Dossier zur Nutzenbewertung gemäß § 35a SGB V

Zolbetuximab (VYLOY™)

Astellas Pharma GmbH

Modul 4 A, Anhang 4-G4

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 SPOTLIGHT

Primärer Datenschnitt vom 09.09.2022

Finaler Datenschnitt vom 08.09.2023

Stand: 30.10.2024

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Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Baseline Charakteristika

Table 301.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Sex		
Male	176 (62.2%)	175 (62.1%)
Female	107 (37.8%)	107 (37.9%)
Unknown	0	0
Age (years)		
n	283	282
Mean (SD)	59.74 (11.75)	58.77 (12.96)
Median	62.0	60.0
Range	27.0 - 83.0	20.0 - 86.0
Age (years)		
>=18 to <=64	171 (60.4%)	174 (61.7%)
>=65 to <85	112 (39.6%)	106 (37.6%)
>=85	0	2 (0.7%)
Age Group 1 (years)		
<=65	181 (64.0%)	181 (64.2%)
>65	102 (36.0%)	101 (35.8%)
Age Group 2 (years)		
<=75	267 (94.3%)	260 (92.2%)
>75	16 (5.7%)	22 (7.8%)
Race		
White	140 (53.6%)	134 (53.0%)
Black or African American	5 (1.9%)	2 (0.8%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Asian	96 (36.8%)	97 (38.3%)
American Indian or Alaska Native	9 (3.4%)	8 (3.2%)
Native Hawaiian or Other Pacific Islander	0	0
Other	11 (4.2%)	12 (4.7%)
Missing	22	29
Ethnicity		
Hispanic or Latino	36 (13.8%)	37 (14.8%)
Not Hispanic or Latino	225 (86.2%)	213 (85.2%)
Missing	22	32
Country 1		
Japan	32 (11.3%)	33 (11.7%)
Non-Japan	251 (88.7%)	249 (88.3%)
Country 2		
China	19 (6.7%)	17 (6.0%)
Non-China	264 (93.3%)	265 (94.0%)
Height (cm)		
n	279	277
Mean (SD)	167.17 (9.25)	166.87 (10.33)
Median	168.0	167.5
Range	145.0 - 188.0	143.0 - 196.0
Weight (kg)		
n	279	278

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Mean (SD)	64.66 (14.47)	65.43 (16.39)
Median	63.0	64.8
Range	38.0 - 110.6	28.5 - 128.3
BMI (kg/m^2)		
<18.5	34 (12.2%)	27 (9.7%)
>=18.5 to <25	168 (60.2%)	169 (61.0%)
>=25 to <30	61 (21.9%)	61 (22.0%)
>=30	16 (5.7%)	20 (7.2%)
Missing	4	5
BSA (m^2)		
n	279	277
Mean (SD)	1.73 (0.23)	1.74 (0.25)
Median	1.7	1.7
Range	1.2 - 2.4	1.1 - 2.5
BSA (m^2)		
<1.7	128 (45.9%)	127 (45.8%)
>=1.7	151 (54.1%)	150 (54.2%)
Missing	4	5
Tobacco History		
Never	142 (50.5%)	137 (48.9%)
Current	26 (9.3%)	25 (8.9%)
Former	113 (40.2%)	118 (42.1%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Missing	2	2
Baseline ECOG Status		
0	125 (44.8%)	115 (41.4%)
>=1	154 (55.2%)	163 (58.6%)
Missing	4	4
Region (IRT)		
Asia	88 (31.1%)	89 (31.6%)
Non-Asia	195 (68.9%)	193 (68.4%)
Region (eCRF)		
Asia	88 (31.1%)	89 (31.6%)
Non-Asia	195 (68.9%)	193 (68.4%)
Number of Organs with Metastatic Sites (IRT)		
0-2	219 (77.4%)	219 (77.7%)
>=3	64 (22.6%)	63 (22.3%)
Number of Organs with Metastatic Sites (eCRF)		
0-2	220 (77.7%)	222 (78.7%)
>=3	63 (22.3%)	60 (21.3%)
Prior Gastrectomy (IRT)		
Yes	84 (29.7%)	82 (29.1%)
No	199 (70.3%)	200 (70.9%)
Prior Gastrectomy (eCRF)		
Yes	82 (29.0%)	83 (29.4%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
No	201 (71.0%)	199 (70.6%)
CPS Status		
<5	170 (60.1%)	173 (61.3%)
>=5	27 (9.5%)	24 (8.5%)
Unknown	86 (30.4%)	85 (30.1%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Medical Condition	Gastric Adenocarcinoma	219 (77.4%)	210 (74.5%)
	Gastro-Esophageal Junction Adenocarcinoma	64 (22.6%)	72 (25.5%)
Duration Since Initial Diagnosis (days)	n	273	275
	Mean (SD)	270.36 (478.45)	297.63 (675.21)
	Median	56.0	56.0
	Range	2 - 3010	7 - 5366
Tumor Location			
All	Proximal	103 (36.8%)	85 (30.2%)
	Distal	110 (39.3%)	118 (42.0%)
	Unknown	67 (23.9%)	78 (27.8%)
	Missing	3	1
Gastric	n	219	210
	Proximal	73 (33.6%)	59 (28.1%)
	Distal	91 (41.9%)	87 (41.4%)
	Unknown	53 (24.4%)	64 (30.5%)
	Missing	2	0
GEJ	n	64	72
	Proximal	30 (47.6%)	26 (36.6%)
	Distal	19 (30.2%)	31 (43.7%)
	Unknown	14 (22.2%)	14 (19.7%)
	Missing	1	1
Tumor Type	Diffuse	82 (29.1%)	117 (42.1%)
	Intestinal	70 (24.8%)	66 (23.7%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastatic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Mixed	31 (11.0%)	13 (4.7%)
	Other	50 (17.7%)	42 (15.1%)
	Unknown	49 (17.4%)	40 (14.4%)
	Missing	1	4
Primary Tumor	TX	62 (22.1%)	46 (16.4%)
	T0	0	0
	Tis	1 (0.4%)	2 (0.7%)
	T1	2 (0.7%)	4 (1.4%)
	T1a	2 (0.7%)	1 (0.4%)
	T1b	2 (0.7%)	6 (2.1%)
	T2	15 (5.3%)	16 (5.7%)
	T3	86 (30.6%)	98 (34.9%)
	T4	32 (11.4%)	35 (12.5%)
	T4a	56 (19.9%)	56 (19.9%)
	T4b	23 (8.2%)	17 (6.0%)
	Missing	2	1
Regional Lymph Nodes	NX	66 (23.7%)	60 (21.4%)
	N0	40 (14.3%)	38 (13.6%)
	N1	56 (20.1%)	66 (23.6%)
	N2	44 (15.8%)	51 (18.2%)
	N3	42 (15.1%)	32 (11.4%)
	N3a	17 (6.1%)	19 (6.8%)
	N3b	14 (5.0%)	14 (5.0%)
	Missing	4	2
Distant Metastasis [1]	M0	85 (30.4%)	70 (24.8%)
	M1	195 (69.6%)	212 (75.2%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastatic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Missing	3	0
Tumor Metastatic [1]	Yes	239 (84.5%)	238 (84.4%)
	No	44 (15.5%)	44 (15.6%)
Metastasis Location	Abdominal Cavity	19 (6.7%)	17 (6.0%)
	Adrenal Gland	7 (2.5%)	6 (2.1%)
	Bladder	1 (0.4%)	0
	Bone	28 (9.9%)	23 (8.2%)
	Brain	0	1 (0.4%)
	Breast	1 (0.4%)	0
	Chest	4 (1.4%)	1 (0.4%)
	Colon	2 (0.7%)	3 (1.1%)
	Esophagus	3 (1.1%)	4 (1.4%)
	Gallbladder	0	1 (0.4%)
	Heart	2 (0.7%)	1 (0.4%)
	Kidney	2 (0.7%)	0
	Liver	62 (21.9%)	75 (26.6%)
	Lung	36 (12.7%)	33 (11.7%)
	Lymph Node	101 (35.7%)	109 (38.7%)
	Mediastinum	5 (1.8%)	2 (0.7%)
	Neck	0	1 (0.4%)
	Omentum	10 (3.5%)	12 (4.3%)
	Other	23 (8.1%)	17 (6.0%)
	Ovary	16 (5.7%)	19 (6.7%)
	Pancreas	2 (0.7%)	4 (1.4%)
	Pelvis	2 (0.7%)	3 (1.1%)
	Pericardium	1 (0.4%)	0

