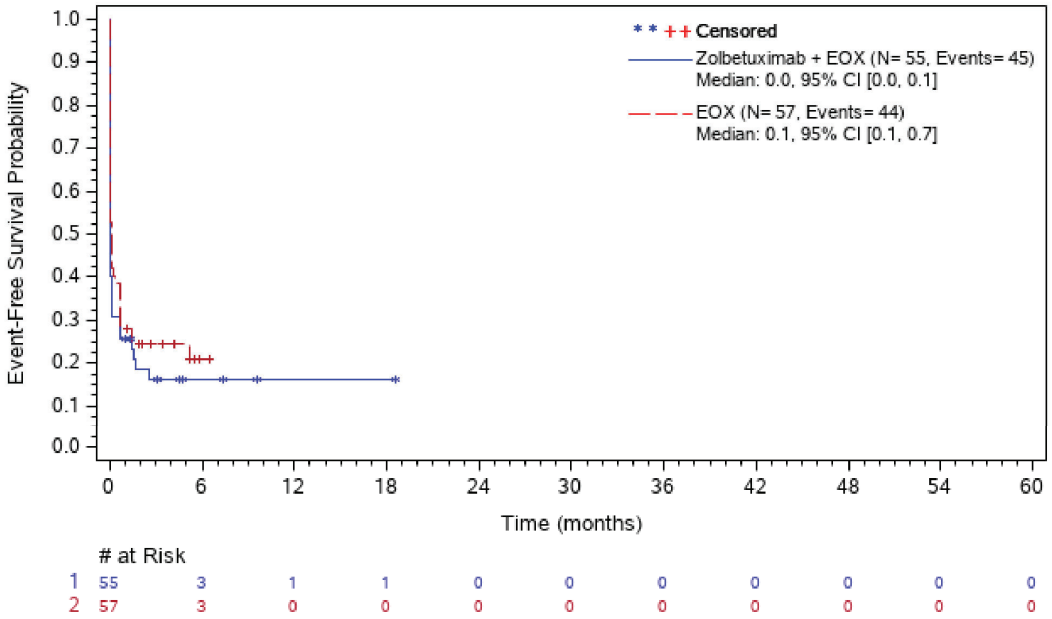
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.73: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



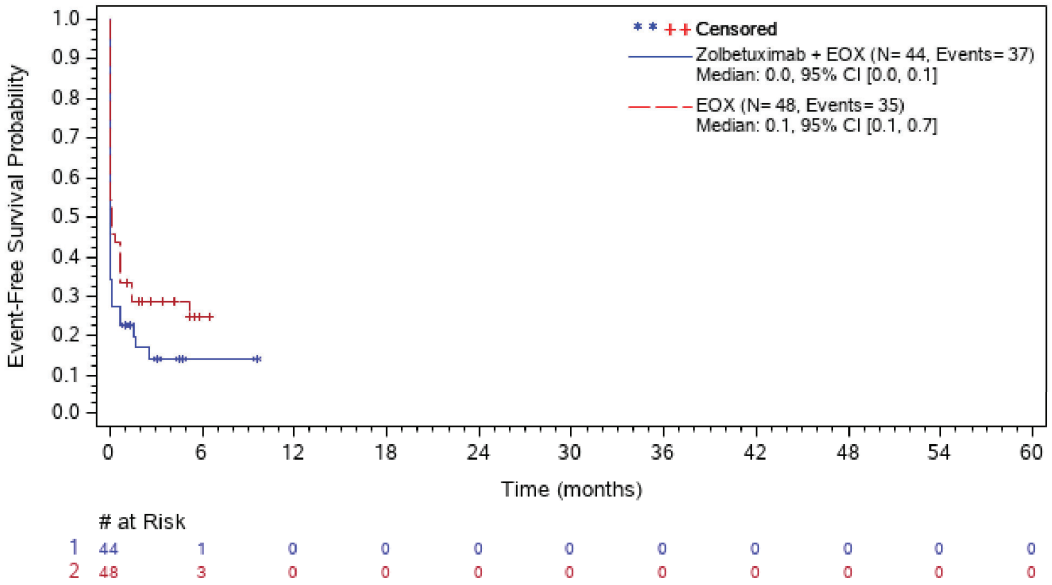
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.74: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Nausea (AESI) - Safety Analysis Set



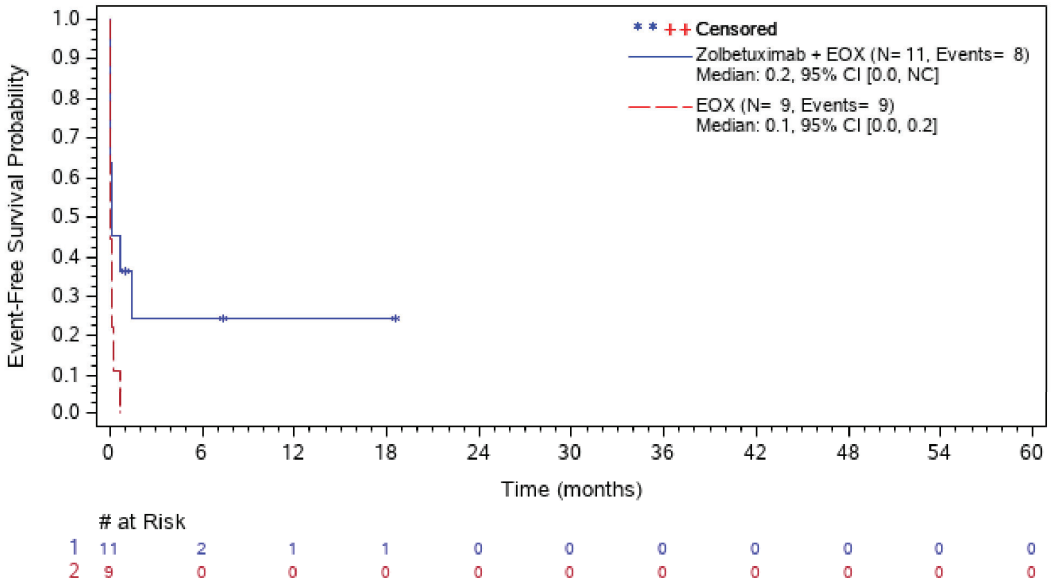
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.74.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set
Age Group 1: <=65 years



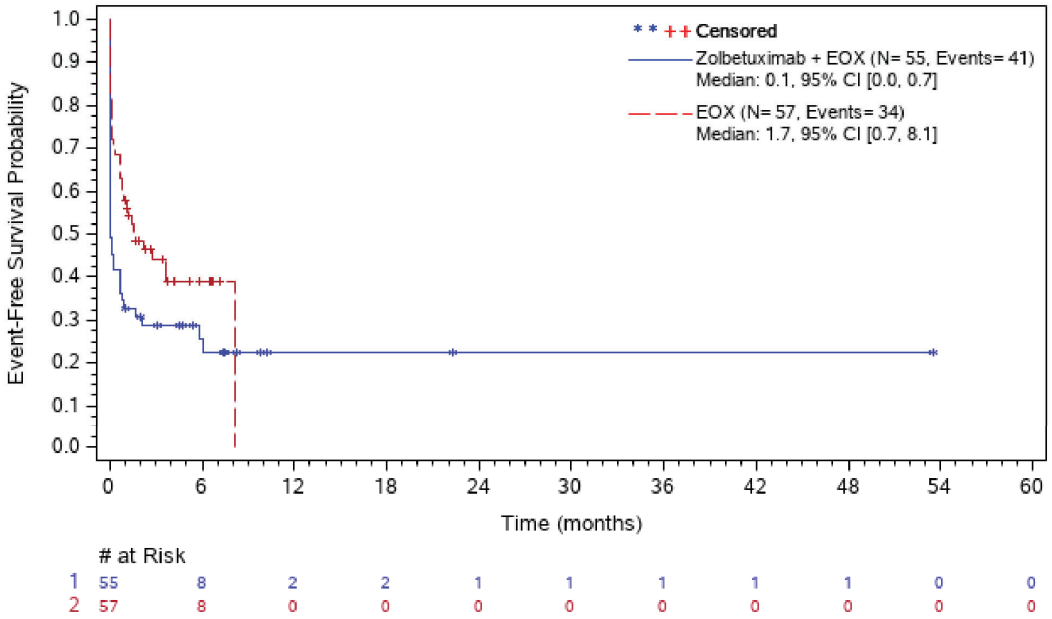
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.74.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set
Age Group 1: >65 years