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastatic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Peritoneum	94 (33.2%)	76 (27.0%)
	Pleura	4 (1.4%)	5 (1.8%)
	Rectum	3 (1.1%)	0
	Retroperitoneum	7 (2.5%)	9 (3.2%)
	Skin	1 (0.4%)	0
	Spleen	2 (0.7%)	3 (1.1%)
	Stomach	5 (1.8%)	5 (1.8%)
History of Helicobacter pylori Infection	Yes	31 (11.0%)	45 (16.0%)
	No	139 (49.1%)	136 (48.2%)
	Unknown	113 (39.9%)	101 (35.8%)
Barrett's Esophagus Diagnosed	Yes	7 (2.5%)	11 (3.9%)
	No	166 (58.7%)	173 (61.3%)
	Unknown	110 (38.9%)	98 (34.8%)
CLDN18.2 Testing Result	<75%	0	0
	>=75%	283 (100.0%)	282 (100.0%)
	Not Applicable	0	0
HER2 Status	Positive	0	0
	Negative	283 (100.0%)	282 (100.0%)
	Not Applicable	0	0
Measurable Disease based on Central	Yes	211 (74.6%)	211 (74.8%)
	No	72 (25.4%)	71 (25.2%)
Measurable Disease based on Local	Yes	235 (83.0%)	227 (80.5%)
	No	48 (17.0%)	55 (19.5%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastatic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Overall	259 (91.5%)	251 (89.0%)	510 (90.3%)
Blood And Lymphatic System Disorders	50 (17.7%)	49 (17.4%)	99 (17.5%)
Anaemia	44 (15.5%)	44 (15.6%)	88 (15.6%)
Iron Deficiency Anaemia	4 (1.4%)	5 (1.8%)	9 (1.6%)
Blood Loss Anaemia	1 (0.4%)	0	1 (0.2%)
Hypochromic Anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenopathy Mediastinal	1 (0.4%)	0	1 (0.2%)
Microcytic Anaemia	0	1 (0.4%)	1 (0.2%)
Pernicious Anaemia	1 (0.4%)	0	1 (0.2%)
Splenic Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	32 (11.3%)	30 (10.6%)	62 (11.0%)
Atrial Fibrillation	6 (2.1%)	7 (2.5%)	13 (2.3%)
Angina Pectoris	1 (0.4%)	6 (2.1%)	7 (1.2%)
Coronary Artery Disease	1 (0.4%)	6 (2.1%)	7 (1.2%)
Bradycardia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Myocardial Ischaemia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Palpitations	2 (0.7%)	2 (0.7%)	4 (0.7%)
Arrhythmia	2 (0.7%)	1 (0.4%)	3 (0.5%)
Myocardial Infarction	2 (0.7%)	1 (0.4%)	3 (0.5%)
Sinus Bradycardia	3 (1.1%)	0	3 (0.5%)
Sinus Tachycardia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Tachycardia	0	3 (1.1%)	3 (0.5%)
Atrial Flutter	2 (0.7%)	0	2 (0.4%)
Cardiovascular Disorder	2 (0.7%)	0	2 (0.4%)
Ischaemic Cardiomyopathy	2 (0.7%)	0	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Mitral Valve Incompetence	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pericardial Effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinus Arrhythmia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Myocardial Infarction	1 (0.4%)	0	1 (0.2%)
Aortic Valve Incompetence	0	1 (0.4%)	1 (0.2%)
Arteriosclerosis Coronary Artery	0	1 (0.4%)	1 (0.2%)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Cardiac Flutter	0	1 (0.4%)	1 (0.2%)
Cardiac Tamponade	1 (0.4%)	0	1 (0.2%)
Cardiomegaly	1 (0.4%)	0	1 (0.2%)
Coronary Artery Stenosis	1 (0.4%)	0	1 (0.2%)
Diastolic Dysfunction	1 (0.4%)	0	1 (0.2%)
Hypertensive Heart Disease	1 (0.4%)	0	1 (0.2%)
Pericarditis	1 (0.4%)	0	1 (0.2%)
Supraventricular Extrasystoles	1 (0.4%)	0	1 (0.2%)
Ventricular Extrasystoles	0	1 (0.4%)	1 (0.2%)
Congenital, Familial And Genetic Disorders	3 (1.1%)	10 (3.5%)	13 (2.3%)
Gilbert's Syndrome	1 (0.4%)	2 (0.7%)	3 (0.5%)
Brugada Syndrome	0	1 (0.4%)	1 (0.2%)
Congenital Musculoskeletal Disorder Of Limbs	1 (0.4%)	0	1 (0.2%)
Deafness Congenital	0	1 (0.4%)	1 (0.2%)
Dermoid Cyst	0	1 (0.4%)	1 (0.2%)
Gene Mutation	0	1 (0.4%)	1 (0.2%)
Porokeratosis	0	1 (0.4%)	1 (0.2%)
Sturge-Weber Syndrome	1 (0.4%)	0	1 (0.2%)
Thalassaemia Minor	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Type V Hyperlipidaemia	0	1 (0.4%)	1 (0.2%)
Ventricular Septal Defect	0	1 (0.4%)	1 (0.2%)
Ear And Labyrinth Disorders	5 (1.8%)	10 (3.5%)	15 (2.7%)
Deafness	0	4 (1.4%)	4 (0.7%)
Hypoacusis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Vertigo	1 (0.4%)	2 (0.7%)	3 (0.5%)
Meniere's Disease	2 (0.7%)	0	2 (0.4%)
Tinnitus	0	2 (0.7%)	2 (0.4%)
Deafness Neurosensory	0	1 (0.4%)	1 (0.2%)
Mastoid Disorder	0	1 (0.4%)	1 (0.2%)
Presbyacusis	0	1 (0.4%)	1 (0.2%)
Endocrine Disorders	24 (8.5%)	19 (6.7%)	43 (7.6%)
Hypothyroidism	18 (6.4%)	16 (5.7%)	34 (6.0%)
Hyperthyroidism	2 (0.7%)	0	2 (0.4%)
Thyroid Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Autoimmune Thyroiditis	1 (0.4%)	0	1 (0.2%)
Goitre	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism Primary	0	1 (0.4%)	1 (0.2%)
Hyperplasia Adrenal	0	1 (0.4%)	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Eye Disorders	11 (3.9%)	17 (6.0%)	28 (5.0%)
Glaucoma	5 (1.8%)	3 (1.1%)	8 (1.4%)
Cataract	4 (1.4%)	3 (1.1%)	7 (1.2%)
Dry Eye	0	3 (1.1%)	3 (0.5%)
Diabetic Retinopathy	0	2 (0.7%)	2 (0.4%)
Macular Degeneration	0	2 (0.7%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Retinal Degeneration	0	2 (0.7%)	2 (0.4%)
Retinal Detachment	0	2 (0.7%)	2 (0.4%)
Vision Blurred	0	2 (0.7%)	2 (0.4%)
Visual Impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Blepharitis	0	1 (0.4%)	1 (0.2%)
Chalazion	1 (0.4%)	0	1 (0.2%)
Chorioretinal Scar	1 (0.4%)	0	1 (0.2%)
Epiretinal Membrane	0	1 (0.4%)	1 (0.2%)
Lacrimation Decreased	0	1 (0.4%)	1 (0.2%)
Macular Oedema	0	1 (0.4%)	1 (0.2%)
Optic Neuropathy	0	1 (0.4%)	1 (0.2%)
Visual Field Defect	0	1 (0.4%)	1 (0.2%)
Vitreous Detachment	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorders	146 (51.6%)	157 (55.7%)	303 (53.6%)
Abdominal Pain	33 (11.7%)	46 (16.3%)	79 (14.0%)
Gastrooesophageal Reflux Disease	35 (12.4%)	44 (15.6%)	79 (14.0%)
Constipation	31 (11.0%)	39 (13.8%)	70 (12.4%)
Dysphagia	34 (12.0%)	31 (11.0%)	65 (11.5%)
Nausea	24 (8.5%)	39 (13.8%)	63 (11.2%)
Abdominal Pain Upper	21 (7.4%)	21 (7.4%)	42 (7.4%)
Vomiting	10 (3.5%)	16 (5.7%)	26 (4.6%)
Dyspepsia	10 (3.5%)	12 (4.3%)	22 (3.9%)
Diarrhoea	7 (2.5%)	12 (4.3%)	19 (3.4%)
Abdominal Distension	6 (2.1%)	11 (3.9%)	17 (3.0%)
Ascites	7 (2.5%)	9 (3.2%)	16 (2.8%)
Gastric Ulcer	4 (1.4%)	12 (4.3%)	16 (2.8%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Gastritis	7 (2.5%)	9 (3.2%)	16 (2.8%)
Abdominal Discomfort	7 (2.5%)	6 (2.1%)	13 (2.3%)
Haemorrhoids	6 (2.1%)	6 (2.1%)	12 (2.1%)
Inguinal Hernia	5 (1.8%)	4 (1.4%)	9 (1.6%)
Chronic Gastritis	4 (1.4%)	4 (1.4%)	8 (1.4%)
Hiatus Hernia	4 (1.4%)	3 (1.1%)	7 (1.2%)
Umbilical Hernia	4 (1.4%)	3 (1.1%)	7 (1.2%)
Diverticulum	1 (0.4%)	5 (1.8%)	6 (1.1%)
Flatulence	1 (0.4%)	4 (1.4%)	5 (0.9%)
Abdominal Pain Lower	2 (0.7%)	2 (0.7%)	4 (0.7%)
Eructation	0	4 (1.4%)	4 (0.7%)
Intestinal Obstruction	1 (0.4%)	3 (1.1%)	4 (0.7%)
Melaena	1 (0.4%)	3 (1.1%)	4 (0.7%)
Peptic Ulcer	2 (0.7%)	2 (0.7%)	4 (0.7%)
Diverticulum Intestinal	1 (0.4%)	2 (0.7%)	3 (0.5%)
Dumping Syndrome	0	3 (1.1%)	3 (0.5%)
Irritable Bowel Syndrome	0	3 (1.1%)	3 (0.5%)
Large Intestine Polyp	3 (1.1%)	0	3 (0.5%)
Barrett's Oesophagus	2 (0.7%)	0	2 (0.4%)
Colitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Duodenal Ulcer	2 (0.7%)	0	2 (0.4%)
Haematochezia	0	2 (0.7%)	2 (0.4%)
Odynophagia	0	2 (0.7%)	2 (0.4%)
Oesophagitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper Gastrointestinal Haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Hernia	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Anal Fistula	1 (0.4%)	0	1 (0.2%)
Anal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Aphthous Ulcer	0	1 (0.4%)	1 (0.2%)
Diaphragmatic Hernia	0	1 (0.4%)	1 (0.2%)
Discoloured Vomit	0	1 (0.4%)	1 (0.2%)
Dry Mouth	0	1 (0.4%)	1 (0.2%)
Duodenitis	1 (0.4%)	0	1 (0.2%)
Epigastric Discomfort	1 (0.4%)	0	1 (0.2%)
Gastritis Erosive	0	1 (0.4%)	1 (0.2%)
Gastritis Hypertrophic	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Hyperchlorhydria	1 (0.4%)	0	1 (0.2%)
Impaired Gastric Emptying	0	1 (0.4%)	1 (0.2%)
Intestinal Cyst	1 (0.4%)	0	1 (0.2%)
Obstruction Gastric	0	1 (0.4%)	1 (0.2%)
Pancreatic Failure	1 (0.4%)	0	1 (0.2%)
Pancreatitis Acute	1 (0.4%)	0	1 (0.2%)
Proctalgia	1 (0.4%)	0	1 (0.2%)
Proctitis Ulcerative	1 (0.4%)	0	1 (0.2%)
Pylorospasm	0	1 (0.4%)	1 (0.2%)
Rectal Polyp	1 (0.4%)	0	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Retching	0	1 (0.4%)	1 (0.2%)
Subileus	1 (0.4%)	0	1 (0.2%)
Tongue Coated	1 (0.4%)	0	1 (0.2%)
Toothache	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
General Disorders And Administration Site Conditions	46 (16.3%)	55 (19.5%)	101 (17.9%)
Fatigue	23 (8.1%)	32 (11.3%)	55 (9.7%)
Asthenia	6 (2.1%)	8 (2.8%)	14 (2.5%)
Early Satiety	4 (1.4%)	5 (1.8%)	9 (1.6%)
Pain	5 (1.8%)	3 (1.1%)	8 (1.4%)
Chest Pain	1 (0.4%)	5 (1.8%)	6 (1.1%)
Non-Cardiac Chest Pain	3 (1.1%)	3 (1.1%)	6 (1.1%)
Oedema Peripheral	4 (1.4%)	2 (0.7%)	6 (1.1%)
Pyrexia	3 (1.1%)	2 (0.7%)	5 (0.9%)
Hernia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Malaise	1 (0.4%)	2 (0.7%)	3 (0.5%)
Catheter Site Pain	0	2 (0.7%)	2 (0.4%)
Medical Device Pain	2 (0.7%)	0	2 (0.4%)
Chills	0	1 (0.4%)	1 (0.2%)
Complication Associated With Device	1 (0.4%)	0	1 (0.2%)
Granuloma	1 (0.4%)	0	1 (0.2%)
Impaired Healing	0	1 (0.4%)	1 (0.2%)
Localised Oedema	1 (0.4%)	0	1 (0.2%)
Peripheral Swelling	0	1 (0.4%)	1 (0.2%)
Swelling	1 (0.4%)	0	1 (0.2%)
Temperature Intolerance	0	1 (0.4%)	1 (0.2%)
Hepatobiliary Disorders	17 (6.0%)	9 (3.2%)	26 (4.6%)
Cholelithiasis	4 (1.4%)	2 (0.7%)	6 (1.1%)
Cholecystitis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatic Function Abnormal	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatic Steatosis	2 (0.7%)	1 (0.4%)	3 (0.5%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Hepatic Cyst	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bile Duct Stone	1 (0.4%)	0	1 (0.2%)
Biliary Dilatation	1 (0.4%)	0	1 (0.2%)
Biliary Obstruction	1 (0.4%)	0	1 (0.2%)
Gallbladder Polyp	1 (0.4%)	0	1 (0.2%)
Hepatic Cirrhosis	0	1 (0.4%)	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	1 (0.4%)	0	1 (0.2%)
Non-Alcoholic Fatty Liver	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	12 (4.2%)	18 (6.4%)	30 (5.3%)
Drug Hypersensitivity	5 (1.8%)	7 (2.5%)	12 (2.1%)
Seasonal Allergy	5 (1.8%)	7 (2.5%)	12 (2.1%)
Hypersensitivity	1 (0.4%)	1 (0.4%)	2 (0.4%)
Allergy To Animal	0	1 (0.4%)	1 (0.2%)
Allergy To Arthropod Sting	0	1 (0.4%)	1 (0.2%)
Food Allergy	0	1 (0.4%)	1 (0.2%)
Hypogammaglobulinaemia	1 (0.4%)	0	1 (0.2%)
Immunodeficiency Common Variable	1 (0.4%)	0	1 (0.2%)
Mite Allergy	0	1 (0.4%)	1 (0.2%)
Rubber Sensitivity	0	1 (0.4%)	1 (0.2%)
Infections And Infestations	38 (13.4%)	31 (11.0%)	69 (12.2%)
Helicobacter Infection	4 (1.4%)	4 (1.4%)	8 (1.4%)
Upper Respiratory Tract Infection	1 (0.4%)	4 (1.4%)	5 (0.9%)
Urinary Tract Infection	3 (1.1%)	2 (0.7%)	5 (0.9%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Helicobacter Gastritis	4 (1.4%)	0	4 (0.7%)
Pneumonia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Bronchitis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatitis A	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatitis B	3 (1.1%)	0	3 (0.5%)
Pulmonary Tuberculosis	3 (1.1%)	0	3 (0.5%)
Chronic Sinusitis	0	2 (0.7%)	2 (0.4%)
Covid-19	1 (0.4%)	1 (0.4%)	2 (0.4%)
Meningitis Viral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rhinitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tuberculosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Abscess	1 (0.4%)	0	1 (0.2%)
Appendicitis	1 (0.4%)	0	1 (0.2%)
Appendicitis Perforated	0	1 (0.4%)	1 (0.2%)
Cellulitis	0	1 (0.4%)	1 (0.2%)
Citrobacter Sepsis	1 (0.4%)	0	1 (0.2%)
Conjunctivitis	1 (0.4%)	0	1 (0.2%)
Covid-19 Pneumonia	0	1 (0.4%)	1 (0.2%)
Cryptococcosis	0	1 (0.4%)	1 (0.2%)
Device Related Infection	0	1 (0.4%)	1 (0.2%)
Encephalitis Viral	0	1 (0.4%)	1 (0.2%)
Endocarditis	0	1 (0.4%)	1 (0.2%)
Enterobacter Infection	1 (0.4%)	0	1 (0.2%)
Epiglottitis	0	1 (0.4%)	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Candidiasis	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Herpes Simplex	0	1 (0.4%)	1 (0.2%)
Infected Dermal Cyst	0	1 (0.4%)	1 (0.2%)
Infective Aneurysm	0	1 (0.4%)	1 (0.2%)
Labyrinthitis	1 (0.4%)	0	1 (0.2%)
Nasopharyngitis	0	1 (0.4%)	1 (0.2%)
Onychomycosis	0	1 (0.4%)	1 (0.2%)
Oral Candidiasis	0	1 (0.4%)	1 (0.2%)
Oral Herpes	0	1 (0.4%)	1 (0.2%)
Papilloma Viral Infection	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Peritonitis	0	1 (0.4%)	1 (0.2%)
Peritonsillar Abscess	0	1 (0.4%)	1 (0.2%)
Pilonidal Disease	1 (0.4%)	0	1 (0.2%)
Pyelonephritis Acute	1 (0.4%)	0	1 (0.2%)
Sinusitis	0	1 (0.4%)	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Viral Hepatitis Carrier	0	1 (0.4%)	1 (0.2%)
Viral Myocarditis	0	1 (0.4%)	1 (0.2%)
Injury, Poisoning And Procedural Complications	13 (4.6%)	18 (6.4%)	31 (5.5%)
Procedural Pain	3 (1.1%)	2 (0.7%)	5 (0.9%)
Gun Shot Wound	0	3 (1.1%)	3 (0.5%)
Stoma Site Pain	1 (0.4%)	2 (0.7%)	3 (0.5%)
Upper Limb Fracture	2 (0.7%)	1 (0.4%)	3 (0.5%)
Ankle Fracture	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fibula Fracture	2 (0.7%)	0	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Scar	2 (0.7%)	0	2 (0.4%)
Anastomotic Complication	0	1 (0.4%)	1 (0.2%)
Aortic Injury	0	1 (0.4%)	1 (0.2%)
Bone Contusion	1 (0.4%)	0	1 (0.2%)
Contusion	0	1 (0.4%)	1 (0.2%)
Exposure To Chemical Pollution	0	1 (0.4%)	1 (0.2%)
Exposure To Radiation	0	1 (0.4%)	1 (0.2%)
Femur Fracture	1 (0.4%)	0	1 (0.2%)
Foot Fracture	0	1 (0.4%)	1 (0.2%)
Head Injury	0	1 (0.4%)	1 (0.2%)
Infusion Related Reaction	0	1 (0.4%)	1 (0.2%)
Joint Dislocation	0	1 (0.4%)	1 (0.2%)
Meniscus Injury	1 (0.4%)	0	1 (0.2%)
Reactive Gastropathy	1 (0.4%)	0	1 (0.2%)
Rib Fracture	0	1 (0.4%)	1 (0.2%)
Skin Abrasion	0	1 (0.4%)	1 (0.2%)
Spinal Compression Fracture	1 (0.4%)	0	1 (0.2%)
Tibia Fracture	1 (0.4%)	0	1 (0.2%)
Wound Complication	0	1 (0.4%)	1 (0.2%)
Investigations	25 (8.8%)	39 (13.8%)	64 (11.3%)
Weight Decreased	12 (4.2%)	20 (7.1%)	32 (5.7%)
Alanine Aminotransferase Increased	2 (0.7%)	4 (1.4%)	6 (1.1%)
Blood Cholesterol Increased	3 (1.1%)	3 (1.1%)	6 (1.1%)
Aspartate Aminotransferase Increased	2 (0.7%)	3 (1.1%)	5 (0.9%)
Blood Alkaline Phosphatase Increased	2 (0.7%)	3 (1.1%)	5 (0.9%)
Arthroscopy	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Blood Creatinine Increased	0	2 (0.7%)	2 (0.4%)
Cardiac Murmur	0	2 (0.7%)	2 (0.4%)
Lymphocyte Count Decreased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oesophagogastroduodenoscopy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Biopsy Fallopian Tube	0	1 (0.4%)	1 (0.2%)
Blood Bilirubin Increased	1 (0.4%)	0	1 (0.2%)
Blood Creatinine Decreased	0	1 (0.4%)	1 (0.2%)
Blood Testosterone Decreased	0	1 (0.4%)	1 (0.2%)
Creatinine Renal Clearance Decreased	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Abnormal	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Q Wave Abnormal	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Qt Prolonged	1 (0.4%)	0	1 (0.2%)
Endoscopic Retrograde Cholangiopancreatography	1 (0.4%)	0	1 (0.2%)
Gamma-Glutamyltransferase Increased	0	1 (0.4%)	1 (0.2%)
Glomerular Filtration Rate Decreased	1 (0.4%)	0	1 (0.2%)
Haemoglobin Decreased	1 (0.4%)	0	1 (0.2%)
Helicobacter Test Positive	1 (0.4%)	0	1 (0.2%)
Neutrophil Count Increased	0	1 (0.4%)	1 (0.2%)
Occult Blood	0	1 (0.4%)	1 (0.2%)
Occult Blood Positive	1 (0.4%)	0	1 (0.2%)
Oesophagogastroscopy	0	1 (0.4%)	1 (0.2%)
Platelet Count Decreased	1 (0.4%)	0	1 (0.2%)
Platelet Count Increased	0	1 (0.4%)	1 (0.2%)
Prostatic Specific Antigen Increased	0	1 (0.4%)	1 (0.2%)
Protein Urine Present	0	1 (0.4%)	1 (0.2%)
Stress Echocardiogram Abnormal	0	1 (0.4%)	1 (0.2%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
White Blood Cell Count Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count Increased	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	103 (36.4%)	107 (37.9%)	210 (37.2%)
Decreased Appetite	32 (11.3%)	35 (12.4%)	67 (11.9%)
Diabetes Mellitus	22 (7.8%)	23 (8.2%)	45 (8.0%)
Hyperlipidaemia	16 (5.7%)	19 (6.7%)	35 (6.2%)
Dyslipidaemia	13 (4.6%)	16 (5.7%)	29 (5.1%)
Type 2 Diabetes Mellitus	13 (4.6%)	14 (5.0%)	27 (4.8%)
Hypercholesterolaemia	10 (3.5%)	11 (3.9%)	21 (3.7%)
Gout	4 (1.4%)	5 (1.8%)	9 (1.6%)
Hyperuricaemia	4 (1.4%)	5 (1.8%)	9 (1.6%)
Hypoalbuminaemia	7 (2.5%)	2 (0.7%)	9 (1.6%)
Glucose Tolerance Impaired	2 (0.7%)	4 (1.4%)	6 (1.1%)
Vitamin D Deficiency	3 (1.1%)	3 (1.1%)	6 (1.1%)
Hyperglycaemia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Hypokalaemia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Obesity	0	4 (1.4%)	4 (0.7%)
Dehydration	1 (0.4%)	2 (0.7%)	3 (0.5%)
Lactose Intolerance	2 (0.7%)	1 (0.4%)	3 (0.5%)
Vitamin B12 Deficiency	0	3 (1.1%)	3 (0.5%)
Abnormal Loss Of Weight	0	2 (0.7%)	2 (0.4%)
Hypoglycaemia	0	2 (0.7%)	2 (0.4%)
Hypomagnesaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyponatraemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Impaired Fasting Glucose	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cachexia	1 (0.4%)	0	1 (0.2%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Hypercalcaemia	0	1 (0.4%)	1 (0.2%)
Hyperkalaemia	1 (0.4%)	0	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypocalcaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	1 (0.4%)	0	1 (0.2%)
Hypotriglyceridaemia	0	1 (0.4%)	1 (0.2%)
Iron Deficiency	0	1 (0.4%)	1 (0.2%)
Malnutrition	0	1 (0.4%)	1 (0.2%)
Type 1 Diabetes Mellitus	1 (0.4%)	0	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	58 (20.5%)	60 (21.3%)	118 (20.9%)
Back Pain	19 (6.7%)	21 (7.4%)	40 (7.1%)
Arthralgia	9 (3.2%)	5 (1.8%)	14 (2.5%)
Osteoarthritis	5 (1.8%)	6 (2.1%)	11 (1.9%)
Intervertebral Disc Protrusion	5 (1.8%)	3 (1.1%)	8 (1.4%)
Osteoporosis	3 (1.1%)	5 (1.8%)	8 (1.4%)
Spinal Osteoarthritis	3 (1.1%)	4 (1.4%)	7 (1.2%)
Spinal Pain	4 (1.4%)	2 (0.7%)	6 (1.1%)
Arthritis	1 (0.4%)	4 (1.4%)	5 (0.9%)
Neck Pain	1 (0.4%)	4 (1.4%)	5 (0.9%)
Musculoskeletal Pain	2 (0.7%)	2 (0.7%)	4 (0.7%)
Spinal Stenosis	3 (1.1%)	1 (0.4%)	4 (0.7%)
Fibromyalgia	0	3 (1.1%)	3 (0.5%)
Lumbar Spinal Stenosis	1 (0.4%)	2 (0.7%)	3 (0.5%)
Pain In Extremity	2 (0.7%)	1 (0.4%)	3 (0.5%)
Bone Pain	2 (0.7%)	0	2 (0.4%)
Flank Pain	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Joint Swelling	2 (0.7%)	0	2 (0.4%)
Muscle Spasms	1 (0.4%)	1 (0.4%)	2 (0.4%)
Musculoskeletal Chest Pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Myalgia	0	2 (0.7%)	2 (0.4%)
Rheumatoid Arthritis	2 (0.7%)	0	2 (0.4%)
Tendonitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ankylosing Spondylitis	1 (0.4%)	0	1 (0.2%)
Bursitis	0	1 (0.4%)	1 (0.2%)
Cervical Spinal Stenosis	0	1 (0.4%)	1 (0.2%)
Chondrocalcinosis	0	1 (0.4%)	1 (0.2%)
Diffuse Idiopathic Skeletal Hyperostosis	0	1 (0.4%)	1 (0.2%)
Dupuytren's Contracture	1 (0.4%)	0	1 (0.2%)
Exostosis	0	1 (0.4%)	1 (0.2%)
Gouty Arthritis	0	1 (0.4%)	1 (0.2%)
Greater Trochanteric Pain Syndrome	1 (0.4%)	0	1 (0.2%)
Intervertebral Disc Degeneration	0	1 (0.4%)	1 (0.2%)
Mobility Decreased	1 (0.4%)	0	1 (0.2%)
Muscular Weakness	0	1 (0.4%)	1 (0.2%)
Musculoskeletal Discomfort	0	1 (0.4%)	1 (0.2%)
Periarthritis	0	1 (0.4%)	1 (0.2%)
Polymyalgia Rheumatica	1 (0.4%)	0	1 (0.2%)
Rotator Cuff Syndrome	1 (0.4%)	0	1 (0.2%)
Sjogren's Syndrome	1 (0.4%)	0	1 (0.2%)
Spondylolisthesis	1 (0.4%)	0	1 (0.2%)
Spondylolysis	0	1 (0.4%)	1 (0.2%)
Temporomandibular Joint Syndrome	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Thoracic Spinal Stenosis	0	1 (0.4%)	1 (0.2%)
Trigger Finger	0	1 (0.4%)	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	33 (11.7%)	37 (13.1%)	70 (12.4%)
Tumour Pain	4 (1.4%)	4 (1.4%)	8 (1.4%)
Prostate Cancer	2 (0.7%)	5 (1.8%)	7 (1.2%)
Basal Cell Carcinoma	3 (1.1%)	2 (0.7%)	5 (0.9%)
Breast Cancer	3 (1.1%)	2 (0.7%)	5 (0.9%)
Cancer Pain	2 (0.7%)	2 (0.7%)	4 (0.7%)
Colorectal Adenoma	1 (0.4%)	3 (1.1%)	4 (0.7%)
Colon Cancer	1 (0.4%)	2 (0.7%)	3 (0.5%)
Malignant Ascites	1 (0.4%)	2 (0.7%)	3 (0.5%)
Uterine Leiomyoma	1 (0.4%)	2 (0.7%)	3 (0.5%)
Acrochordon	1 (0.4%)	1 (0.4%)	2 (0.4%)
Benign Ovarian Tumour	0	2 (0.7%)	2 (0.4%)
Bladder Transitional Cell Carcinoma	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gastric Cancer	2 (0.7%)	0	2 (0.4%)
Squamous Cell Carcinoma Of Skin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Adenocarcinoma Gastric	0	1 (0.4%)	1 (0.2%)
Benign Neoplasm Of Bladder	1 (0.4%)	0	1 (0.2%)
Benign Neoplasm Of Optic Nerve	1 (0.4%)	0	1 (0.2%)
Benign Neoplasm Of Thyroid Gland	0	1 (0.4%)	1 (0.2%)
Benign Pancreatic Neoplasm	0	1 (0.4%)	1 (0.2%)
Benign Salivary Gland Neoplasm	0	1 (0.4%)	1 (0.2%)
Bowen's Disease	0	1 (0.4%)	1 (0.2%)
Carcinoid Tumour Pulmonary	0	1 (0.4%)	1 (0.2%)
Cardiac Valve Fibroelastoma	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Cervix Carcinoma	1 (0.4%)	0	1 (0.2%)
Fibroadenoma Of Breast	0	1 (0.4%)	1 (0.2%)
Fibroma	1 (0.4%)	0	1 (0.2%)
Haemangioma	1 (0.4%)	0	1 (0.2%)
Haemangioma Of Liver	1 (0.4%)	0	1 (0.2%)
Haemangioma Of Skin	0	1 (0.4%)	1 (0.2%)
Hodgkin's Disease	1 (0.4%)	0	1 (0.2%)
Invasive Ductal Breast Carcinoma	1 (0.4%)	0	1 (0.2%)
Laryngeal Cancer	0	1 (0.4%)	1 (0.2%)
Leiomyoma	0	1 (0.4%)	1 (0.2%)
Malignant Melanoma	1 (0.4%)	0	1 (0.2%)
Melanocytic Naevus	0	1 (0.4%)	1 (0.2%)
Neuroendocrine Tumour	1 (0.4%)	0	1 (0.2%)
Neuroma	1 (0.4%)	0	1 (0.2%)
Non-Hodgkin's Lymphoma	0	1 (0.4%)	1 (0.2%)
Osteochondroma	0	1 (0.4%)	1 (0.2%)
Papillary Thyroid Cancer	1 (0.4%)	0	1 (0.2%)
Pericardial Effusion Malignant	1 (0.4%)	0	1 (0.2%)
Pituitary Tumour	1 (0.4%)	0	1 (0.2%)
Pyogenic Granuloma	0	1 (0.4%)	1 (0.2%)
Rectal Adenocarcinoma	1 (0.4%)	0	1 (0.2%)
Rectal Cancer	0	1 (0.4%)	1 (0.2%)
Renal Cancer	0	1 (0.4%)	1 (0.2%)
Seborrhoeic Keratosis	0	1 (0.4%)	1 (0.2%)
Squamous Cell Carcinoma	0	1 (0.4%)	1 (0.2%)
Testis Cancer	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Nervous System Disorders	36 (12.7%)	38 (13.5%)	74 (13.1%)
Peripheral Sensory Neuropathy	5 (1.8%)	5 (1.8%)	10 (1.8%)
Epilepsy	5 (1.8%)	3 (1.1%)	8 (1.4%)
Headache	4 (1.4%)	4 (1.4%)	8 (1.4%)
Neuropathy Peripheral	3 (1.1%)	3 (1.1%)	6 (1.1%)
Carpal Tunnel Syndrome	2 (0.7%)	3 (1.1%)	5 (0.9%)
Migraine	3 (1.1%)	2 (0.7%)	5 (0.9%)
Transient Ischaemic Attack	2 (0.7%)	2 (0.7%)	4 (0.7%)
Diabetic Neuropathy	2 (0.7%)	1 (0.4%)	3 (0.5%)
Dizziness	2 (0.7%)	1 (0.4%)	3 (0.5%)
Paraesthesia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Sciatica	1 (0.4%)	2 (0.7%)	3 (0.5%)
Carotid Arteriosclerosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebral Infarction	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebrovascular Accident	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysgeusia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Memory Impairment	0	2 (0.7%)	2 (0.4%)
Nerve Compression	0	2 (0.7%)	2 (0.4%)
Neuralgia	0	2 (0.7%)	2 (0.4%)
Polyneuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tremor	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anosmia	0	1 (0.4%)	1 (0.2%)
Ataxia	1 (0.4%)	0	1 (0.2%)
Cerebellar Infarction	0	1 (0.4%)	1 (0.2%)
Cerebral Small Vessel Ischaemic Disease	0	1 (0.4%)	1 (0.2%)
Cerebral Venous Sinus Thrombosis	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Dystonia	0	1 (0.4%)	1 (0.2%)
Hypoaesthesia	0	1 (0.4%)	1 (0.2%)
Ischaemic Stroke	1 (0.4%)	0	1 (0.2%)
Myelopathy	0	1 (0.4%)	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Occipital Neuralgia	0	1 (0.4%)	1 (0.2%)
Parkinson's Disease	0	1 (0.4%)	1 (0.2%)
Periodic Limb Movement Disorder	0	1 (0.4%)	1 (0.2%)
Peripheral Motor Neuropathy	1 (0.4%)	0	1 (0.2%)
Peripheral Sensorimotor Neuropathy	0	1 (0.4%)	1 (0.2%)
Peroneal Nerve Palsy	0	1 (0.4%)	1 (0.2%)
Sensory Disturbance	1 (0.4%)	0	1 (0.2%)
Vocal Cord Paresis	0	1 (0.4%)	1 (0.2%)
Pregnancy, Puerperium And Perinatal Conditions	2 (0.7%)	2 (0.7%)	4 (0.7%)
Abortion Spontaneous	1 (0.4%)	0	1 (0.2%)
Abortion Spontaneous Incomplete	0	1 (0.4%)	1 (0.2%)
Cervical Incompetence	1 (0.4%)	0	1 (0.2%)
Delivery	1 (0.4%)	0	1 (0.2%)
Ectopic Pregnancy	0	1 (0.4%)	1 (0.2%)
Gestational Hypertension	1 (0.4%)	0	1 (0.2%)
Postpartum Haemorrhage	0	1 (0.4%)	1 (0.2%)
Product Issues	0	1 (0.4%)	1 (0.2%)
Thrombosis In Device	0	1 (0.4%)	1 (0.2%)
Psychiatric Disorders	51 (18.0%)	59 (20.9%)	110 (19.5%)
Anxiety	16 (5.7%)	30 (10.6%)	46 (8.1%)
Insomnia	17 (6.0%)	28 (9.9%)	45 (8.0%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Depression	16 (5.7%)	11 (3.9%)	27 (4.8%)
Alcoholism	2 (0.7%)	1 (0.4%)	3 (0.5%)
Tobacco Abuse	2 (0.7%)	1 (0.4%)	3 (0.5%)
Mixed Anxiety And Depressive Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nicotine Dependence	2 (0.7%)	0	2 (0.4%)
Adjustment Disorder	1 (0.4%)	0	1 (0.2%)
Affective Disorder	1 (0.4%)	0	1 (0.2%)
Alcohol Abuse	1 (0.4%)	0	1 (0.2%)
Alcohol Withdrawal Syndrome	1 (0.4%)	0	1 (0.2%)
Anticipatory Anxiety	0	1 (0.4%)	1 (0.2%)
Anxiety Disorder	0	1 (0.4%)	1 (0.2%)
Bipolar Disorder	0	1 (0.4%)	1 (0.2%)
Bruxism	0	1 (0.4%)	1 (0.2%)
Depressed Mood	1 (0.4%)	0	1 (0.2%)
Major Depression	0	1 (0.4%)	1 (0.2%)
Panic Attack	0	1 (0.4%)	1 (0.2%)
Post-Traumatic Stress Disorder	1 (0.4%)	0	1 (0.2%)
Stress	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	27 (9.5%)	28 (9.9%)	55 (9.7%)
Hydronephrosis	3 (1.1%)	7 (2.5%)	10 (1.8%)
Nephrolithiasis	5 (1.8%)	4 (1.4%)	9 (1.6%)
Dysuria	3 (1.1%)	4 (1.4%)	7 (1.2%)
Renal Cyst	3 (1.1%)	4 (1.4%)	7 (1.2%)
Acute Kidney Injury	1 (0.4%)	2 (0.7%)	3 (0.5%)
Chronic Kidney Disease	0	3 (1.1%)	3 (0.5%)
Pollakiuria	1 (0.4%)	2 (0.7%)	3 (0.5%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Proteinuria	2 (0.7%)	1 (0.4%)	3 (0.5%)
Ureterolithiasis	3 (1.1%)	0	3 (0.5%)
Calculus Urinary	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haematuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypertonic Bladder	2 (0.7%)	0	2 (0.4%)
Nocturia	0	2 (0.7%)	2 (0.4%)
Urinary Retention	2 (0.7%)	0	2 (0.4%)
Urinary Tract Obstruction	0	2 (0.7%)	2 (0.4%)
Bladder Obstruction	1 (0.4%)	0	1 (0.2%)
Bladder Spasm	0	1 (0.4%)	1 (0.2%)
Calculus Bladder	0	1 (0.4%)	1 (0.2%)
Cystitis Glandularis	1 (0.4%)	0	1 (0.2%)
Renal Impairment	1 (0.4%)	0	1 (0.2%)
Renal Pain	0	1 (0.4%)	1 (0.2%)
Stress Urinary Incontinence	0	1 (0.4%)	1 (0.2%)
Ureteric Obstruction	1 (0.4%)	0	1 (0.2%)
Urge Incontinence	0	1 (0.4%)	1 (0.2%)
Reproductive System And Breast Disorders	25 (8.8%)	34 (12.1%)	59 (10.4%)
Benign Prostatic Hyperplasia	16 (5.7%)	16 (5.7%)	32 (5.7%)
Erectile Dysfunction	3 (1.1%)	5 (1.8%)	8 (1.4%)
Pelvic Pain	1 (0.4%)	3 (1.1%)	4 (0.7%)
Ovarian Cyst	2 (0.7%)	1 (0.4%)	3 (0.5%)
Prostatomegaly	0	3 (1.1%)	3 (0.5%)
Adenomyosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Prostatic Calcification	0	2 (0.7%)	2 (0.4%)
Breast Cyst	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Cervical Dysplasia	1 (0.4%)	0	1 (0.2%)
Endometrial Hyperplasia	1 (0.4%)	0	1 (0.2%)
Female Genital Tract Fistula	0	1 (0.4%)	1 (0.2%)
Menstruation Irregular	0	1 (0.4%)	1 (0.2%)
Penile Pain	1 (0.4%)	0	1 (0.2%)
Polycystic Ovaries	1 (0.4%)	0	1 (0.2%)
Sexual Dysfunction	0	1 (0.4%)	1 (0.2%)
Testicular Atrophy	0	1 (0.4%)	1 (0.2%)
Vaginal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Vulvovaginal Dryness	0	1 (0.4%)	1 (0.2%)
Vulvovaginal Pruritus	0	1 (0.4%)	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	47 (16.6%)	49 (17.4%)	96 (17.0%)
Cough	7 (2.5%)	13 (4.6%)	20 (3.5%)
Asthma	9 (3.2%)	8 (2.8%)	17 (3.0%)
Dyspnoea	9 (3.2%)	6 (2.1%)	15 (2.7%)
Chronic Obstructive Pulmonary Disease	6 (2.1%)	7 (2.5%)	13 (2.3%)
Rhinitis Allergic	8 (2.8%)	4 (1.4%)	12 (2.1%)
Pulmonary Embolism	4 (1.4%)	5 (1.8%)	9 (1.6%)
Pleural Effusion	2 (0.7%)	4 (1.4%)	6 (1.1%)
Obstructive Sleep Apnoea Syndrome	2 (0.7%)	2 (0.7%)	4 (0.7%)
Pneumothorax	0	4 (1.4%)	4 (0.7%)
Pulmonary Mass	1 (0.4%)	3 (1.1%)	4 (0.7%)
Sleep Apnoea Syndrome	2 (0.7%)	2 (0.7%)	4 (0.7%)
Bronchiectasis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Emphysema	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hiccups	3 (1.1%)	0	3 (0.5%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Rhinorrhoea	2 (0.7%)	1 (0.4%)	3 (0.5%)
Atelectasis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphonia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dyspnoea Exertional	0	2 (0.7%)	2 (0.4%)
Nasal Polyps	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinus Congestion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper-Airway Cough Syndrome	2 (0.7%)	0	2 (0.4%)
Allergic Sinusitis	1 (0.4%)	0	1 (0.2%)
Nasal Cavity Mass	1 (0.4%)	0	1 (0.2%)
Nasal Congestion	0	1 (0.4%)	1 (0.2%)
Nasal Septum Deviation	0	1 (0.4%)	1 (0.2%)
Obstructive Airways Disorder	1 (0.4%)	0	1 (0.2%)
Pleuritic Pain	0	1 (0.4%)	1 (0.2%)
Pneumonitis	0	1 (0.4%)	1 (0.2%)
Pulmonary Congestion	0	1 (0.4%)	1 (0.2%)
Pulmonary Hypertension	0	1 (0.4%)	1 (0.2%)
Pulmonary Thrombosis	0	1 (0.4%)	1 (0.2%)
Rhinitis Hypertrophic	0	1 (0.4%)	1 (0.2%)
Wheezing	1 (0.4%)	0	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	14 (4.9%)	24 (8.5%)	38 (6.7%)
Psoriasis	2 (0.7%)	5 (1.8%)	7 (1.2%)
Dry Skin	1 (0.4%)	5 (1.8%)	6 (1.1%)
Eczema	1 (0.4%)	4 (1.4%)	5 (0.9%)
Pruritus	1 (0.4%)	3 (1.1%)	4 (0.7%)
Actinic Keratosis	0	2 (0.7%)	2 (0.4%)
Alopecia	0	2 (0.7%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Dermatitis Atopic	2 (0.7%)	0	2 (0.4%)
Night Sweats	1 (0.4%)	1 (0.4%)	2 (0.4%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.7%)	0	2 (0.4%)
Skin Lesion	0	2 (0.7%)	2 (0.4%)
Alopecia Areata	1 (0.4%)	0	1 (0.2%)
Dermatitis	0	1 (0.4%)	1 (0.2%)
Hand Dermatitis	1 (0.4%)	0	1 (0.2%)
Hyperhidrosis	0	1 (0.4%)	1 (0.2%)
Itching Scar	0	1 (0.4%)	1 (0.2%)
Lipohypertrophy	0	1 (0.4%)	1 (0.2%)
Rash	1 (0.4%)	0	1 (0.2%)
Seborrhoea	0	1 (0.4%)	1 (0.2%)
Skin Mass	1 (0.4%)	0	1 (0.2%)
Skin Ulcer	1 (0.4%)	0	1 (0.2%)
Vitiligo	1 (0.4%)	0	1 (0.2%)
Social Circumstances	8 (2.8%)	8 (2.8%)	16 (2.8%)
Ex-Tobacco User	4 (1.4%)	1 (0.4%)	5 (0.9%)
Tobacco User	1 (0.4%)	3 (1.1%)	4 (0.7%)
Alcohol Use	1 (0.4%)	2 (0.7%)	3 (0.5%)
Menopause	1 (0.4%)	2 (0.7%)	3 (0.5%)
Social Alcohol Drinker	0	3 (1.1%)	3 (0.5%)
Postmenopause	2 (0.7%)	0	2 (0.4%)
Surgical And Medical Procedures	40 (14.1%)	50 (17.7%)	90 (15.9%)
Appendicectomy	4 (1.4%)	11 (3.9%)	15 (2.7%)
Cholecystectomy	3 (1.1%)	6 (2.1%)	9 (1.6%)
Cataract Operation	1 (0.4%)	5 (1.8%)	6 (1.1%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Gastrectomy	4 (1.4%)	2 (0.7%)	6 (1.1%)
Hysterectomy	2 (0.7%)	3 (1.1%)	5 (0.9%)
Inguinal Hernia Repair	3 (1.1%)	1 (0.4%)	4 (0.7%)
Polypectomy	1 (0.4%)	3 (1.1%)	4 (0.7%)
Caesarean Section	1 (0.4%)	2 (0.7%)	3 (0.5%)
Haemorrhoid Operation	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hysterosalpingo-Oophorectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Intervertebral Disc Operation	1 (0.4%)	2 (0.7%)	3 (0.5%)
Knee Operation	1 (0.4%)	2 (0.7%)	3 (0.5%)
Prostatectomy	2 (0.7%)	1 (0.4%)	3 (0.5%)
Salpingo-Oophorectomy Bilateral	2 (0.7%)	1 (0.4%)	3 (0.5%)
Splenectomy	3 (1.1%)	0	3 (0.5%)
Tonsillectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Vasectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Cardiac Pacemaker Insertion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Coronary Arterial Stent Insertion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hip Arthroplasty	2 (0.7%)	0	2 (0.4%)
Jejunostomy	0	2 (0.7%)	2 (0.4%)
Meniscus Operation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nephrostomy	2 (0.7%)	0	2 (0.4%)
Oesophageal Prosthesis Insertion	2 (0.7%)	0	2 (0.4%)
Oophorectomy	2 (0.7%)	0	2 (0.4%)
Salpingo-Oophorectomy Unilateral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Shoulder Operation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Thyroidectomy	0	2 (0.7%)	2 (0.4%)
Abdominoplasty	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Adenoidectomy	0	1 (0.4%)	1 (0.2%)
Amblyopia Therapy	0	1 (0.4%)	1 (0.2%)
Ankle Operation	0	1 (0.4%)	1 (0.2%)
Apicectomy	1 (0.4%)	0	1 (0.2%)
Bone Graft	0	1 (0.4%)	1 (0.2%)
Brachytherapy To Prostate	0	1 (0.4%)	1 (0.2%)
Brain Operation	0	1 (0.4%)	1 (0.2%)
Breast Conserving Surgery	1 (0.4%)	0	1 (0.2%)
Breast Cyst Excision	0	1 (0.4%)	1 (0.2%)
Cardiac Ablation	1 (0.4%)	0	1 (0.2%)
Central Venous Catheterisation	1 (0.4%)	0	1 (0.2%)
Colectomy	0	1 (0.4%)	1 (0.2%)
Colostomy	0	1 (0.4%)	1 (0.2%)
Coronary Artery Bypass	0	1 (0.4%)	1 (0.2%)
Female Sterilisation	0	1 (0.4%)	1 (0.2%)
Finger Amputation	0	1 (0.4%)	1 (0.2%)
Foot Operation	1 (0.4%)	0	1 (0.2%)
Gallbladder Operation	0	1 (0.4%)	1 (0.2%)
Gastric Bypass	1 (0.4%)	0	1 (0.2%)
Gastric Operation	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Tube Insertion	0	1 (0.4%)	1 (0.2%)
Haematopoietic Stem Cell Mobilisation	1 (0.4%)	0	1 (0.2%)
Hernia Repair	1 (0.4%)	0	1 (0.2%)
Implantable Defibrillator Insertion	0	1 (0.4%)	1 (0.2%)
Internal Fixation Of Fracture	1 (0.4%)	0	1 (0.2%)
Intraocular Lens Implant	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Knee Arthroplasty	0	1 (0.4%)	1 (0.2%)
Large Intestinal Polypectomy	0	1 (0.4%)	1 (0.2%)
Lens Extraction	0	1 (0.4%)	1 (0.2%)
Ligament Operation	0	1 (0.4%)	1 (0.2%)
Mammoplasty	1 (0.4%)	0	1 (0.2%)
Mass Excision	0	1 (0.4%)	1 (0.2%)
Mastectomy	0	1 (0.4%)	1 (0.2%)
Mitral Valve Replacement	0	1 (0.4%)	1 (0.2%)
Oesophagoenterostomy	0	1 (0.4%)	1 (0.2%)
Oophorectomy Bilateral	0	1 (0.4%)	1 (0.2%)
Open Reduction Of Fracture	0	1 (0.4%)	1 (0.2%)
Optic Nerve Operation	1 (0.4%)	0	1 (0.2%)
Pituitary Tumour Removal	1 (0.4%)	0	1 (0.2%)
Pleural Decortication	0	1 (0.4%)	1 (0.2%)
Proctectomy	1 (0.4%)	0	1 (0.2%)
Roux Loop Conversion	1 (0.4%)	0	1 (0.2%)
Salpingectomy	0	1 (0.4%)	1 (0.2%)
Skin Neoplasm Excision	1 (0.4%)	0	1 (0.2%)
Spinal Operation	1 (0.4%)	0	1 (0.2%)
Thrombosis Prophylaxis	1 (0.4%)	0	1 (0.2%)
Tooth Extraction	1 (0.4%)	0	1 (0.2%)
Transurethral Bladder Resection	1 (0.4%)	0	1 (0.2%)
Transurethral Prostatectomy	0	1 (0.4%)	1 (0.2%)
Tumour Excision	1 (0.4%)	0	1 (0.2%)
Umbilical Hernia Repair	0	1 (0.4%)	1 (0.2%)
Urethral Stent Insertion	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Wound Closure	0	1 (0.4%)	1 (0.2%)
Vascular Disorders	86 (30.4%)	97 (34.4%)	183 (32.4%)
Hypertension	80 (28.3%)	90 (31.9%)	170 (30.1%)
Deep Vein Thrombosis	2 (0.7%)	2 (0.7%)	4 (0.7%)
Hypotension	1 (0.4%)	3 (1.1%)	4 (0.7%)
Aortic Aneurysm	0	2 (0.7%)	2 (0.4%)
Peripheral Vascular Disorder	0	2 (0.7%)	2 (0.4%)
Peripheral Venous Disease	0	2 (0.7%)	2 (0.4%)
Phlebitis	0	2 (0.7%)	2 (0.4%)
Aortic Stenosis	0	1 (0.4%)	1 (0.2%)
Arteriosclerosis	1 (0.4%)	0	1 (0.2%)
Atheroembolism	0	1 (0.4%)	1 (0.2%)
Embolism Arterial	0	1 (0.4%)	1 (0.2%)
Essential Hypertension	0	1 (0.4%)	1 (0.2%)
Hot Flush	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)
Pelvic Venous Thrombosis	1 (0.4%)	0	1 (0.2%)
Raynaud's Phenomenon	1 (0.4%)	0	1 (0.2%)
Subclavian Artery Stenosis	0	1 (0.4%)	1 (0.2%)
Subclavian Vein Thrombosis	0	1 (0.4%)	1 (0.2%)
Varicose Vein	1 (0.4%)	0	1 (0.2%)
Vena Cava Thrombosis	1 (0.4%)	0	1 (0.2%)
Venous Thrombosis	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G4 Gesamtüberleben