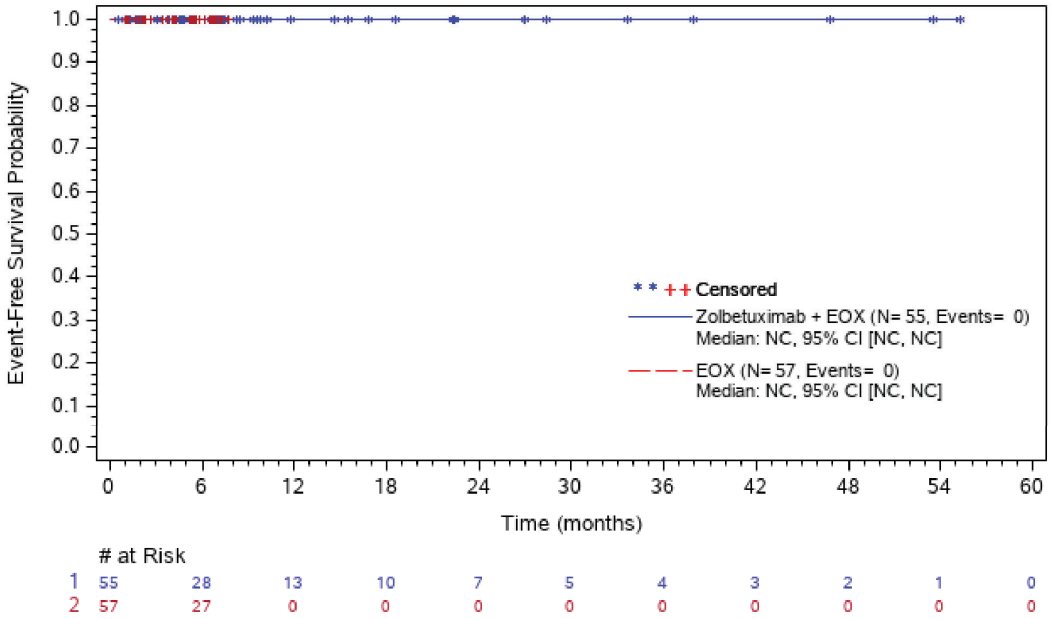
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.75: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Vomiting (AESI) - Safety Analysis Set



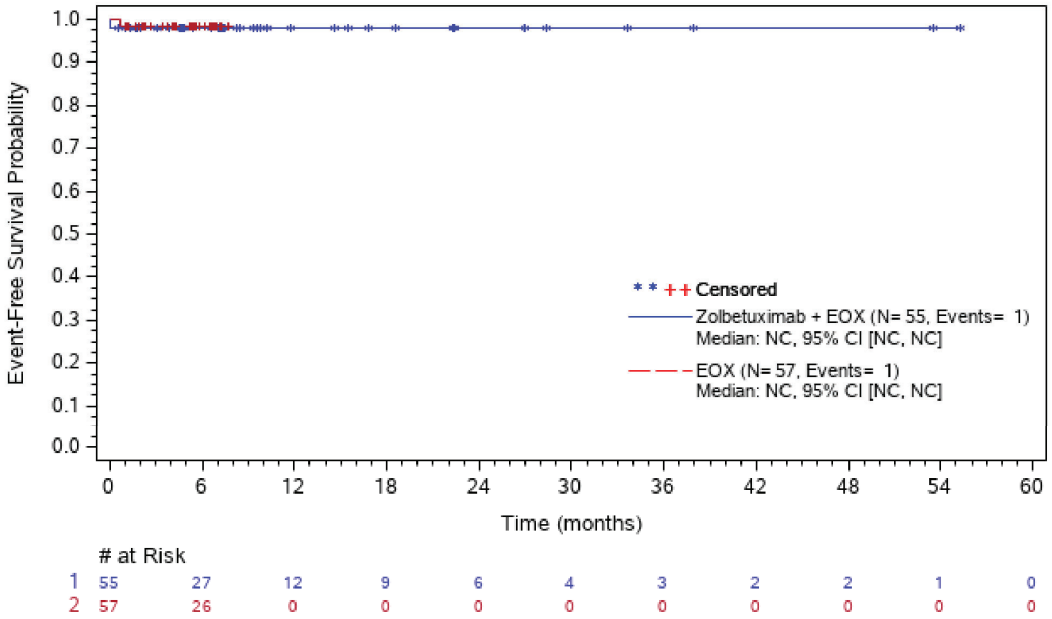
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.76: Kaplan-Meier Plot of Time to first Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



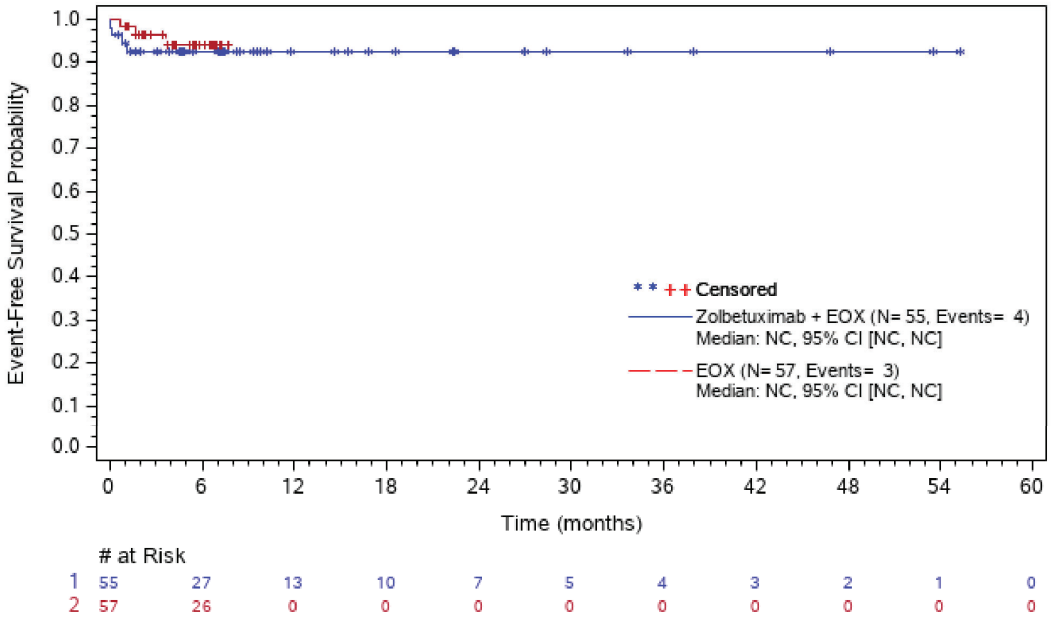
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.77: Kaplan-Meier Plot of Time to first Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



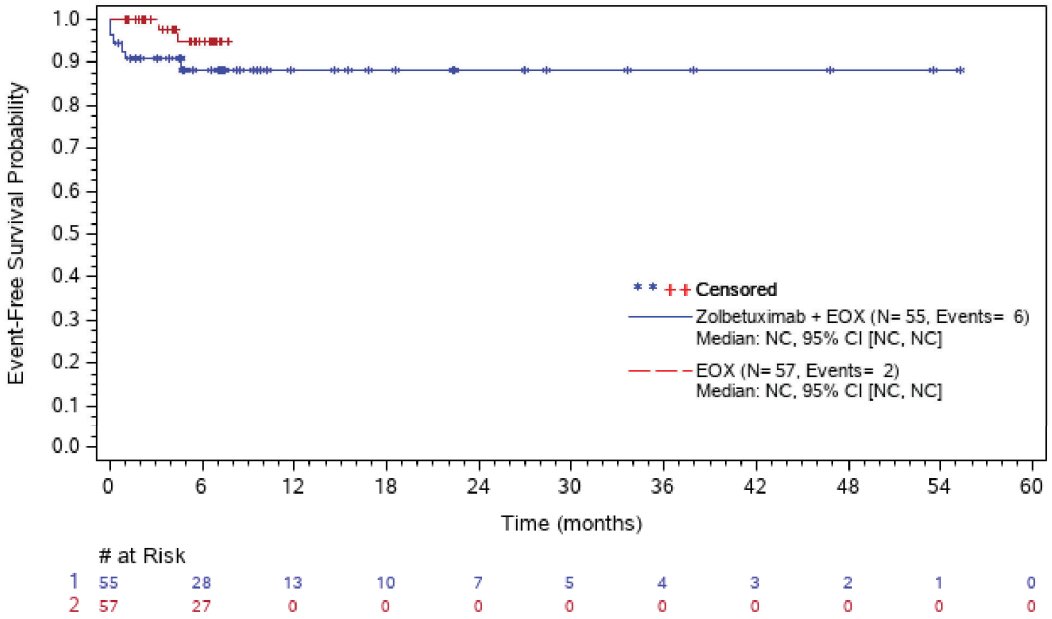
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.78: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (AESI) - Safety Analysis Set