1. Time-to-Event-Analyse

Table 301.1.1002.1.1: Summary of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	149 (52.7%)	177 (62.8%)	
Number of patients censored	134 (47.3%)	105 (37.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	18.2 [16.4, 22.9]	15.5 [13.5, 16.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.750 [0.601, 0.936]
Log-rank test			
Two-sided stratified log-rank p-value			0.0107

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.1.2: Type of Events and Censoring of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	149 (52.7%)	177 (62.8%)
Death Before Analysis Cutoff Date	149 (52.7%)	177 (62.8%)
Number of patients censored	134 (47.3%)	105 (37.2%)
Last Known Alive Date Is Before Cutoff Date	115 (40.6%)	85 (30.1%)
Censored At Cutoff Date	19 (6.7%)	20 (7.1%)

Abbreviations: N=number of patients.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.1.3: Summary of Overall Survival by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	89 (49.2)	20.2 [17.0, 23.8]	181	112 (61.9)	15.6 [13.5, 17.7]	0.741 [0.561, 0.980]	0.0348	0.9663
>65 years	102	60 (58.8)	16.2 [13.2, 19.8]	101	65 (64.4)	15.3 [10.4, 17.1]	0.761 [0.533, 1.086]	0.1308	
Age Group 2									
<=75 years	267	138 (51.7)	18.9 [16.7, 23.1]	260	165 (63.5)	15.5 [13.5, 16.5]	0.713 [0.568, 0.895]	0.0034	0.1660
>75 years	16	11 (68.8)	9.8 [8.5, 25.3]	22	12 (54.5)	15.6 [9.0, 35.1]	1.315 [0.578, 2.996]	0.5197	
Sex									
Male	176	98 (55.7)	17.4 [15.7, 19.8]	175	113 (64.6)	15.6 [12.2, 17.1]	0.760 [0.579, 0.999]	0.0492	0.7817
Female	107	51 (47.7)	23.8 [17.0, 25.3]	107	64 (59.8)	15.3 [11.6, 19.3]	0.726 [0.502, 1.049]	0.0854	
Race									
White	140	81 (57.9)	16.1 [12.5, 18.6]	134	81 (60.4)	15.3 [13.6, 17.1]	0.948 [0.696, 1.291]	0.7349	0.0550
Asian	96	49 (51.0)	23.3 [19.0, 28.6]	97	65 (67.0)	16.5 [13.1, 19.3]	0.572 [0.393, 0.832]	0.0031	
Tobacco History									
Current	26	15 (57.7)	19.4 [14.3, 23.8]	25	15 (60.0)	15.6 [10.4, 27.5]	0.819 [0.398, 1.686]	0.5866	0.6629
Former	113	64 (56.6)	17.8 [15.1, 24.8]	118	74 (62.7)	15.8 [13.7, 17.8]	0.807 [0.576, 1.131]	0.2123	
Never	142	70 (49.3)	19.0 [15.9, 24.1]	137	87 (63.5)	13.5 [10.7, 17.7]	0.678 [0.494, 0.930]	0.0151	
Region									
Asia	88	47 (53.4)	21.5 [17.7, 28.6]	89	59 (66.3)	17.7 [13.5, 19.7]	0.643 [0.437, 0.947]	0.0244	0.5099
Non-Asia	195	102 (52.3)	17.0 [13.5, 21.5]	193	118 (61.1)	13.7 [11.6, 15.8]	0.796 [0.610, 1.039]	0.0930	
Number of Organs with Metastatic Sites									
0-2	219	110 (50.2)	19.7 [17.0, 23.6]	219	129 (58.9)	15.8 [13.7, 19.0]	0.767 [0.594, 0.990]	0.0410	0.5739
>=3	64	39 (60.9)	16.4 [9.8, 19.4]	63	48 (76.2)	12.0 [9.5, 15.6]	0.670 [0.436, 1.030]	0.0664	
Prior Gastrectomy (total or partial)									
Yes	84	40 (47.6)	24.8 [19.0, 30.0]	82	52 (63.4)	15.7 [13.1, 19.7]	0.575 [0.380, 0.869]	0.0080	0.1607
No	199	109 (54.8)	17.0 [13.9, 18.9]	200	125 (62.5)	14.3 [11.9, 16.5]	0.839 [0.648, 1.086]	0.1807	

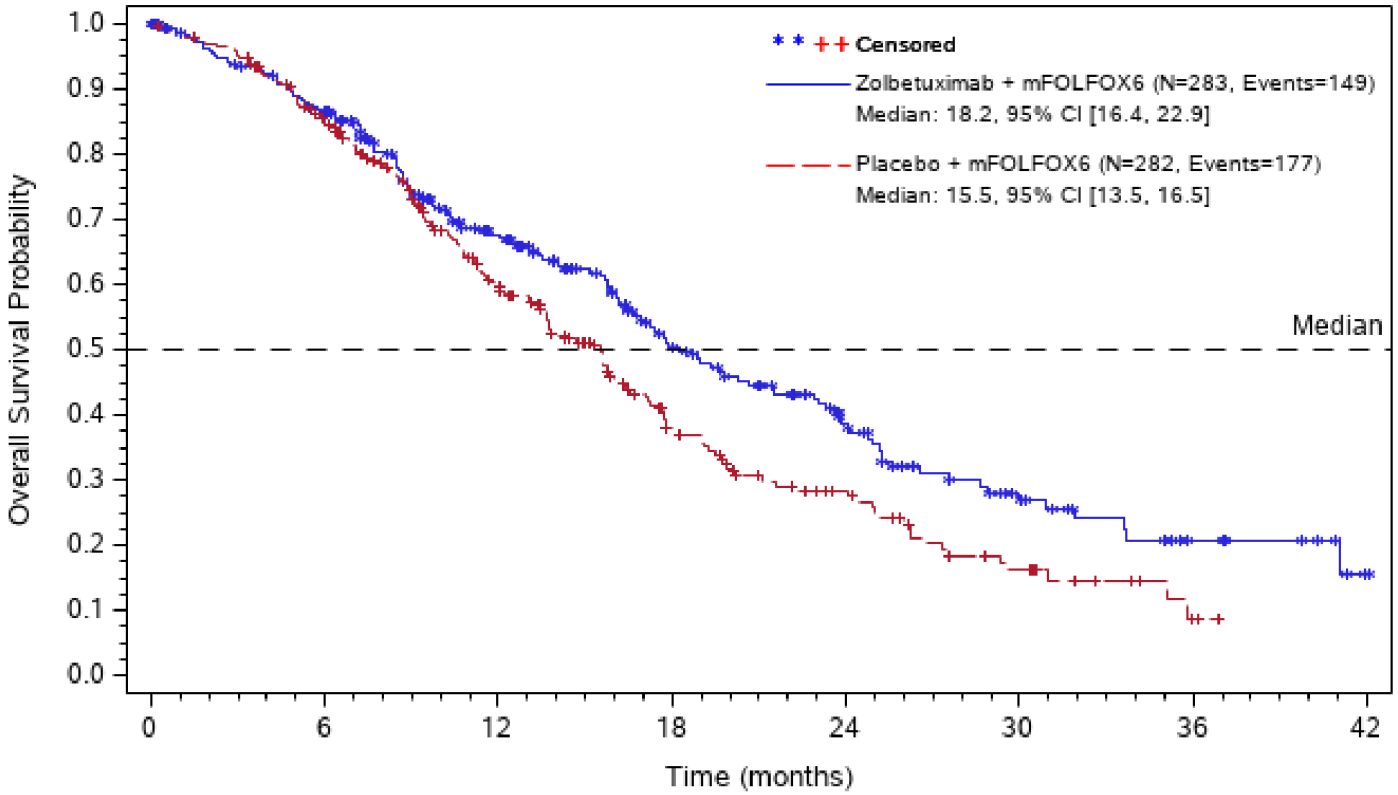
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	82	46 (56.1)	20.6 [17.5, 24.8]	117	75 (64.1)	15.8 [11.7, 19.0]	0.766 [0.530, 1.108]	0.1565	0.2257
Intestinal	70	38 (54.3)	22.9 [15.5, 28.9]	66	48 (72.7)	13.8 [10.3, 17.7]	0.552 [0.358, 0.851]	0.0063	
Mixed/Other	81	48 (59.3)	16.1 [10.4, 19.8]	55	34 (61.8)	14.7 [13.1, 19.5]	0.992 [0.638, 1.543]	0.9714	
Tumor Location 1									
Gastric	219	111 (50.7)	20.2 [17.0, 24.1]	210	135 (64.3)	13.8 [11.9, 16.5]	0.666 [0.517, 0.858]	0.0015	0.0766
GEJ	64	38 (59.4)	15.8 [11.7, 17.7]	72	42 (58.3)	16.4 [13.7, 19.9]	1.072 [0.690, 1.666]	0.7596	
Tumor Location 2									
Gastric Proximal	73	40 (54.8)	19.7 [15.9, 26.6]	59	37 (62.7)	17.7 [13.6, 19.7]	0.736 [0.467, 1.158]	0.1827	0.7157
Gastric Distal	91	43 (47.3)	21.5 [16.7, 25.3]	87	53 (60.9)	13.7 [10.8, 15.7]	0.660 [0.441, 0.989]	0.0429	
Tumor Location 3									
GEJ Proximal	30	16 (53.3)	17.5 [15.5, 33.7]	26	18 (69.2)	16.5 [7.4, 26.3]	0.629 [0.316, 1.255]	0.1846	0.0841
GEJ Distal	19	12 (63.2)	15.7 [8.7, 19.4]	31	16 (51.6)	17.1 [11.6, NC]	1.505 [0.710, 3.191]	0.2834	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; 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.
[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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G4 Gesamtüberleben