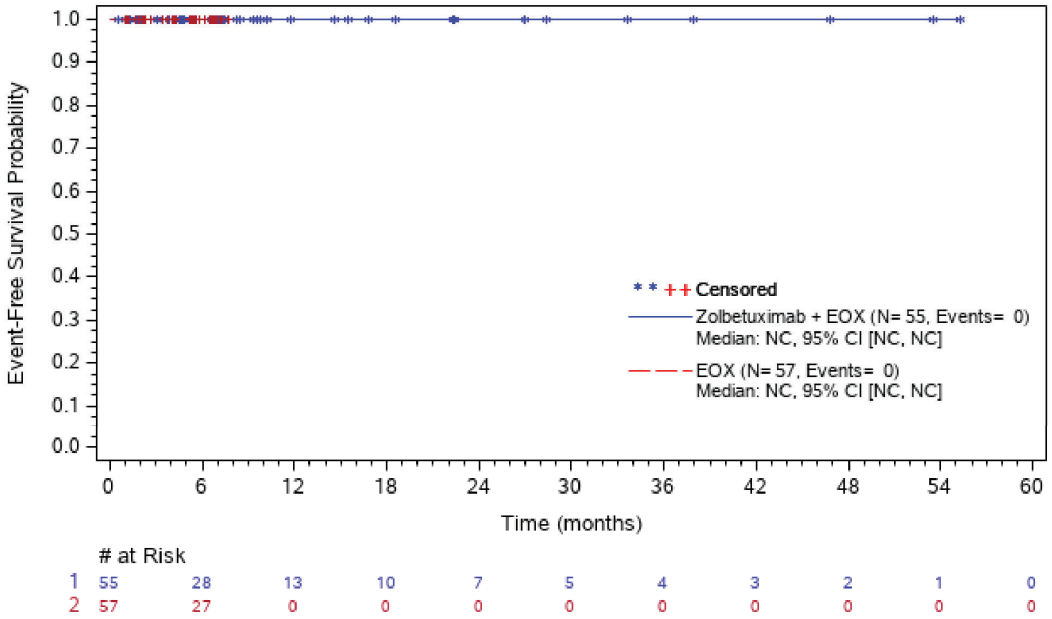
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.79: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (AESI) - Safety Analysis Set



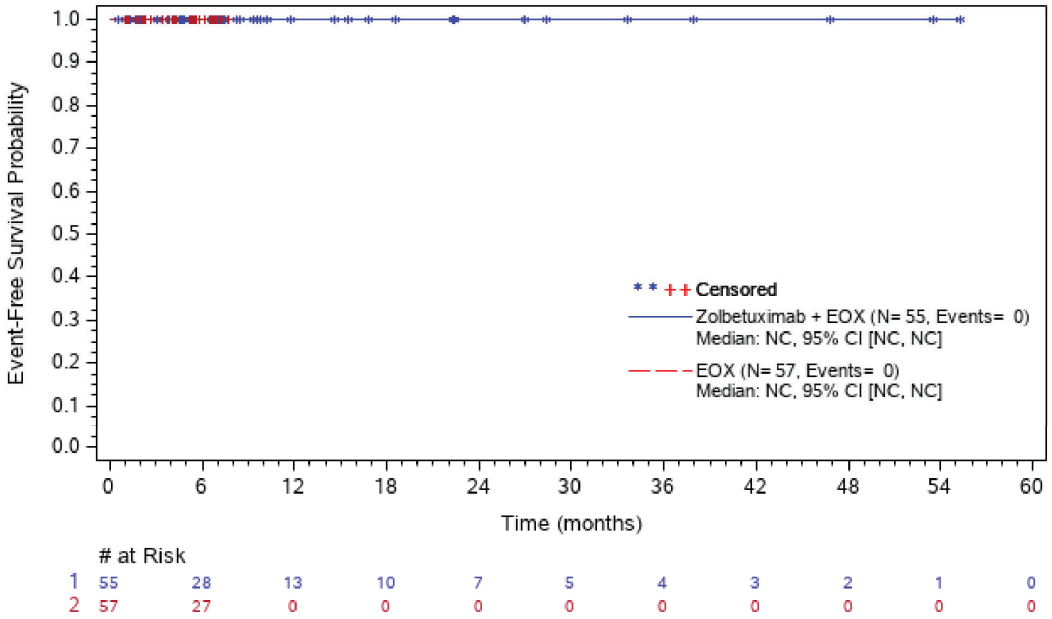
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.80: Kaplan-Meier Plot of Time to first TESAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



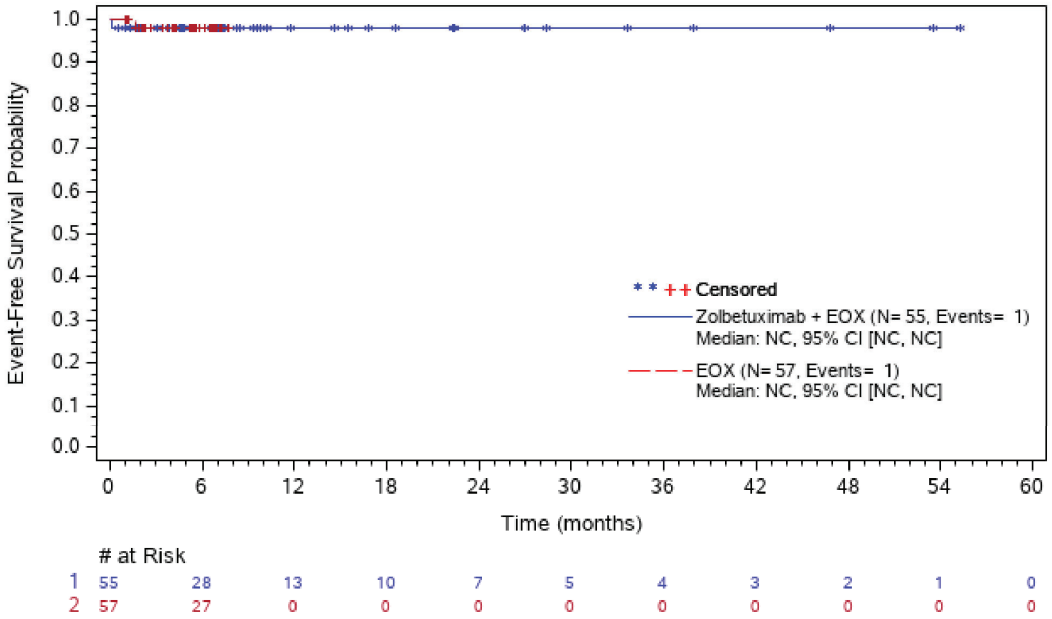
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.81: Kaplan-Meier Plot of Time to first TESAE - Infusion Related Reaction (AESI) - Safety Analysis Set