2. Kaplan-Meier-Plots

Figure 301.1.1002.1: Kaplan-Meier Plot of Overall Survival - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G4 Progressionsfreies Überleben (IRC und INV)

1. Time-to-Event-Analysen

Table 301.1.1002.2.1: Summary of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	146 (51.6%)	167 (59.2%)	
Number of patients censored	137 (48.4%)	115 (40.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.6 [8.9, 12.5]	8.7 [8.2, 10.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.751 [0.598, 0.942]
Log-rank test			
Two-sided stratified log-rank p-value			0.0132

Abbreviations: CI=confidence interval; HR=hazard ratio; IRC=independent review committee; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.2.2: Type of Events and Censoring of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	146 (51.6%)	167 (59.2%)
rPD	87 (30.7%)	98 (34.8%)
No rPD, but death recorded on eCRF	59 (20.8%)	69 (24.5%)
Number of patients censored	137 (48.4%)	115 (40.8%)

Abbreviations: eCRF=electronic case report form; IRC=independent review committee; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	94 (51.9)	11.0 [8.8, 12.6]	181	106 (58.6)	8.9 [7.9, 10.5]	0.771 [0.583, 1.019]	0.0668	0.6914
>65 years	102	52 (51.0)	10.6 [8.3, 17.4]	101	61 (60.4)	8.6 [7.4, 10.4]	0.714 [0.492, 1.038]	0.0751	
Age Group 2									
<=75 years	267	138 (51.7)	10.6 [8.9, 12.5]	260	154 (59.2)	8.4 [8.0, 10.3]	0.739 [0.586, 0.931]	0.0098	0.7321
>75 years	16	8 (50.0)	8.3 [4.4, NC]	22	13 (59.1)	10.4 [7.1, 15.8]	0.955 [0.390, 2.342]	0.9067	
Sex									
Male	176	95 (54.0)	10.6 [8.6, 12.5]	175	106 (60.6)	8.9 [8.2, 10.4]	0.776 [0.587, 1.024]	0.0721	0.6583
Female	107	51 (47.7)	11.0 [8.5, 17.9]	107	61 (57.0)	8.4 [7.2, 10.5]	0.711 [0.488, 1.034]	0.0724	
Race									
White	140	77 (55.0)	8.9 [8.3, 12.4]	134	82 (61.2)	10.2 [8.4, 10.8]	0.930 [0.681, 1.271]	0.6455	0.0351
Asian	96	47 (49.0)	14.0 [12.3, 18.1]	97	51 (52.6)	8.2 [6.5, 8.7]	0.527 [0.352, 0.788]	0.0016	
Tobacco History									
Current	26	15 (57.7)	10.3 [7.4, 13.2]	25	14 (56.0)	8.7 [4.4, 17.6]	1.001 [0.480, 2.086]	0.9894	0.7503
Former	113	56 (49.6)	12.3 [8.8, 15.3]	118	70 (59.3)	9.8 [8.0, 10.8]	0.714 [0.501, 1.018]	0.0603	
Never	142	75 (52.8)	10.3 [8.3, 16.7]	137	82 (59.9)	8.2 [7.1, 10.3]	0.737 [0.538, 1.011]	0.0574	
Region									
Asia	88	45 (51.1)	12.6 [10.4, 17.8]	89	47 (52.8)	8.2 [6.5, 9.1]	0.563 [0.372, 0.852]	0.0060	0.1064
Non-Asia	195	101 (51.8)	9.7 [8.4, 12.2]	193	120 (62.2)	9.4 [8.2, 10.7]	0.848 [0.650, 1.106]	0.2209	
Number of Organs with Metastatic Sites									
0-2	219	107 (48.9)	12.4 [10.3, 15.8]	219	123 (56.2)	9.2 [8.2, 10.6]	0.726 [0.559, 0.943]	0.0157	0.6418
>=3	64	39 (60.9)	8.1 [6.2, 9.7]	63	44 (69.8)	8.2 [6.3, 9.8]	0.844 [0.548, 1.301]	0.4412	
Prior Gastrectomy (total or partial)									
Yes	84	40 (47.6)	12.4 [10.4, 18.2]	82	50 (61.0)	9.3 [7.2, 11.3]	0.622 [0.410, 0.943]	0.0242	0.2535
No	199	106 (53.3)	9.3 [8.4, 12.5]	200	117 (58.5)	8.6 [8.2, 10.3]	0.808 [0.620, 1.053]	0.1130	

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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]**
Histology (Tumor Type)									
Diffuse	82	40 (48.8)	12.5 [9.3, 18.2]	117	64 (54.7)	10.3 [8.4, 13.2]	0.756 [0.506, 1.129]	0.1693	0.1756
Intestinal	70	41 (58.6)	10.3 [8.3, 12.5]	66	46 (69.7)	6.6 [6.0, 9.3]	0.582 [0.379, 0.894]	0.0122	
Mixed/Other	81	49 (60.5)	9.8 [8.1, 14.0]	55	35 (63.6)	8.7 [6.8, 10.5]	0.929 [0.601, 1.434]	0.7403	
Tumor Location 1									
Gastric	219	109 (49.8)	12.2 [9.3, 14.0]	210	126 (60.0)	8.4 [7.8, 10.3]	0.688 [0.531, 0.890]	0.0042	0.1478
GEJ	64	37 (57.8)	8.8 [7.4, 15.8]	72	41 (56.9)	8.9 [8.2, 11.3]	1.015 [0.649, 1.586]	0.9498	
Tumor Location 2									
Gastric Proximal	73	40 (54.8)	10.2 [8.2, 18.2]	59	31 (52.5)	8.3 [7.1, 15.0]	0.876 [0.545, 1.409]	0.5830	0.2419
Gastric Distal	91	39 (42.9)	14.0 [10.4, 18.1]	87	50 (57.5)	9.1 [6.8, 10.5]	0.581 [0.381, 0.885]	0.0105	
Tumor Location 3									
GEJ Proximal	30	14 (46.7)	15.8 [8.3, 20.6]	26	20 (76.9)	7.4 [4.1, 8.7]	0.387 [0.189, 0.794]	0.0076	0.0145
GEJ Distal	19	12 (63.2)	8.8 [6.4, 12.5]	31	16 (51.6)	10.8 [8.2, 18.0]	1.369 [0.646, 2.903]	0.4109	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; HR=hazard ratio; IRC=independent review committee; KME=Kaplan-Meier Estimate of time to event (months); 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: 09SEP22

Table 301.1.1002.3.1: Summary of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	171 (60.4%)	198 (70.2%)	
Number of patients censored	112 (39.6%)	84 (29.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.4 [8.4, 11.8]	8.4 [7.8, 9.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.728 [0.590, 0.898]
Log-rank test			
Two-sided stratified log-rank p-value			0.0031

Abbreviations: CI=confidence interval; HR=hazard ratio; INV=investigator; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.3.2: Type of Events and Censoring of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	171 (60.4%)	198 (70.2%)
rPD	130 (45.9%)	159 (56.4%)
No rPD, but death recorded on eCRF	41 (14.5%)	39 (13.8%)
Number of patients censored	112 (39.6%)	84 (29.8%)

Abbreviations: eCRF= electronic case report form; INV=investigator; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1002.3.3: Summary of Progression-Free Survival (INV) by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	113 (62.4)	10.4 [8.3, 11.8]	181	121 (66.9)	8.5 [7.8, 10.3]	0.798 [0.616, 1.033]	0.0862	0.2246
>65 years	102	58 (56.9)	10.4 [8.3, 12.5]	101	77 (76.2)	8.2 [6.3, 9.3]	0.631 [0.448, 0.890]	0.0080	
Age Group 2									
<=75 years	267	162 (60.7)	10.4 [8.4, 11.8]	260	184 (70.8)	8.3 [7.8, 9.6]	0.726 [0.587, 0.898]	0.0030	0.7667
>75 years	16	9 (56.3)	9.7 [4.4, 18.1]	22	14 (63.6)	9.3 [5.9, 10.7]	0.843 [0.357, 1.988]	0.6802	
Sex									
Male	176	112 (63.6)	10.4 [8.3, 12.3]	175	128 (73.1)	8.3 [7.6, 9.6]	0.723 [0.559, 0.934]	0.0127	0.9940
Female	107	59 (55.1)	10.4 [8.3, 12.4]	107	70 (65.4)	8.4 [6.4, 10.5]	0.742 [0.524, 1.051]	0.0907	
Race									
White	140	92 (65.7)	8.3 [6.5, 10.6]	134	94 (70.1)	8.7 [7.6, 10.4]	0.975 [0.731, 1.301]	0.8609	0.0076
Asian	96	58 (60.4)	12.4 [10.4, 15.2]	97	66 (68.0)	8.3 [5.8, 10.2]	0.521 [0.364, 0.746]	0.0003	
Tobacco History									
Current	26	16 (61.5)	10.4 [7.9, 13.2]	25	19 (76.0)	8.4 [4.3, 11.0]	0.729 [0.374, 1.423]	0.3544	0.9311
Former	113	73 (64.6)	10.3 [8.3, 12.5]	118	82 (69.5)	8.9 [7.9, 10.2]	0.749 [0.544, 1.031]	0.0747	
Never	142	82 (57.7)	8.4 [7.9, 12.3]	137	96 (70.1)	8.0 [6.3, 10.2]	0.710 [0.528, 0.956]	0.0234	
Region									
Asia	88	54 (61.4)	12.4 [10.4, 15.1]	89	60 (67.4)	8.3 [6.2, 10.2]	0.545 [0.375, 0.792]	0.0013	0.0631
Non-Asia	195	117 (60.0)	8.8 [7.5, 10.6]	193	138 (71.5)	8.4 [7.6, 10.2]	0.848 [0.663, 1.086]	0.1893	
Number of Organs with Metastatic Sites									
0-2	219	127 (58.0)	11.0 [10.2, 12.5]	219	147 (67.1)	8.9 [8.0, 10.3]	0.709 [0.558, 0.901]	0.0048	0.5801
>=3	64	44 (68.8)	6.5 [6.1, 9.3]	63	51 (81.0)	6.8 [6.0, 8.4]	0.834 [0.556, 1.252]	0.3754	
Prior Gastrectomy (total or partial)									
Yes	84	49 (58.3)	12.3 [10.4, 15.2]	82	59 (72.0)	9.3 [7.1, 11.3]	0.605 [0.413, 0.887]	0.0091	0.2521
No	199	122 (61.3)	8.8 [7.7, 11.0]	200	139 (69.5)	8.3 [6.5, 9.6]	0.803 [0.629, 1.026]	0.0787	

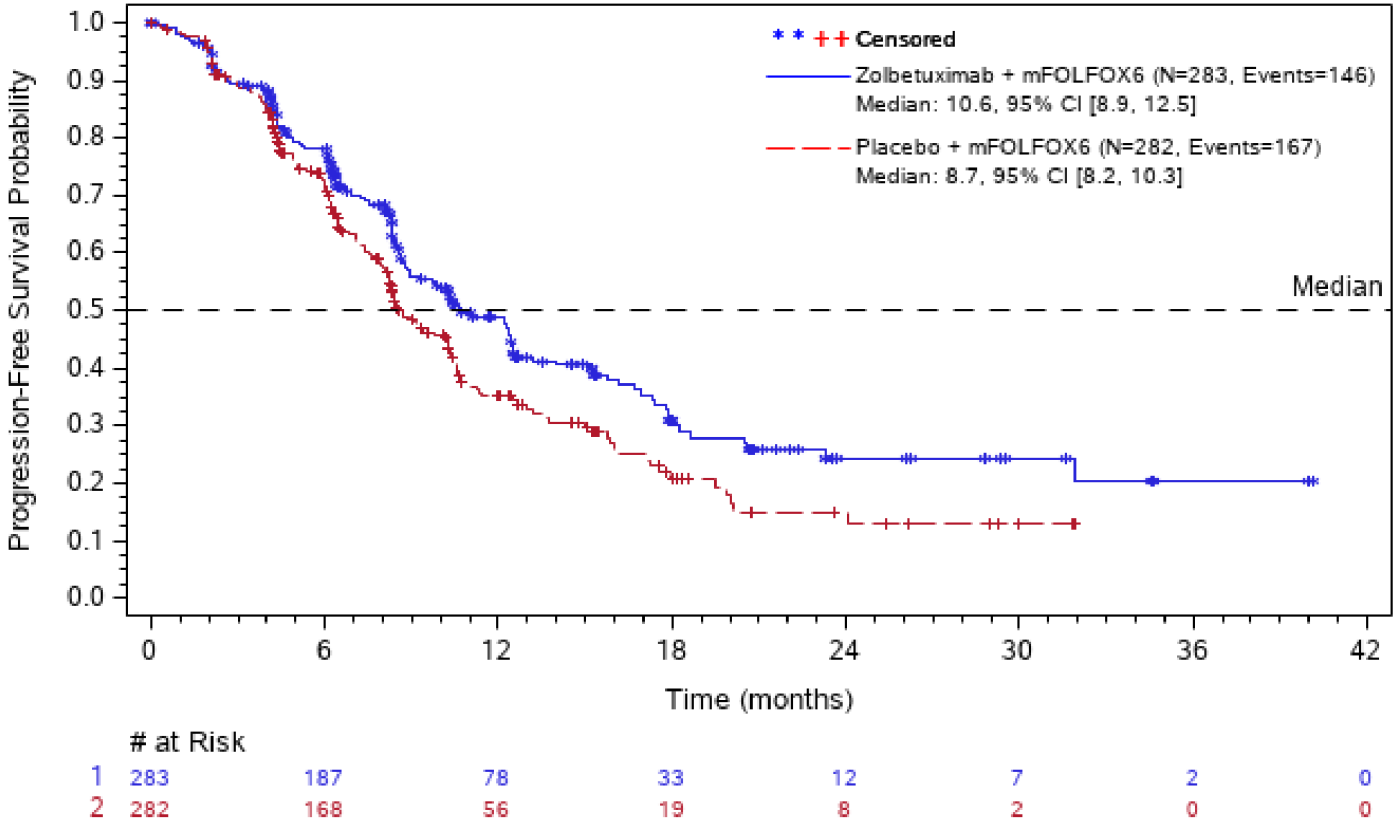
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	82	53 (64.6)	10.4 [8.3, 14.9]	117	78 (66.7)	10.2 [8.3, 10.8]	0.828 [0.583, 1.177]	0.2932	0.1594
Intestinal	70	46 (65.7)	10.4 [6.7, 13.2]	66	51 (77.3)	8.0 [5.7, 9.3]	0.548 [0.362, 0.831]	0.0042	
Mixed/Other	81	53 (65.4)	9.7 [7.7, 12.4]	55	42 (76.4)	8.4 [6.3, 10.3]	0.846 [0.564, 1.270]	0.4190	
Tumor Location 1									
Gastric	219	131 (59.8)	10.6 [8.5, 12.3]	210	146 (69.5)	8.3 [7.8, 10.2]	0.710 [0.560, 0.901]	0.0046	0.5492
GEJ	64	40 (62.5)	8.3 [6.2, 11.6]	72	52 (72.2)	8.4 [6.2, 9.8]	0.845 [0.559, 1.279]	0.4242	
Tumor Location 2									
Gastric Proximal	73	48 (65.8)	8.4 [8.0, 12.3]	59	41 (69.5)	8.4 [7.1, 10.7]	0.822 [0.539, 1.253]	0.3611	0.4207
Gastric Distal	91	48 (52.7)	13.2 [10.4, 15.2]	87	57 (65.5)	8.5 [6.3, 10.5]	0.621 [0.422, 0.913]	0.0142	
Tumor Location 3									
GEJ Proximal	30	17 (56.7)	10.4 [6.5, 17.8]	26	23 (88.5)	5.9 [4.1, 8.4]	0.395 [0.206, 0.756]	0.0039	0.0230
GEJ Distal	19	12 (63.2)	8.3 [4.3, 15.1]	31	21 (67.7)	10.2 [6.2, 12.1]	1.189 [0.580, 2.437]	0.6363	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event.
[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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G4 Progressionsfreies Überleben (IRC und INV)