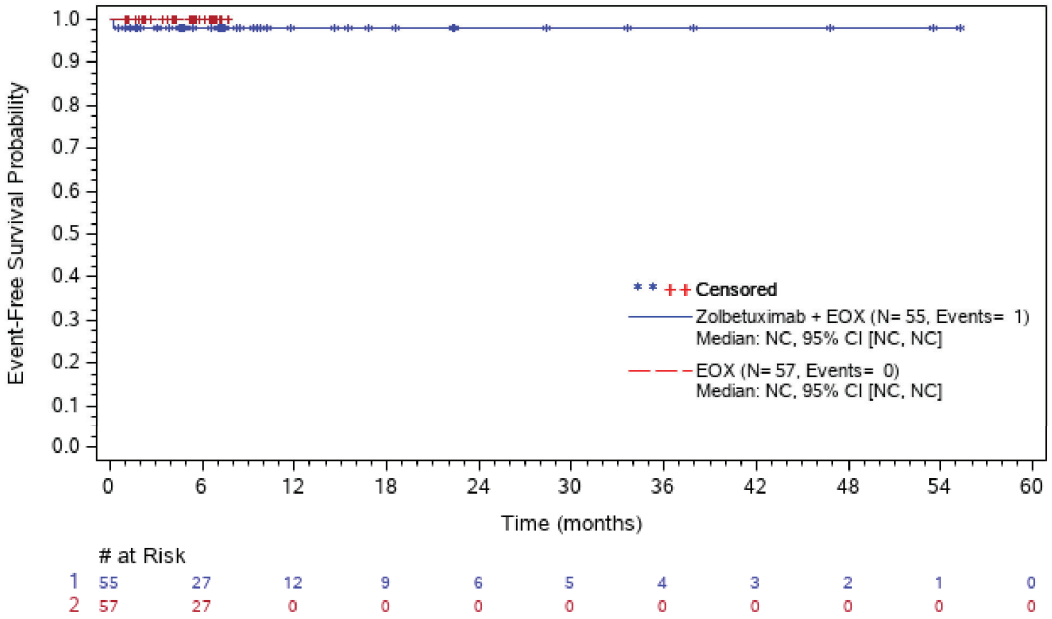
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.82: Kaplan-Meier Plot of Time to first TESAE - Nausea (AESI) - Safety Analysis Set



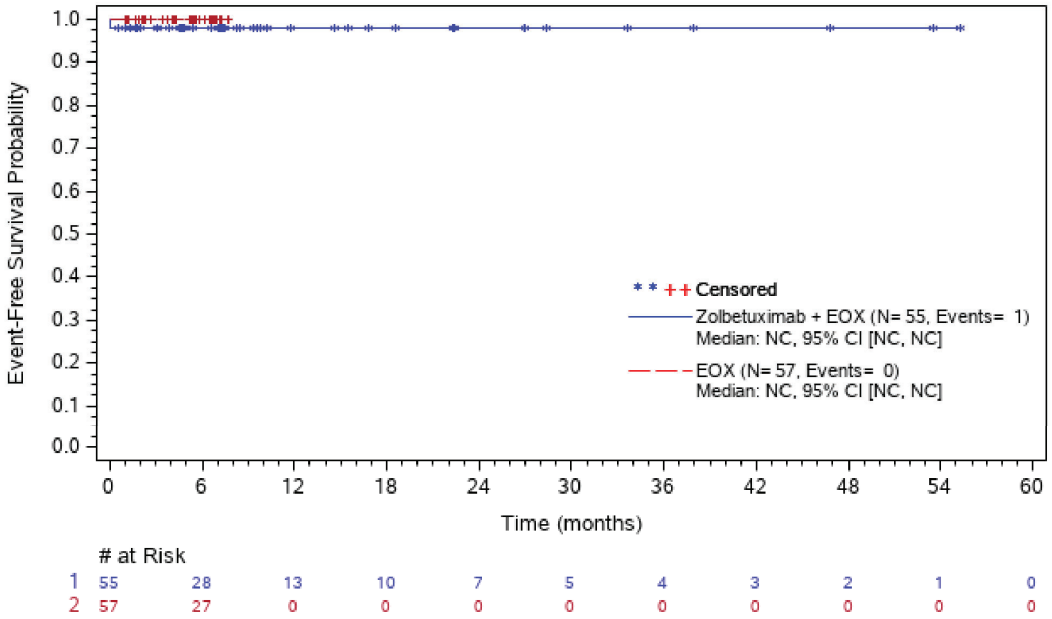
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.83: Kaplan-Meier Plot of Time to first TESAE - Vomiting (AESI) - Safety Analysis Set



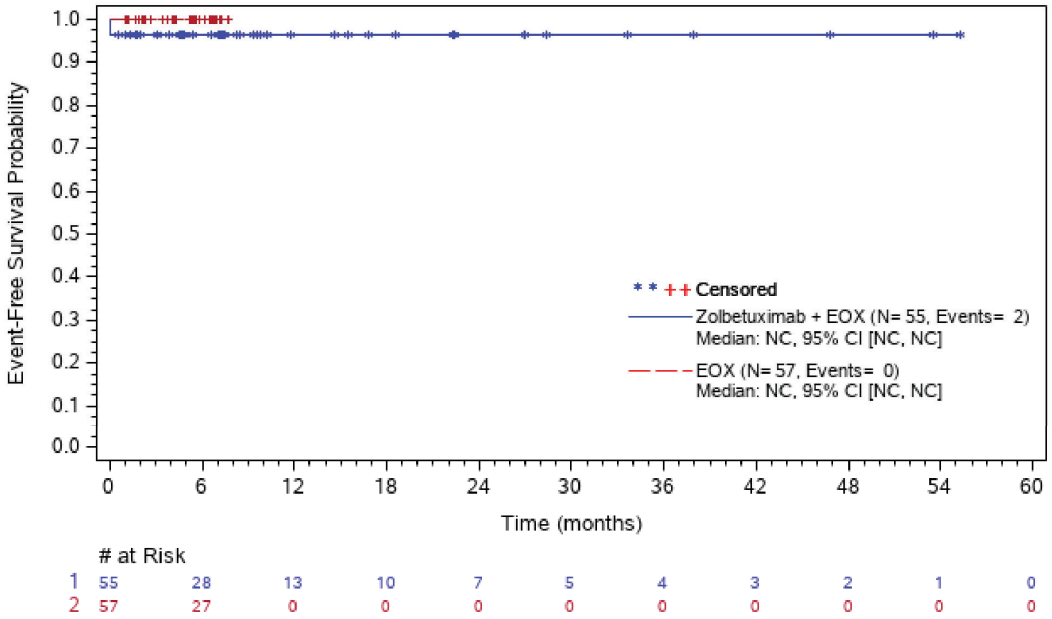
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.84: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set



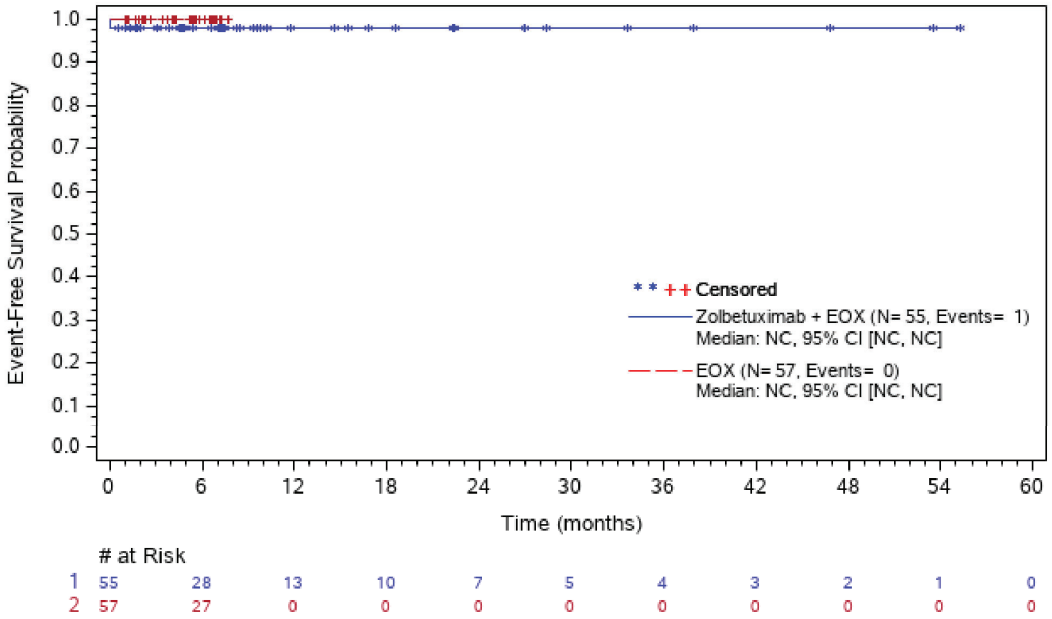
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.85: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set



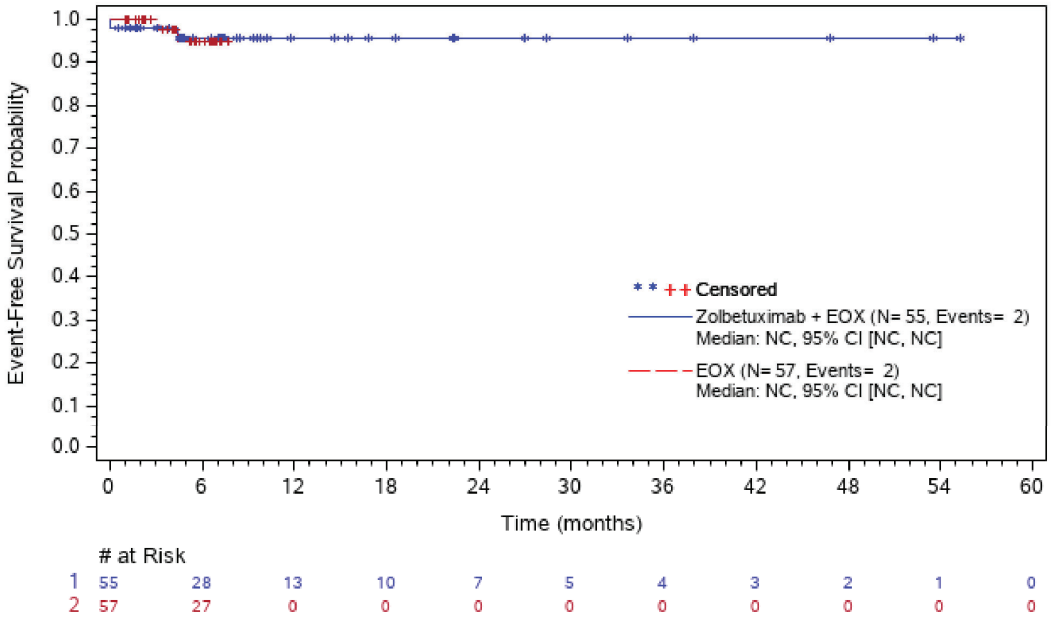
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.86: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set



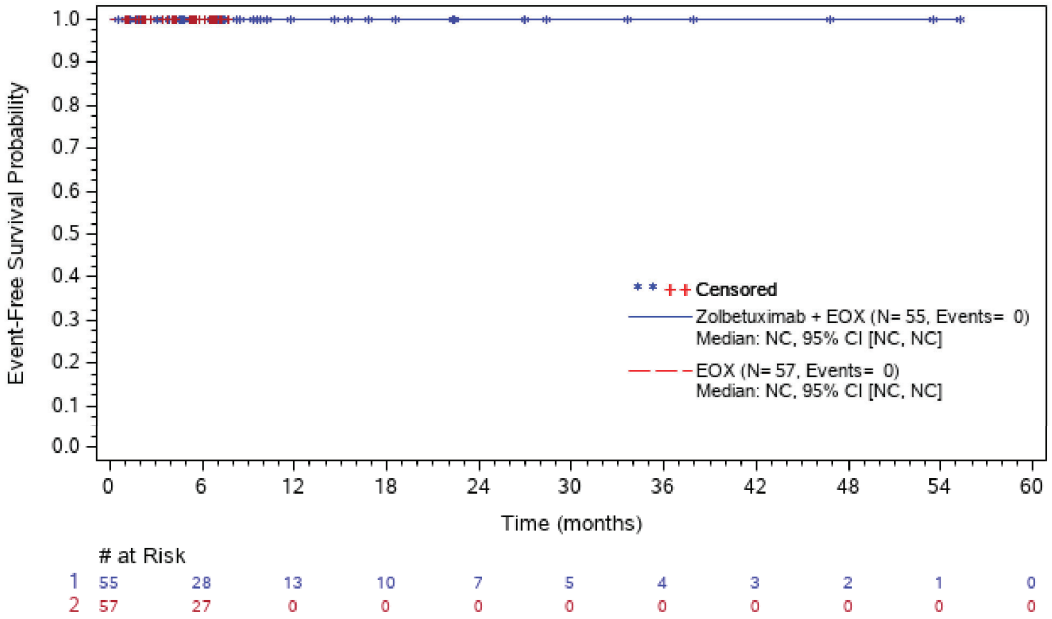
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.87: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set



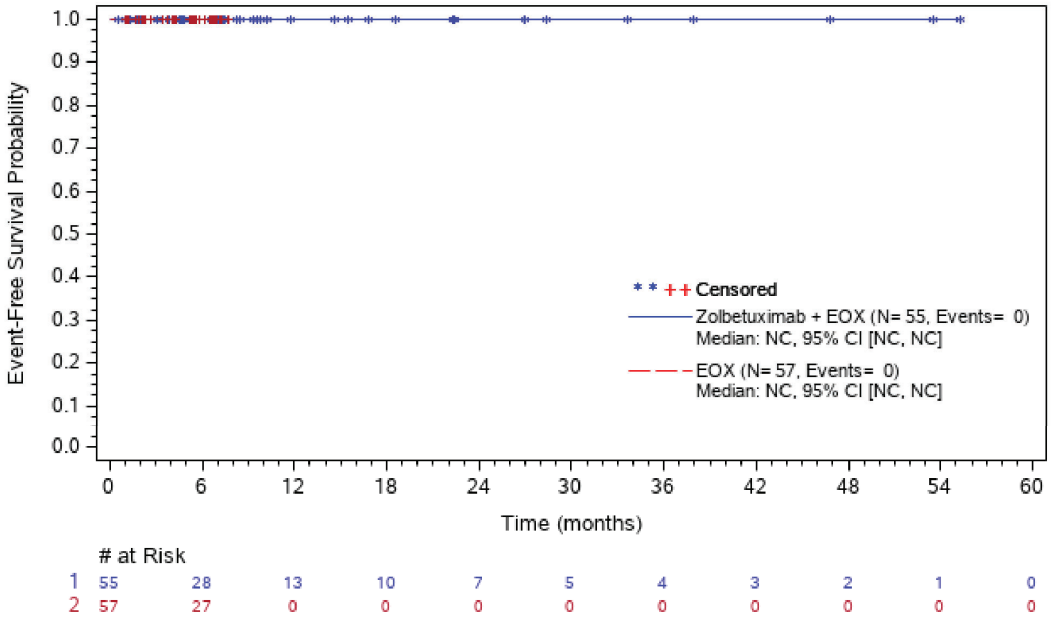
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.96: Kaplan-Meier Plot of Time to first TEAE leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set



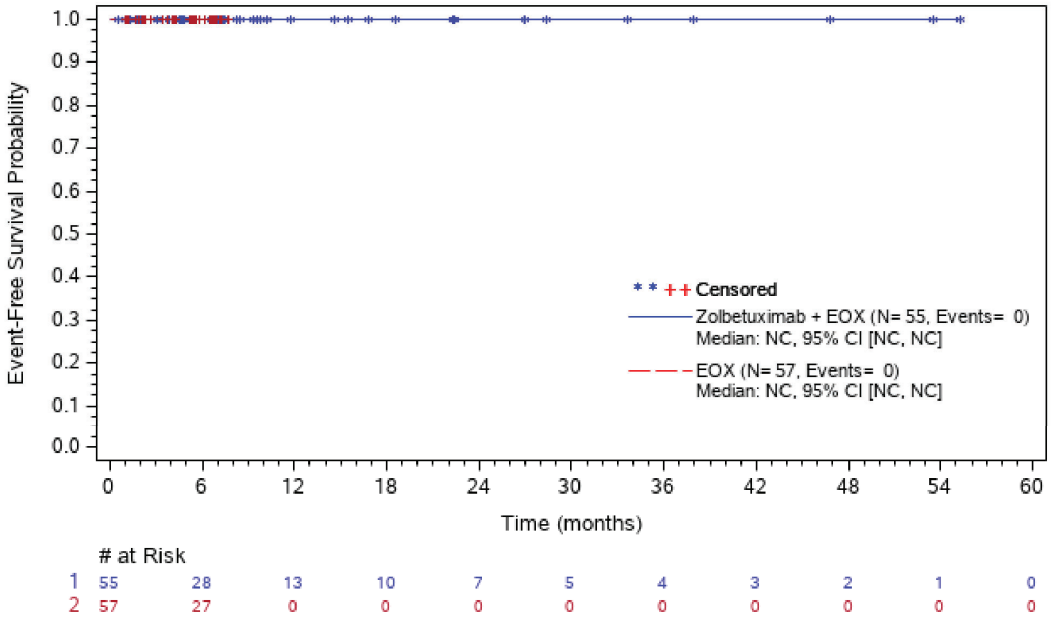
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.97: Kaplan-Meier Plot of Time to first TEAE leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set