2. Kaplan-Meier-Plots

Figure 301.1.1002.2: Kaplan-Meier Plot of Progression-Free Survival (IRC) - Full Analysis Set

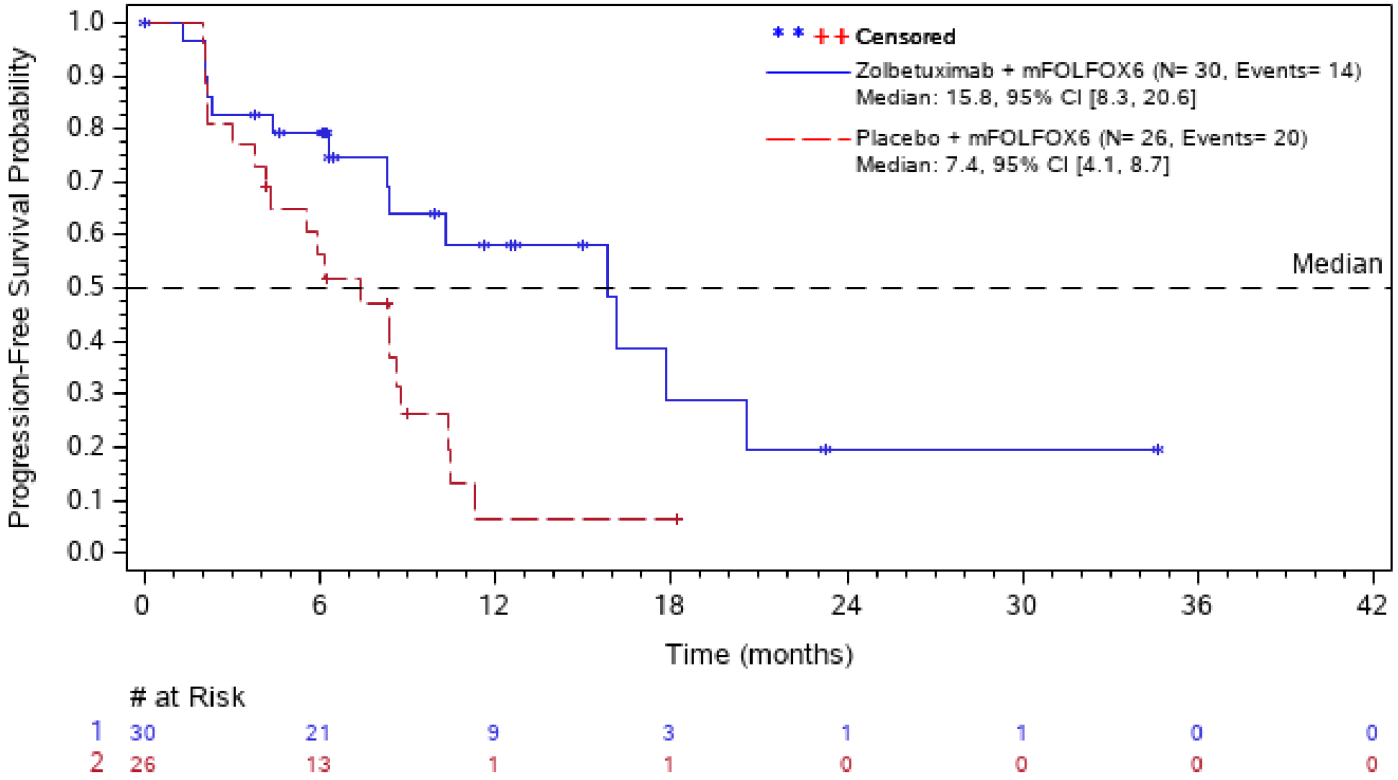


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.2.12: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 3 - Full Analysis Set

Tumor Location 3: GEJ Proximal

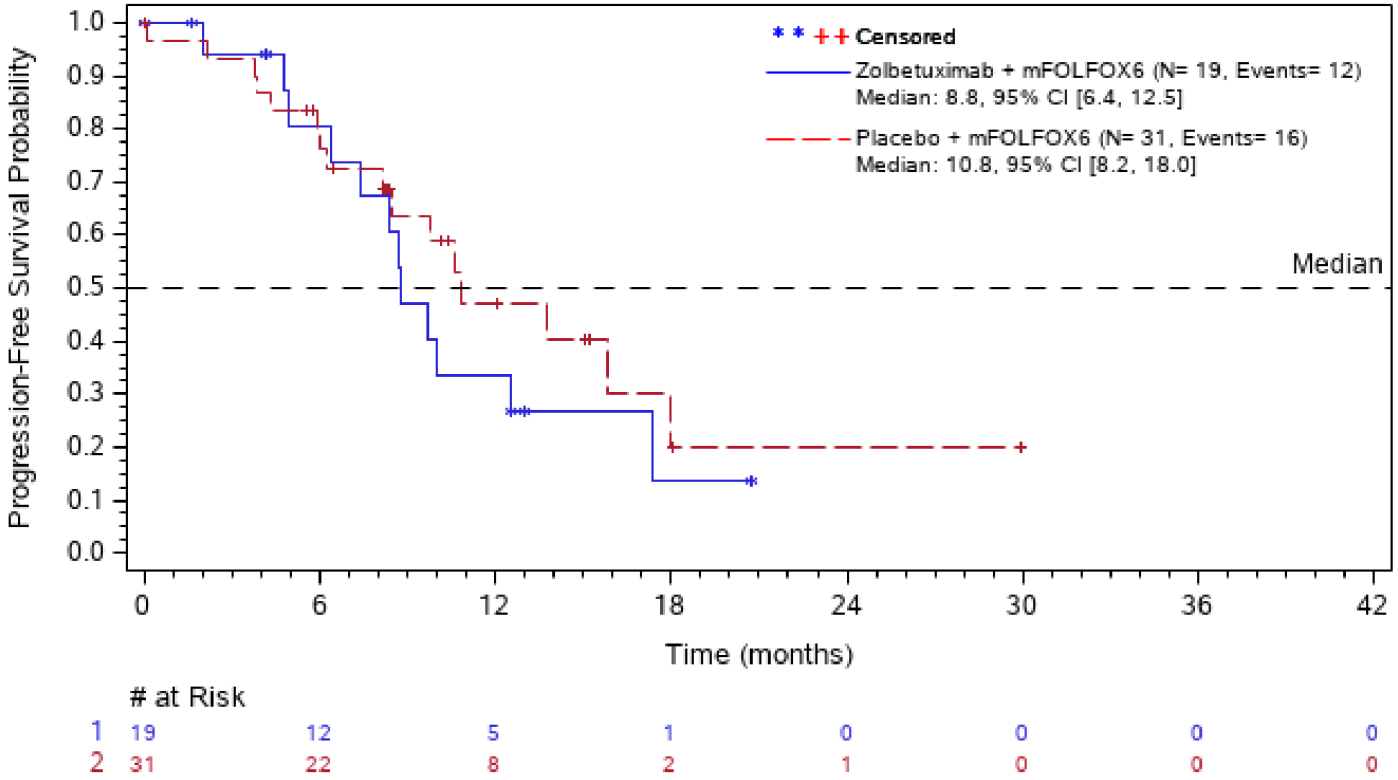


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.2.12: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Tumor Location 3 - Full Analysis Set

Tumor Location 3: GEJ Distal

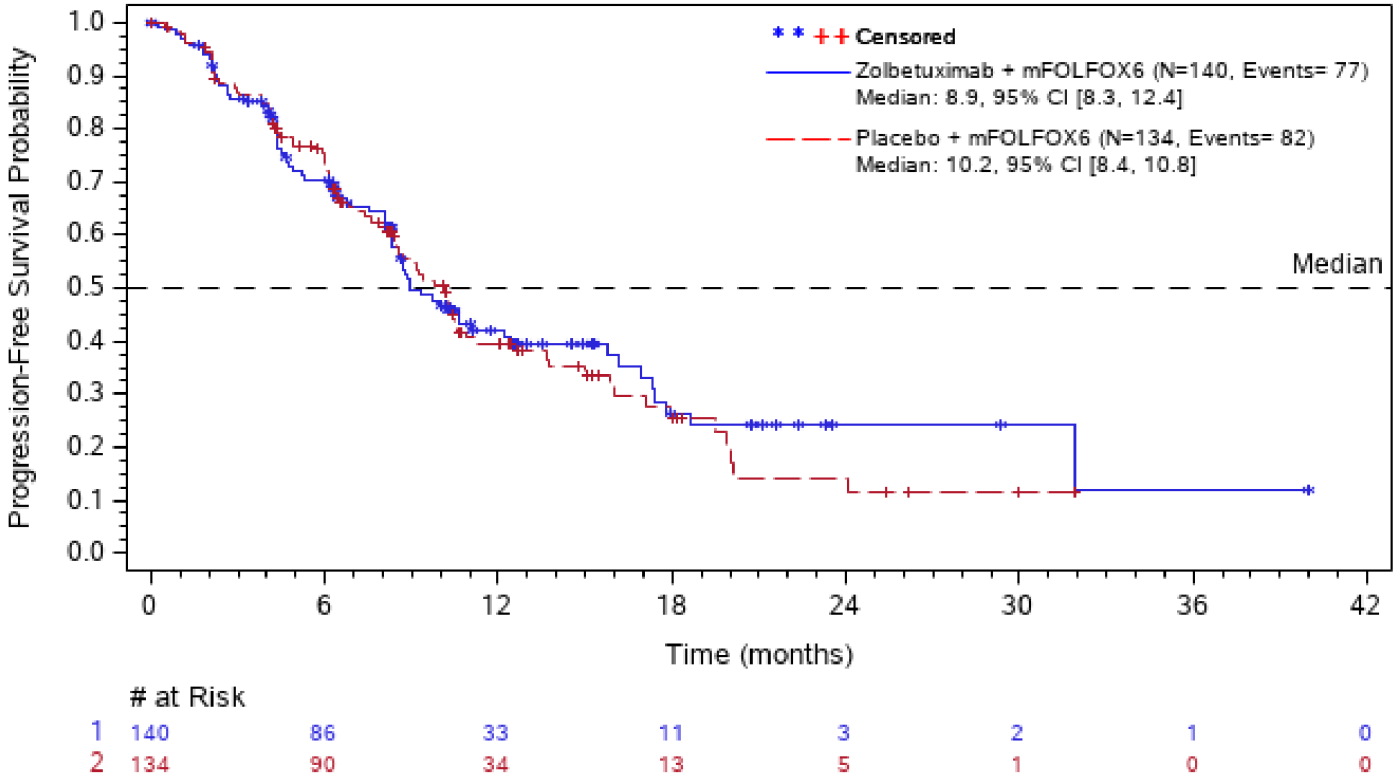


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.2.4: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Race - Full Analysis Set

Race: White

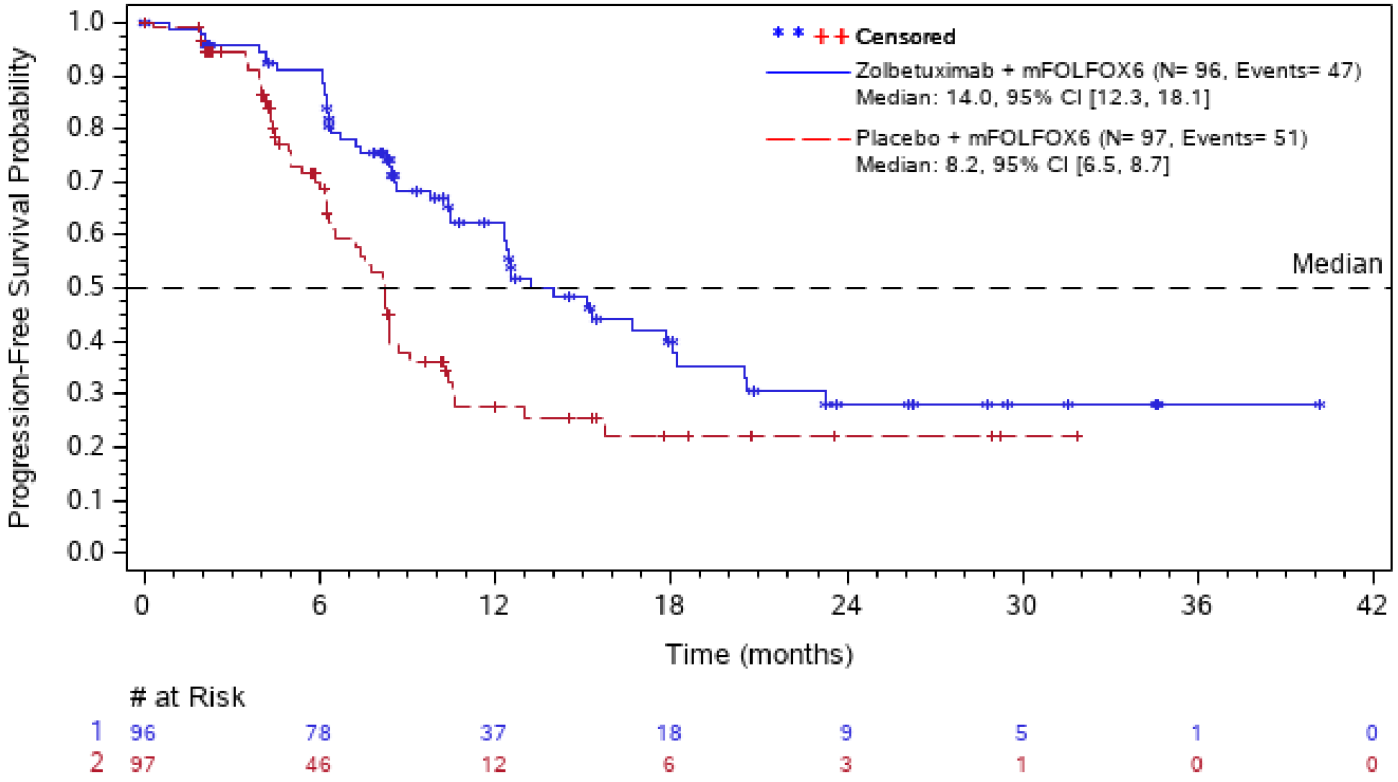


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.2.4: Kaplan-Meier Plot of Progression-Free Survival (IRC) by Race - Full Analysis Set