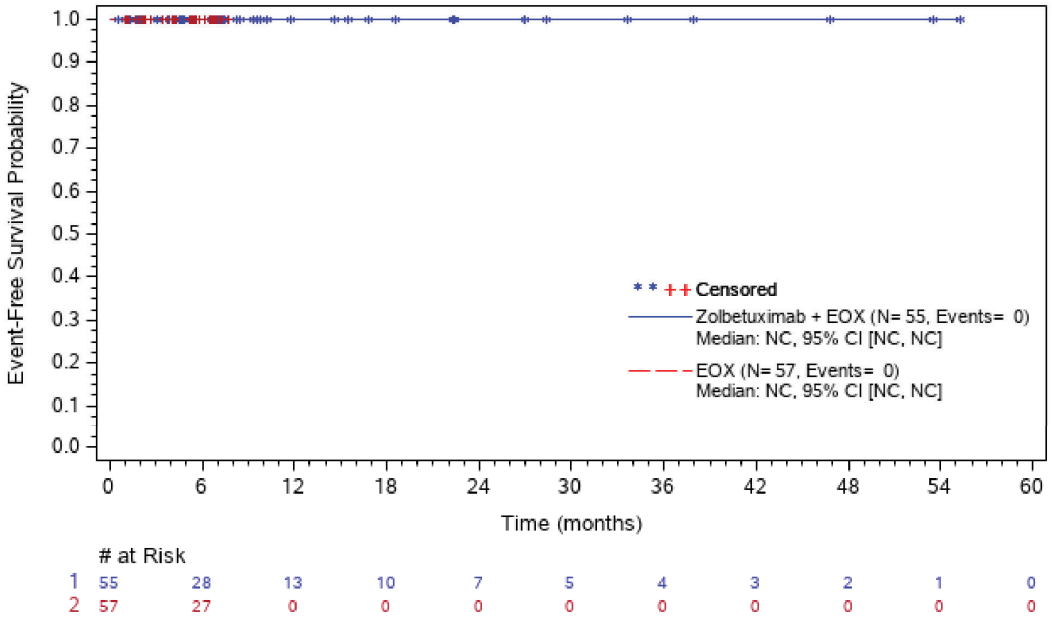
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.98: Kaplan-Meier Plot of Time to first TEAE leading to Death - Nausea (AESI) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Figure GM03.1.2001.99: Kaplan-Meier Plot of Time to first TEAE leading to Death - Vomiting (AESI) - Safety Analysis Set



Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Weitere Analysen

Anhang 4-G2 Beobachtungsdauern

Table GM03.1.1001.2.1: Summary of Duration of Observation Time of Overall Survival - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Duration of observation period (months)		
n	56	58
Mean (SD)	20.2 (17.76)	11.9 (13.47)
Median	14.3	8.6
Q1-Q3	7.3 - 28.3	5.3 - 13.4
Range	1 - 68	0 - 66

Abbreviations: mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for overall survival will include the time from randomisation until the last date endpoint data are collected for overall survival.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.2.2: Summary of Duration of Observation Time of Progression-Free Survival (IRC) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Duration of observation period (months)		
n	56	58
Mean (SD)	7.8 (7.16)	5.2 (3.79)
Median	5.4	4.3
Q1-Q3	2.8 - 10.8	2.8 - 7.2
Range	0 - 28	0 - 20

Abbreviations: IRC=independent review committee; mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for progression-free survival (IRC) will include the time from randomisation until the last date endpoint data are collected for progression-free survival (IRC).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.2.3: Summary of Duration of Observation Time of Progression-Free Survival (INV) - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Duration of observation period (months)		
n	56	58
Mean (SD)	10.8 (12.78)	5.9 (4.85)
Median	6.3	5.2
Q1-Q3	2.8 - 13.0	2.8 - 7.3
Range	0 - 55	0 - 26

Abbreviations: INV=investigator; mITT=modified intention-to-treat; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for progression-free survival (INV) will include the time from randomisation until the last date endpoint data are collected for progression-free survival (INV).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3000.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Duration of observation period (months)		
n	55	58
Mean (SD)	10.4 (12.60)	5.5 (4.46)
Median	6.2	5.1
Q1-Q3	2.9 - 12.4	2.8 - 7.3
Range	0 - 54	0 - 22

Abbreviations: EORTC QLQ-C30=European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EORTC QLQ-C30 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-C30 questionnaire.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.3000.2: EORTC QLQ-STO22 - Summary of Duration of Observation Time - mITT Analysis Set

	Zolbetuximab + EOX (N= 56)	**EOX (N= 58)**
Duration of observation period (months)		
n	55	58
Mean (SD)	10.4 (12.60)	5.5 (4.46)
Median	6.2	5.1
Q1-Q3	2.9 - 12.4	2.8 - 7.3
Range	0 - 54	0 - 22

Abbreviations: EORTC QLQ-STO22=European Organisation for Research and Treatment of Cancer Gastric Cancer Module; mITT=modified intention to treat; N=number of patients; n=number of patients with non-missing values; Q1= first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EORTC QLQ-STO22 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-STO22 questionnaire.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2000.6.1: Summary of Duration of Observation Time for Safety Endpoints - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**
Duration of observation period (months)		
n	55	57
Mean (SD)	7.1 (2.26)	6.6 (2.56)
Median	8.2	7.5
Q1-Q3	5.6 - 8.8	5.2 - 8.5
Range	1 - 10	1 - 10

Abbreviations: DCO=data cut-off; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation time for safety endpoints is defined as the time from first dose until DCO, study treatment discontinuation +90 days or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.2000.6.2: Summary of Duration of Observation Time for any TEAE - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**
Duration of observation period (months)		
n	55	57
Mean (SD)	5.4 (1.92)	5.3 (1.95)
Median	6.5	6.5
Q1-Q3	4.0 - 6.8	3.8 - 6.6
Range	1 - 8	1 - 8

Abbreviations: DCO=data cut-off; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation; TEAE=treatment-emergent adverse event.
Observation time for any TEAE is defined as the time from first dose until DCO, study treatment discontinuation +30 days or death, whichever occured first and stopped the collection of endpoint data.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Weitere Analysen

Anhang 4-G2 Begleitmedikationen

Table GM03.1.1001.5: Summary of Concomitant Therapies - mITT Analysis Set

Therapeutic Subgroup	Zolbetuximab + EOX (N=56)	EOX (N=58)
Overall	55 (98.2%)	56 (96.6%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	10 (17.9%)	6 (10.3%)
ALL OTHER THERAPEUTIC PRODUCTS	2 (3.6%)	1 (1.7%)
ANALGESICS	15 (26.8%)	12 (20.7%)
ANESTHETICS	1 (1.8%)	0
ANTIANEMIC PREPARATIONS	14 (25.0%)	19 (32.8%)
ANTIBACTERIALS FOR SYSTEMIC USE	8 (14.3%)	5 (8.6%)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	6 (10.7%)	16 (27.6%)
ANTIEMETICS AND ANTINAUSEANTS	55 (98.2%)	54 (93.1%)
ANTIHEMORRHAGICS	3 (5.4%)	4 (6.9%)
ANTIHISTAMINES FOR SYSTEMIC USE	28 (50.0%)	19 (32.8%)
ANTIHYPERTENSIVES	1 (1.8%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	7 (12.5%)	7 (12.1%)
ANTIMYCOTICS FOR SYSTEMIC USE	2 (3.6%)	1 (1.7%)
ANTITHROMBOTIC AGENTS	5 (8.9%)	5 (8.6%)
ANTIVIRALS FOR SYSTEMIC USE	1 (1.8%)	1 (1.7%)

Abbreviations: ATC=anatomical therapeutic chemical; mITT=modified intention-to-treat; N=number of patients in treatment arm.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.5: Summary of Concomitant Therapies - mITT Analysis Set

Therapeutic Subgroup	Zolbetuximab + EOX (N=56)	EOX (N=58)
BETA BLOCKING AGENTS	7 (12.5%)	8 (13.8%)
BILE AND LIVER THERAPY	6 (10.7%)	4 (6.9%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	12 (21.4%)	11 (19.0%)
CALCIUM CHANNEL BLOCKERS	2 (3.6%)	1 (1.7%)
CARDIAC THERAPY	10 (17.9%)	7 (12.1%)
CORTICOSTEROIDS FOR SYSTEMIC USE	9 (16.1%)	10 (17.2%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	2 (3.6%)	0
COUGH AND COLD PREPARATIONS	3 (5.4%)	3 (5.2%)
DIGESTIVES, INCL. ENZYMES	1 (1.8%)	5 (8.6%)
DIURETICS	6 (10.7%)	5 (8.6%)
DRUGS FOR ACID RELATED DISORDERS	45 (80.4%)	42 (72.4%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	40 (71.4%)	29 (50.0%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	1 (1.8%)	3 (5.2%)
DRUGS FOR TREATMENT OF BONE DISEASES	0	1 (1.7%)
DRUGS USED IN DIABETES	4 (7.1%)	3 (5.2%)
EMOLLIENTS AND PROTECTIVES	2 (3.6%)	2 (3.4%)

Abbreviations: ATC=anatomical therapeutic chemical; mITT=modified intention-to-treat; N=number of patients in treatment arm.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.5: Summary of Concomitant Therapies - mITT Analysis Set

Therapeutic Subgroup	Zolbetuximab + EOX (N=56)	EOX (N=58)
IMMUNOSTIMULANTS	13 (23.2%)	5 (8.6%)
LAXATIVES	2 (3.6%)	4 (6.9%)
LIPID MODIFYING AGENTS	1 (1.8%)	1 (1.7%)
MINERAL SUPPLEMENTS	2 (3.6%)	2 (3.4%)
NASAL PREPARATIONS	0	1 (1.7%)
OPHTHALMOLOGICALS	1 (1.8%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	5 (8.9%)	10 (17.2%)
OTHER DERMATOLOGICAL PREPARATIONS	2 (3.6%)	0
OTHER NERVOUS SYSTEM DRUGS	0	1 (1.7%)
PERIPHERAL VASODILATORS	1 (1.8%)	0
PSYCHOANALEPTICS	1 (1.8%)	1 (1.7%)
PSYCHOLEPTICS	6 (10.7%)	4 (6.9%)
STOMATOLOGICAL PREPARATIONS	1 (1.8%)	2 (3.4%)
THROAT PREPARATIONS	1 (1.8%)	0
THYROID THERAPY	1 (1.8%)	1 (1.7%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (1.8%)	3 (5.2%)

Abbreviations: ATC=anatomical therapeutic chemical; mITT=modified intention-to-treat; N=number of patients in treatment arm.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.5: Summary of Concomitant Therapies - mITT Analysis Set

Therapeutic Subgroup	Zolbetuximab + EOX (N=56)	EOX (N=58)
UROLOGICALS	1 (1.8%)	2 (3.4%)
VASOPROTECTIVES	2 (3.6%)	1 (1.7%)
VITAMINS	18 (32.1%)	9 (15.5%)
Not Coded	3 (5.4%)	7 (12.1%)

Abbreviations: ATC=anatomical therapeutic chemical; mITT=modified intention-to-treat; N=number of patients in treatment arm.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Weitere Analysen

Anhang 4-G2 Studienmedikation - Exposition

Table GM03.1.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + EOX (N= 55)	**EOX (N= 57)**
Duration of Zolbetuximab (days)		
n	55	0
Mean (SD)	309.8 (392.4)	
Median	171.0	
Range	1 - 1653	
Duration of Epirrubicin (days)		
n	54	57
Mean (SD)	115.2 (53.26)	107.2 (51.64)
Median	141.5	114.0
Range	1 - 182	1 - 183
Duration of Oxaliplatin (days)		
n	54	57
Mean (SD)	116.9 (53.02)	108.4 (51.47)
Median	148.0	127.0
Range	1 - 182	1 - 183
Duration of Capecitabine (days)		
n	52	51
Mean (SD)	112.3 (56.69)	108.8 (52.27)
Median	141.5	128.0
Range	1 - 182	1 - 178

Abbreviations: N=number of patients; n=number of patients treated with respective study drug; SD=standard deviation.
Duration of each component is defined as (date of last infusion) - (date of first infusion) + 1.
EOX components: epirrubicin, oxiplatin and capecitabine.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Weitere Analysen

Anhang 4-G2 Patientenfluss

Table GM03.1.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + EOX	EOX	Total
Screened			131 (100.0%)
Screen Failures			17 (13.0%)
Reasons for Screen-Failure			
CLDN18.2 Not Assessable			0
CLDN18.2 Negativity			0
CLDN18.2 Positive but Other Criteria not Fulfilled			17 (13.0%)
Adverse Event			0
Withdrawal of Consent			4 (3.1%)
Death			0
Eligibility Criteria not Fulfilled			13 (9.9%)
Other			0
Missing			0
Randomized Patients			114 (87.0%)
Randomized but not Treated			2 (1.5%)
mITT Population	56 (100.0%)	58 (100.0%)	114 (100.0%)
Completed 2 Cycles + CT	52 (92.9%)	56 (96.6%)	108 (94.7%)
Discontinued within First 2 Cycles	4 (7.1%)	2 (3.4%)	6 (5.3%)
Reasons for Study Discontinuation within First 2 Cycles			
Progressive Disease	0	0	0
Clinical Progression	0	0	0
Eligibility Criteria Not Fulfilled	0	0	0
Adverse Event	0	1 (1.7%)	1 (0.9%)
Lost To Follow-Up	0	0	0
Protocol Violation Or Non-Compliance	0	0	0
Not Receiving the Treatment the Patient was Randomized to	0	0	0
Intercurrent Illness	0	0	0
Physician Decision	0	1 (1.7%)	1 (0.9%)
Withdrawal By Subject	3 (5.4%)	0	3 (2.6%)

Abbreviations: CT=computed tomography; mITT=modified intention-to-treat.
*Completed 8 cycles and EOT visit.
Note: Number of patients with continued Zolbetuximab treatment includes patients regardless of status at the end of EOX. Patients with at least one continuing treatment are reported.
Patient is considered to have died under treatment if he discontinued the EOX treatment phase due to death.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + EOX	EOX	Total
Missing	0	0	0
Other	1 (1.8%)	0	1 (0.9%)
No CT Scan	0	0	0
Completed the EOX*	28 (50.0%)	26 (44.8%)	54 (47.4%)
Discontinued Within First 8 Cycles	28 (50.0%)	32 (55.2%)	60 (52.6%)
Did not Complete the EOX but Continued with Zolbetuximab	1 (1.8%)	0	1 (0.9%)
Reasons for Study Discontinuation Within First 8 Cycles			
Progressive Disease	12 (21.4%)	15 (25.9%)	27 (23.7%)
Clinical Progression	0	5 (8.6%)	5 (4.4%)
Eligibility Criteria Not Fulfilled	0	0	0
Adverse Event	3 (5.4%)	3 (5.2%)	6 (5.3%)
Lost To Follow-Up	0	0	0
Protocol Violation Or Non-Compliance	0	1 (1.7%)	1 (0.9%)
Not Receiving the Treatment the Patient was Randomized to	0	0	0
Intercurrent Illness	0	0	0
Physician Decision	3 (5.4%)	3 (5.2%)	6 (5.3%)
Withdrawal By Subject	7 (12.5%)	3 (5.2%)	10 (8.8%)
Missing	0	0	0
Other	3 (5.4%)	2 (3.4%)	5 (4.4%)
Number of Patients with Continued Zolbetuximab Treatment	27 (48.2%)	0	27 (23.7%)
Number of Patients Died During the Study	45 (80.4%)	54 (93.1%)	99 (86.8%)
Not Therapy/Tumor Related	2 (3.6%)	1 (1.7%)	3 (2.6%)
Tumor Related	41 (73.2%)	52 (89.7%)	93 (81.6%)
Unknown	2 (3.6%)	1 (1.7%)	3 (2.6%)

Abbreviations: CT=computed tomography; mITT=modified intention-to-treat.
*Completed 8 cycles and EOT visit.
Note: Number of patients with continued Zolbetuximab treatment includes patients regardless of status at the end of EOX. Patients with at least one continuing treatment are reported.
Patient is considered to have died under treatment if he discontinued the EOX treatment phase due to death.
ASTELLAS Data Cutoff Date: 31JAN2019