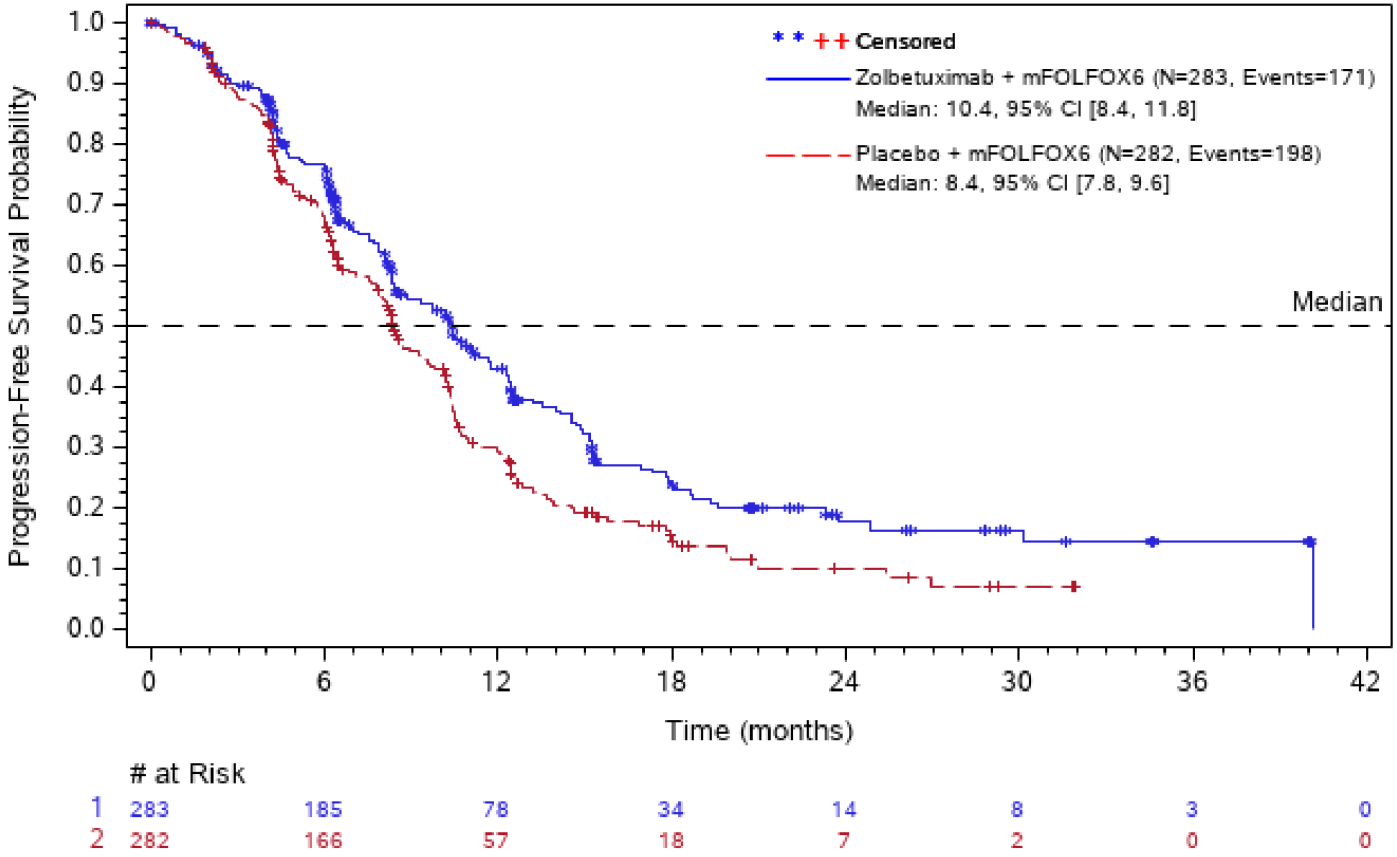
Race: Asian



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

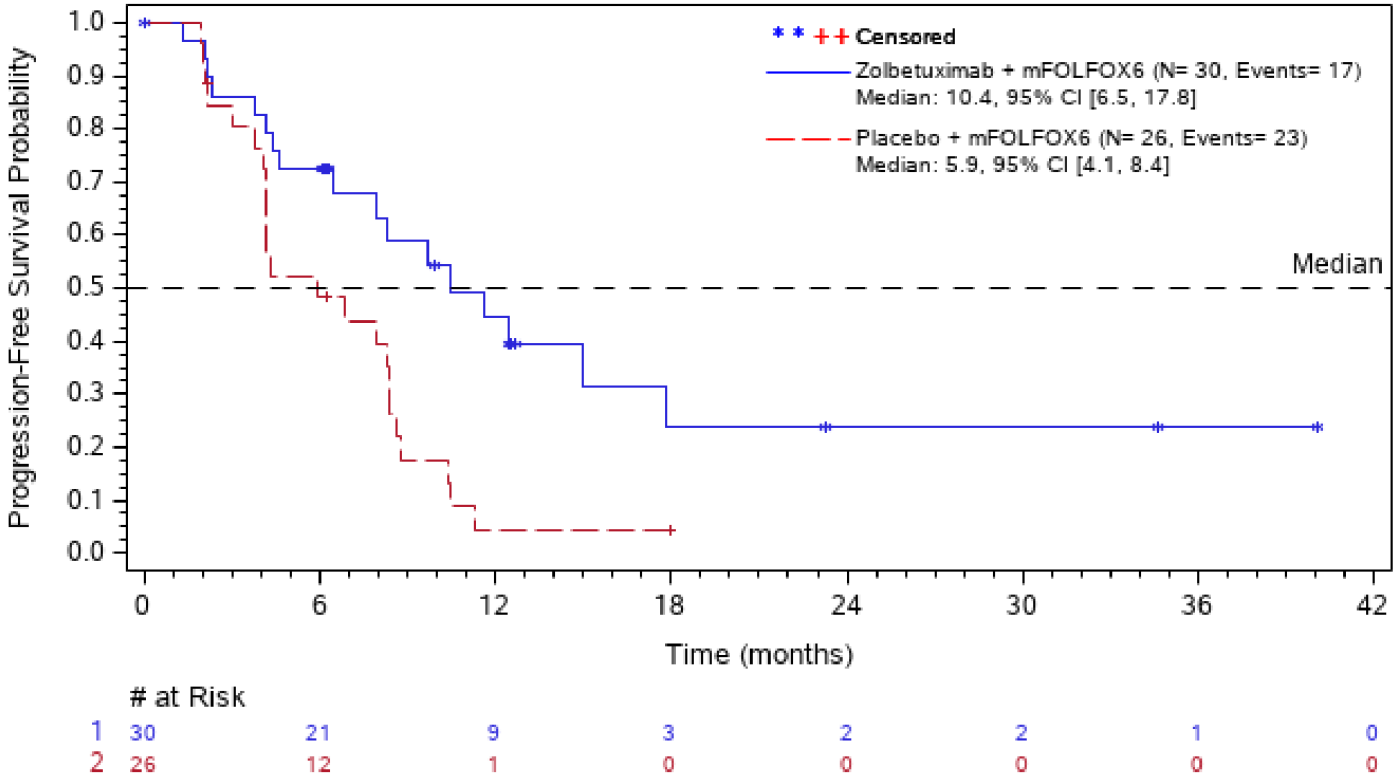
Figure 301.1.1002.3: Kaplan-Meier Plot of Progression-Free Survival (INV) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.3.12: Kaplan-Meier Plot of Progression-Free Survival (INV) by Tumor Location 3 - Full Analysis Set

Tumor Location 3: GEJ Proximal

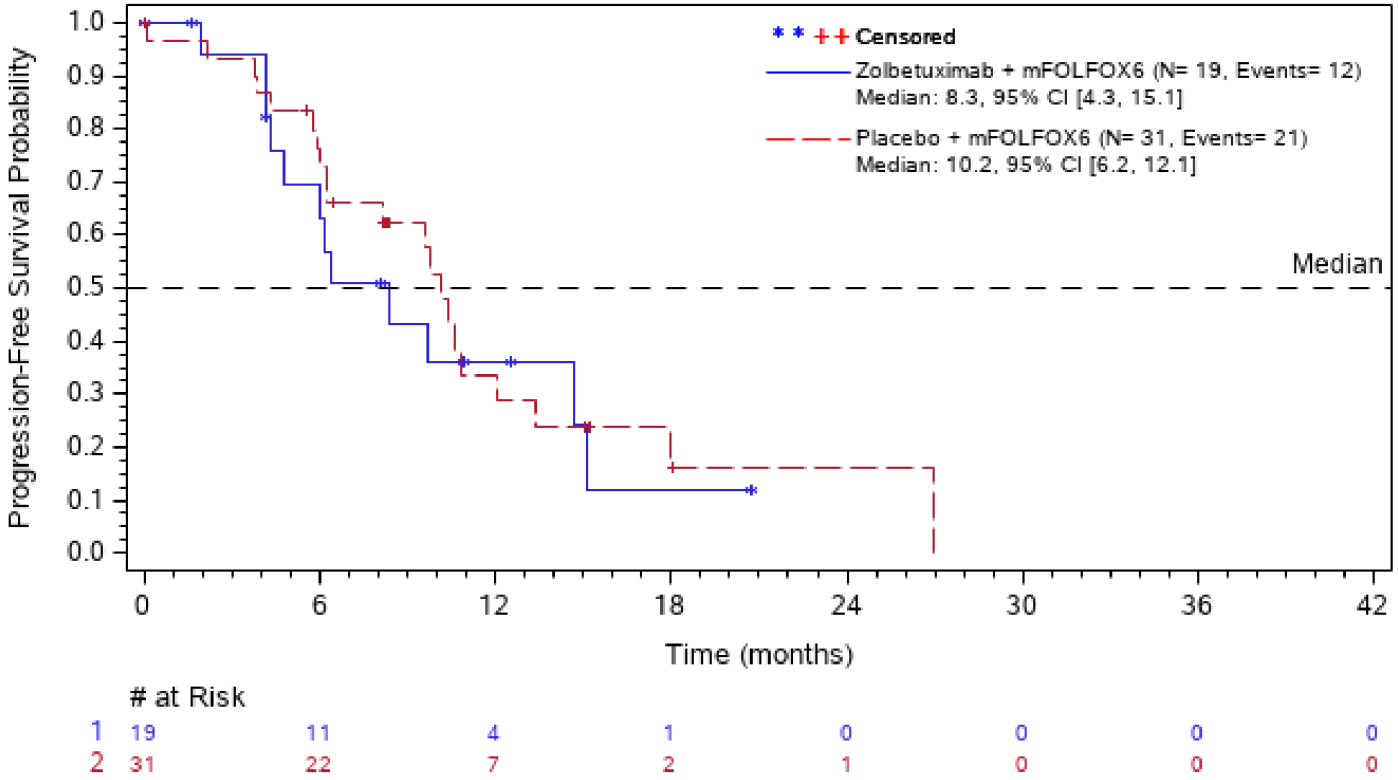


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; INV=investigator; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.3.12: Kaplan-Meier Plot of Progression-Free Survival (INV) by Tumor Location 3 - Full Analysis Set

Tumor Location 3: GEJ Distal

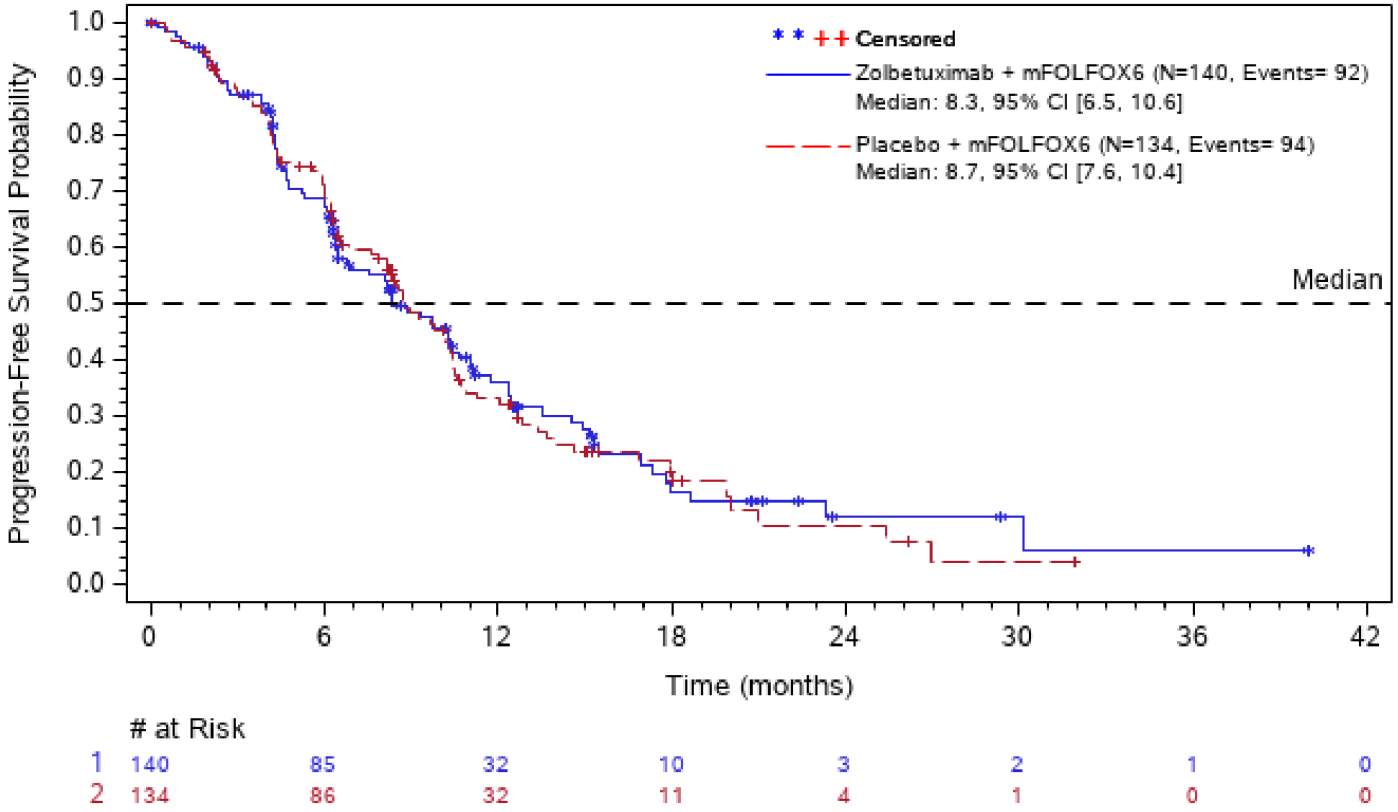


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; GEJ=gastro-esophageal junction; INV=investigator; N=number of patients.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.3.4: Kaplan-Meier Plot of Progression-Free Survival (INV) by Race - Full Analysis Set

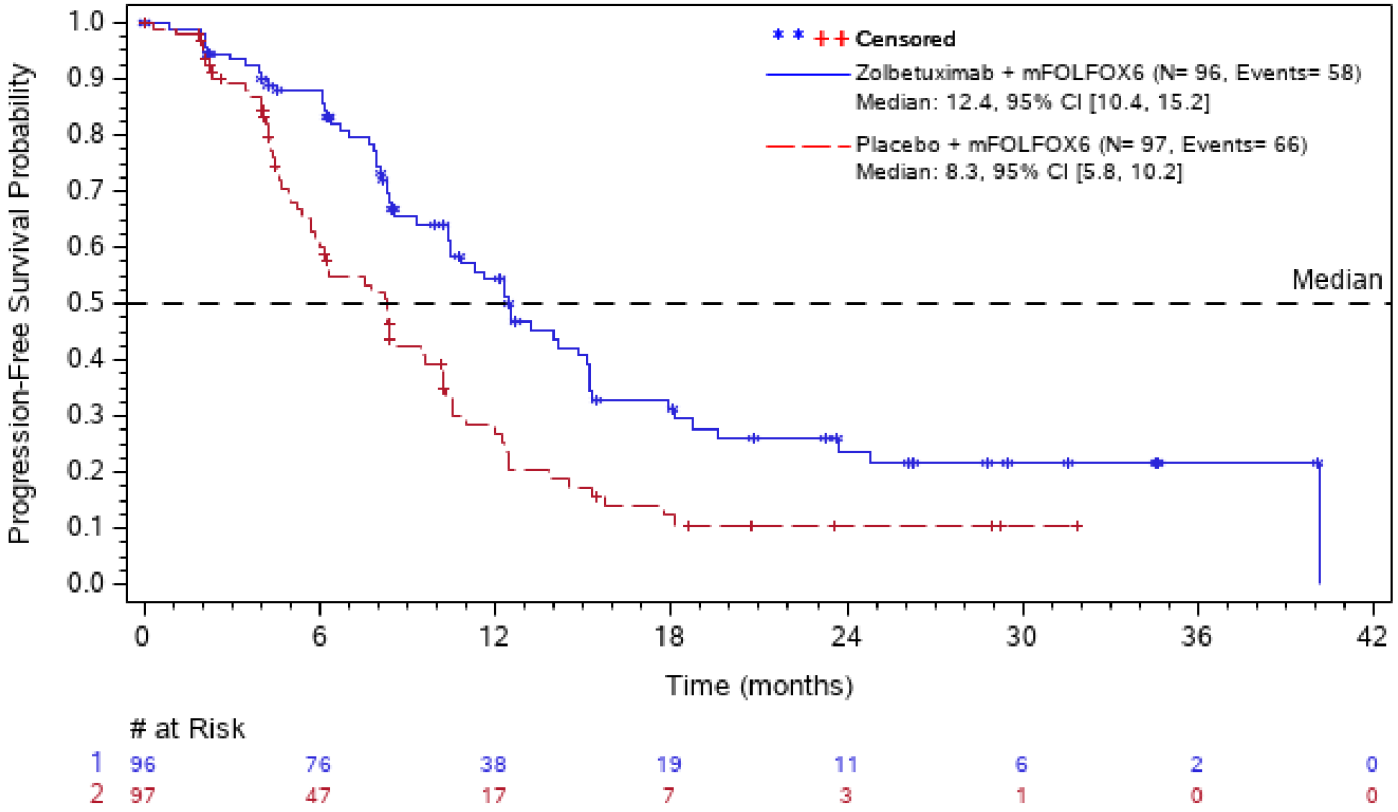
Race: White



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.1002.3.4: Kaplan-Meier Plot of Progression-Free Survival (INV) by Race - Full Analysis Set