Anhang 4-G2 Weitere Analysen

Anhang 4-G2 Folgetherapien

Table GM03.1.1001.8: Summary of Subsequent Therapies - Safety Analysis Set

Subsequent Therapies	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Any Follow-Up Chemotherapy	24 (43.6%)	23 (40.4%)	47 (42.0%)
Farmorubicin	0 (0.0%)	1 (1.8%)	1 (0.9%)
Cisplatinum	1 (1.8%)	1 (1.8%)	2 (1.8%)
Hydrazini Sulfas	1 (1.8%)	0 (0.0%)	1 (0.9%)
Rad-Pac	0 (0.0%)	1 (1.8%)	1 (0.9%)
Epirubicin	2 (3.6%)	2 (3.5%)	4 (3.6%)
Tegafurum	1 (1.8%)	0 (0.0%)	1 (0.9%)
5fluoruracilum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Folin Acid	1 (1.8%)	0 (0.0%)	1 (0.9%)
Docetaxel+cisplatin+5-Ftoruracil	1 (1.8%)	0 (0.0%)	1 (0.9%)
Irinotekan+cysplatin	0 (0.0%)	1 (1.8%)	1 (0.9%)
Oxaliplatini	0 (0.0%)	1 (1.8%)	1 (0.9%)
Doxorubicin11	0 (0.0%)	1 (1.8%)	1 (0.9%)
Paclitaxel+carboplatin	0 (0.0%)	1 (1.8%)	1 (0.9%)
Cisplatin	1 (1.8%)	4 (7.0%)	5 (4.5%)
Taxol	1 (1.8%)	0 (0.0%)	1 (0.9%)
Etoposide	1 (1.8%)	1 (1.8%)	2 (1.8%)
Etopozid+leukoverin+ftoruracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
5 Fu	0 (0.0%)	1 (1.8%)	1 (0.9%)
Fluorouracil	3 (5.5%)	0 (0.0%)	3 (2.7%)
Denosumab	1 (1.8%)	0 (0.0%)	1 (0.9%)
Folinic Acid	1 (1.8%)	1 (1.8%)	2 (1.8%)
Bondronat	1 (1.8%)	0 (0.0%)	1 (0.9%)
Irinotecanum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Docetaxelum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Leucovarin	0 (0.0%)	1 (1.8%)	1 (0.9%)
Leukovorin+etopozid+ftoruracil	1 (1.8%)	0 (0.0%)	1 (0.9%)
Doxorubicin	0 (0.0%)	1 (1.8%)	1 (0.9%)

Abbreviations: N=number of patients in treatment arm.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.8: Summary of Subsequent Therapies - Safety Analysis Set

Subsequent Therapies	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Oxaliplatin	4 (7.3%)	1 (1.8%)	5 (4.5%)
Capecitabine	2 (3.6%)	5 (8.8%)	7 (6.3%)
Paclitaxel	4 (7.3%)	3 (5.3%)	7 (6.3%)
Doxorubicinum	0 (0.0%)	1 (1.8%)	1 (0.9%)
Rad 001 / Paclitaxel	1 (1.8%)	0 (0.0%)	1 (0.9%)
5-Fu Bolus	0 (0.0%)	1 (1.8%)	1 (0.9%)
Ramucirumab	1 (1.8%)	0 (0.0%)	1 (0.9%)
Epirubicinum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Taxotere	0 (0.0%)	1 (1.8%)	1 (0.9%)
Cisplatin, Paclitaxel	0 (0.0%)	1 (1.8%)	1 (0.9%)
Unknown	0 (0.0%)	1 (1.8%)	1 (0.9%)
Cisplatine	0 (0.0%)	1 (1.8%)	1 (0.9%)
Fap (Doxorubicin, Cisplatin, Fu)	1 (1.8%)	0 (0.0%)	1 (0.9%)
5 Fluoruracili	0 (0.0%)	1 (1.8%)	1 (0.9%)
Fluoracil	1 (1.8%)	0 (0.0%)	1 (0.9%)
Cysplatin	1 (1.8%)	0 (0.0%)	1 (0.9%)
Fluoruracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
5fu	2 (3.6%)	1 (1.8%)	3 (2.7%)
Folinacid	1 (1.8%)	1 (1.8%)	2 (1.8%)
Docetaxel	2 (3.6%)	3 (5.3%)	5 (4.5%)
Ftoruracil+leukoverin	0 (0.0%)	1 (1.8%)	1 (0.9%)
5-Fluorouracil	2 (3.6%)	1 (1.8%)	3 (2.7%)
Irinotecan	2 (3.6%)	3 (5.3%)	5 (4.5%)
Docetaxeli	0 (0.0%)	1 (1.8%)	1 (0.9%)
Irinotekan	2 (3.6%)	0 (0.0%)	2 (1.8%)
Bonefos	0 (0.0%)	1 (1.8%)	1 (0.9%)
Iriontecan	0 (0.0%)	1 (1.8%)	1 (0.9%)
Doksorubicin+cysplatin+etopozid	0 (0.0%)	1 (1.8%)	1 (0.9%)

Abbreviations: N=number of patients in treatment arm.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.8: Summary of Subsequent Therapies - Safety Analysis Set

Subsequent Therapies	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Leucovorin	3 (5.5%)	3 (5.3%)	6 (5.4%)
Leucovorinum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Doxirubicin	0 (0.0%)	1 (1.8%)	1 (0.9%)
Leukovorin	1 (1.8%)	0 (0.0%)	1 (0.9%)
Capecitabin	2 (3.6%)	1 (1.8%)	3 (2.7%)
Mitomycinum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Doxorubicin 50 Mg	0 (0.0%)	1 (1.8%)	1 (0.9%)
Oxaliplatina	0 (0.0%)	1 (1.8%)	1 (0.9%)
5-Fu	2 (3.6%)	3 (5.3%)	5 (4.5%)
Oxaliplatinum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Doxorubicine	1 (1.8%)	1 (1.8%)	2 (1.8%)
Paclitaxel + Carboplatin	1 (1.8%)	0 (0.0%)	1 (0.9%)
Carboplatin	3 (5.5%)	1 (1.8%)	4 (3.6%)
Phtoruracilum	1 (1.8%)	0 (0.0%)	1 (0.9%)
Eloxatin	0 (0.0%)	2 (3.5%)	2 (1.8%)
Rad Pac	0 (0.0%)	1 (1.8%)	1 (0.9%)
5 Ftoruracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
Rad001/Placebo	0 (0.0%)	1 (1.8%)	1 (0.9%)
Epirubicini	0 (0.0%)	1 (1.8%)	1 (0.9%)
Segidrine	0 (0.0%)	1 (1.8%)	1 (0.9%)
Cisplatin 100 Mg	0 (0.0%)	1 (1.8%)	1 (0.9%)
Taxoter	1 (1.8%)	0 (0.0%)	1 (0.9%)
Etoposid	1 (1.8%)	0 (0.0%)	1 (0.9%)
Tegafur	0 (0.0%)	2 (3.5%)	2 (1.8%)
5fluoruracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
Teysuno	0 (0.0%)	1 (1.8%)	1 (0.9%)
Etopozid	1 (1.8%)	0 (0.0%)	1 (0.9%)
Xeloda	1 (1.8%)	2 (3.5%)	3 (2.7%)

Abbreviations: N=number of patients in treatment arm.
ASTELLAS Data Cutoff Date: 31JAN2019

Table GM03.1.1001.8: Summary of Subsequent Therapies - Safety Analysis Set

Subsequent Therapies	Zolbetuximab + EOX (N=55)	EOX (N=57)	Total (N=112)
Leucovorine	1 (1.8%)	0 (0.0%)	1 (0.9%)
5 Fluorouracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
5 Fluoruracil	1 (1.8%)	1 (1.8%)	2 (1.8%)
5 Ftor Uracil 100 Mg	0 (0.0%)	1 (1.8%)	1 (0.9%)
5-Ftoruracil	0 (0.0%)	1 (1.8%)	1 (0.9%)
Calcium Folinate	1 (1.8%)	0 (0.0%)	1 (0.9%)
Doxetacel	1 (1.8%)	0 (0.0%)	1 (0.9%)
Leucovorin+etoposide+5-Fluorouracil	0 (0.0%)	1 (1.8%)	1 (0.9%)

Abbreviations: N=number of patients in treatment arm.
ASTELLAS Data Cutoff Date: 31JAN2019