Race: Asian



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

1. Rücklaufquoten

Table 301.1.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/244 (71.3%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/241 (53.1%)	128/283 (45.2%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	113/151 (74.8%)	114/236 (48.3%)	114/283 (40.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	93/120 (77.5%)	93/242 (38.4%)	93/282 (33.0%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	32/ 45 (71.1%)	32/229 (14.0%)	32/283 (11.3%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 301.1.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	64.20	20.86	0.0	66.67	100.0						
Cycle 1 Day 22	187	60.83	20.24	0.0	66.67	100.0	177	-5.18	20.75	-75.0	0.00	75.0
Cycle 2 Day 1	217	66.78	19.25	16.7	66.67	100.0	207	1.61	20.40	-58.3	0.00	66.7
Cycle 2 Day 22	157	64.38	16.58	16.7	66.67	100.0	150	0.17	18.51	-41.7	0.00	83.3
Cycle 3 Day 1	200	69.63	16.02	16.7	66.67	100.0	190	2.85	17.89	-50.0	0.00	66.7
Cycle 3 Day 22	161	62.84	18.11	0.0	66.67	100.0	152	-3.13	19.10	-75.0	0.00	41.7
Cycle 4 Day 1	178	67.13	17.49	16.7	66.67	100.0	170	0.64	20.49	-58.3	0.00	66.7
Cycle 4 Day 22	128	64.65	17.27	25.0	66.67	100.0	123	-2.78	18.16	-41.7	0.00	50.0
Cycle 5 Day 1	156	65.17	18.78	16.7	66.67	100.0	148	-0.84	20.57	-50.0	0.00	66.7
Cycle 5 Day 22	114	66.45	18.93	16.7	66.67	100.0	107	0.86	21.01	-58.3	0.00	66.7
Cycle 6 Day 1	125	67.60	18.46	16.7	66.67	100.0	116	0.65	20.27	-58.3	0.00	58.3
Cycle 6 Day 22	102	69.04	17.25	33.3	66.67	100.0	97	3.44	18.39	-33.3	0.00	50.0
Cycle 7 Day 1	111	67.72	17.48	25.0	66.67	100.0	105	-0.08	20.30	-66.7	0.00	66.7
Cycle 7 Day 22	80	69.69	15.92	33.3	66.67	100.0	74	2.36	18.33	-41.7	0.00	50.0
Cycle 8 Day 1	81	69.75	15.84	25.0	66.67	100.0	74	2.70	20.37	-41.7	0.00	50.0
Cycle 8 Day 22	71	69.60	18.64	0.0	75.00	100.0	66	1.89	20.45	-50.0	0.00	50.0
Cycle 9 Day 1	73	69.86	16.00	33.3	66.67	100.0	66	5.68	18.50	-33.3	0.00	58.3
Cycle 9 Day 22	54	68.98	18.49	0.0	66.67	100.0	50	4.17	20.77	-50.0	0.00	58.3
Cycle 10 Day 1	58	68.39	17.15	16.7	66.67	100.0	53	1.89	18.25	-50.0	0.00	50.0
Cycle 10 Day 22	47	67.20	16.43	16.7	66.67	83.3	44	-1.33	19.93	-50.0	0.00	33.3
Cycle 11 Day 1	50	70.83	16.69	16.7	70.83	100.0	46	3.62	16.91	-50.0	0.00	50.0
Cycle 11 Day 22	35	68.57	16.43	33.3	66.67	100.0	32	-0.78	18.97	-41.7	0.00	33.3
Cycle 12 Day 1	43	67.05	16.56	16.7	66.67	100.0	39	-0.85	17.71	-50.0	0.00	50.0
Cycle 12 Day 22	32	68.23	14.58	33.3	66.67	100.0	30	-3.06	14.60	-33.3	0.00	33.3
Cycle 13 Day 1	37	70.50	15.66	33.3	75.00	100.0	34	1.23	17.42	-33.3	0.00	41.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	66.67	20.00	16.7	66.67	100.0	31	-5.38	17.15	-41.7	0.00	33.3
Cycle 14 Day 1	31	65.05	19.77	16.7	66.67	100.0	30	-4.17	24.15	-83.3	0.00	50.0
Cycle 14 Day 22	24	66.67	13.90	50.0	66.67	100.0	24	-5.21	17.52	-33.3	-8.33	25.0
Cycle 15 Day 1	26	66.35	19.07	0.0	66.67	100.0	26	-3.85	28.01	-100.0	0.00	41.7
Cycle 15 Day 22	22	61.36	14.90	33.3	58.33	83.3	22	-9.47	22.17	-66.7	-8.33	33.3
Cycle 16 Day 1	25	69.00	14.93	50.0	66.67	91.7	25	-0.33	19.47	-33.3	0.00	41.7
Cycle 16 Day 22	19	59.21	15.19	33.3	66.67	83.3	19	-7.89	16.78	-33.3	-8.33	16.7
Cycle 17 Day 1	19	61.84	19.51	25.0	50.00	91.7	19	-5.26	25.94	-58.3	-8.33	50.0
Cycle 17 Day 22	14	60.12	17.66	33.3	54.17	100.0	14	-9.52	24.86	-50.0	-8.33	25.0
Cycle 18 Day 1	16	63.54	14.23	50.0	62.50	83.3	16	-2.60	23.12	-41.7	0.00	41.7
Cycle 18 Day 22	11	61.36	17.59	33.3	66.67	83.3	11	-9.09	20.23	-41.7	-8.33	33.3
Cycle 19 Day 1	13	69.87	15.79	50.0	66.67	91.7	13	1.28	25.88	-41.7	0.00	50.0
Cycle 19 Day 22	11	65.15	17.41	33.3	66.67	83.3	11	-9.85	18.94	-41.7	-16.67	33.3
Cycle 20 Day 1	13	68.59	15.27	50.0	66.67	91.7	13	-2.56	24.86	-33.3	-16.67	50.0
Cycle 21 Day 1	11	71.21	14.61	50.0	66.67	91.7	11	0.76	25.67	-33.3	-8.33	50.0
Study Disc 1	132	56.12	22.67	0.0	58.33	100.0	125	-8.80	20.20	-50.0	-8.33	58.3
30 D SFU Z/P	69	57.73	20.82	8.3	58.33	100.0	64	-6.38	21.50	-66.7	0.00	41.7
90 D SFU Z/P	83	60.04	19.64	0.0	66.67	100.0	80	-6.15	21.94	-58.3	0.00	33.3
Placebo + mFOLFOX6 (N=282)												
Baseline	258	63.47	20.63	0.0	66.67	100.0						
Cycle 1 Day 22	212	64.27	19.55	0.0	66.67	100.0	210	0.48	17.98	-83.3	0.00	50.0
Cycle 2 Day 1	231	69.44	18.64	0.0	66.67	100.0	225	5.56	18.68	-50.0	0.00	58.3
Cycle 2 Day 22	185	65.77	19.73	0.0	66.67	100.0	181	1.98	20.79	-66.7	0.00	66.7
Cycle 3 Day 1	204	70.18	17.76	8.3	66.67	100.0	198	5.77	19.92	-58.3	0.00	58.3
Cycle 3 Day 22	156	68.64	17.30	16.7	66.67	100.0	149	3.13	18.03	-41.7	0.00	66.7
Cycle 4 Day 1	171	70.66	17.58	16.7	66.67	100.0	163	6.65	21.04	-58.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	65.66	19.07	16.7	66.67	100.0	127	1.57	22.44	-50.0	0.00	66.7
Cycle 5 Day 1	147	68.93	17.97	8.3	66.67	100.0	143	4.78	20.64	-66.7	0.00	58.3
Cycle 5 Day 22	120	64.72	21.08	0.0	66.67	100.0	113	-0.22	21.46	-58.3	0.00	75.0
Cycle 6 Day 1	122	66.19	20.73	0.0	66.67	100.0	117	0.57	21.07	-58.3	0.00	75.0
Cycle 6 Day 22	93	70.07	18.11	33.3	75.00	100.0	89	2.62	18.32	-33.3	0.00	66.7
Cycle 7 Day 1	91	72.71	16.15	33.3	66.67	100.0	88	4.64	18.08	-33.3	0.00	66.7
Cycle 7 Day 22	66	71.72	16.27	33.3	66.67	100.0	64	3.13	19.27	-41.7	0.00	58.3
Cycle 8 Day 1	73	74.32	17.50	16.7	83.33	100.0	72	5.09	18.27	-33.3	0.00	58.3
Cycle 8 Day 22	56	75.30	17.55	33.3	79.17	100.0	54	7.72	18.59	-33.3	8.33	58.3
Cycle 9 Day 1	53	75.47	17.17	16.7	83.33	100.0	51	4.25	14.85	-33.3	0.00	33.3
Cycle 9 Day 22	46	72.64	18.81	0.0	70.83	100.0	44	3.22	18.26	-50.0	0.00	41.7
Cycle 10 Day 1	47	74.47	17.58	25.0	83.33	100.0	45	4.44	16.82	-33.3	0.00	33.3
Cycle 10 Day 22	35	71.43	17.77	33.3	66.67	100.0	34	4.41	16.70	-16.7	0.00	33.3
Cycle 11 Day 1	37	75.45	16.31	33.3	83.33	100.0	35	5.00	15.15	-25.0	0.00	33.3
Cycle 11 Day 22	22	71.21	19.54	33.3	70.83	100.0	20	0.00	16.45	-33.3	0.00	33.3
Cycle 12 Day 1	32	74.74	16.46	41.7	75.00	100.0	30	2.50	11.61	-16.7	0.00	33.3
Cycle 12 Day 22	20	69.17	16.02	33.3	66.67	100.0	18	-3.70	9.99	-16.7	0.00	16.7
Cycle 13 Day 1	25	73.67	16.61	41.7	83.33	100.0	24	-0.69	13.66	-25.0	0.00	33.3
Cycle 13 Day 22	15	71.11	14.73	41.7	66.67	100.0	14	-0.60	8.31	-16.7	0.00	16.7
Cycle 14 Day 1	23	75.00	13.99	50.0	75.00	100.0	22	3.41	15.57	-25.0	0.00	33.3
Cycle 14 Day 22	13	68.59	16.01	33.3	66.67	100.0	12	-5.56	13.45	-33.3	0.00	16.7
Cycle 15 Day 1	19	72.37	16.91	33.3	83.33	100.0	19	-1.32	11.20	-16.7	0.00	33.3
Cycle 16 Day 1	11	69.70	19.46	50.0	66.67	100.0	11	0.00	12.36	-16.7	0.00	16.7
Cycle 17 Day 1	10	74.17	16.87	50.0	83.33	100.0	10	2.50	14.72	-16.7	4.17	16.7
Study Disc 1	137	58.82	22.73	0.0	66.67	100.0	133	-1.94	23.43	-83.3	0.00	50.0
Study Disc 2	10	53.33	23.64	16.7	62.50	83.3	10	-10.83	32.88	-58.3	-12.50	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	58.74	18.35	16.7	66.67	100.0	79	-4.43	21.13	-66.7	0.00	50.0
90 D SFU Z/P	71	58.92	22.11	0.0	66.67	100.0	70	-3.33	22.81	-66.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	79.71	20.37	13.3	86.67	100.0						
Cycle 1 Day 22	187	77.47	20.30	6.7	80.00	100.0	177	-4.22	17.23	-93.3	0.00	40.0
Cycle 2 Day 1	217	79.23	20.35	6.7	86.67	100.0	207	-1.90	18.80	-53.3	0.00	60.0
Cycle 2 Day 22	157	80.47	19.47	13.3	86.67	100.0	150	-0.98	17.69	-73.3	0.00	46.7
Cycle 3 Day 1	200	81.30	18.83	0.0	86.67	100.0	190	-0.84	19.51	-80.0	0.00	60.0
Cycle 3 Day 22	161	79.59	17.60	20.0	80.00	100.0	152	-1.36	17.26	-66.7	0.00	46.7
Cycle 4 Day 1	178	82.40	16.67	20.0	86.67	100.0	170	0.12	19.69	-53.3	0.00	60.0
Cycle 4 Day 22	128	80.89	17.19	20.0	83.33	100.0	123	-2.60	19.87	-60.0	0.00	60.0
Cycle 5 Day 1	156	79.10	20.17	13.3	86.67	100.0	148	-3.24	22.42	-80.0	0.00	60.0
Cycle 5 Day 22	114	80.64	18.83	13.3	86.67	100.0	107	-1.87	20.64	-60.0	0.00	53.3
Cycle 6 Day 1	125	80.21	18.04	13.3	86.67	100.0	116	-1.78	21.16	-80.0	0.00	53.3
Cycle 6 Day 22	102	78.24	20.42	6.7	83.33	100.0	97	-2.54	22.90	-86.7	0.00	46.7
Cycle 7 Day 1	111	81.62	16.34	6.7	86.67	100.0	105	-1.21	21.10	-86.7	0.00	53.3
Cycle 7 Day 22	80	81.50	15.48	33.3	86.67	100.0	74	-1.35	17.17	-60.0	0.00	46.7
Cycle 8 Day 1	81	82.39	17.99	0.0	86.67	100.0	74	0.72	21.36	-93.3	0.00	46.7
Cycle 8 Day 22	71	82.63	15.10	33.3	86.67	100.0	66	0.40	18.45	-46.7	0.00	46.7
Cycle 9 Day 1	73	81.64	17.91	13.3	86.67	100.0	66	0.81	20.07	-60.0	0.00	46.7
Cycle 9 Day 22	54	83.70	13.38	53.3	86.67	100.0	50	3.33	21.22	-40.0	0.00	60.0
Cycle 10 Day 1	58	83.10	14.47	46.7	86.67	100.0	53	2.39	20.68	-53.3	0.00	46.7
Cycle 10 Day 22	47	84.26	14.14	40.0	86.67	100.0	44	2.42	17.50	-53.3	0.00	40.0
Cycle 11 Day 1	50	85.20	14.65	33.3	86.67	100.0	46	3.48	19.51	-66.7	3.33	46.7
Cycle 11 Day 22	35	85.90	14.17	53.3	86.67	100.0	32	4.58	17.55	-20.0	0.00	46.7
Cycle 12 Day 1	43	82.95	16.98	20.0	86.67	100.0	39	-0.51	21.38	-60.0	0.00	40.0
Cycle 12 Day 22	32	84.58	15.00	46.7	86.67	100.0	30	2.00	19.51	-53.3	6.67	33.3
Cycle 13 Day 1	37	83.06	15.92	46.7	86.67	100.0	34	1.18	18.46	-53.3	3.33	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	84.12	13.44	53.3	86.67	100.0	31	-0.22	19.81	-46.7	0.00	46.7
Cycle 14 Day 1	31	82.80	18.20	13.3	86.67	100.0	30	2.44	16.28	-46.7	3.33	33.3
Cycle 14 Day 22	24	83.06	14.44	53.3	86.67	100.0	24	0.56	21.44	-46.7	6.67	46.7
Cycle 15 Day 1	26	84.36	13.85	53.3	86.67	100.0	26	2.05	17.36	-46.7	6.67	40.0
Cycle 15 Day 22	22	85.45	13.90	53.3	86.67	100.0	22	3.94	20.23	-46.7	6.67	53.3
Cycle 16 Day 1	25	84.27	16.09	40.0	86.67	100.0	25	4.00	19.91	-53.3	6.67	46.7
Cycle 16 Day 22	19	89.12	12.21	60.0	93.33	100.0	19	10.18	17.12	-33.3	13.33	60.0
Cycle 17 Day 1	19	83.86	22.81	6.7	86.67	100.0	19	1.75	25.32	-86.7	6.67	20.0
Cycle 17 Day 22	14	83.33	25.72	6.7	93.33	100.0	14	-0.95	29.57	-86.7	6.67	33.3
Cycle 18 Day 1	16	86.25	13.21	66.7	86.67	100.0	16	3.33	17.55	-33.3	6.67	26.7
Cycle 18 Day 22	11	87.88	13.93	66.7	93.33	100.0	11	1.82	18.40	-33.3	6.67	20.0
Cycle 19 Day 1	13	91.28	12.59	66.7	100.00	100.0	13	4.62	15.00	-33.3	6.67	20.0
Cycle 19 Day 22	11	87.27	13.48	66.7	86.67	100.0	11	-1.21	19.74	-33.3	6.67	20.0
Cycle 20 Day 1	13	90.77	14.79	66.7	100.00	100.0	13	3.59	18.78	-33.3	13.33	20.0
Cycle 21 Day 1	11	89.70	12.06	66.7	93.33	100.0	11	1.21	14.55	-26.7	6.67	20.0
Study Disc 1	132	70.15	27.00	0.0	80.00	100.0	125	-10.45	25.85	-93.3	-6.67	46.7
30 D SFU Z/P	69	69.37	24.42	0.0	73.33	100.0	64	-10.73	25.44	-100.0	-6.67	46.7
90 D SFU Z/P	83	68.84	24.77	0.0	73.33	100.0	80	-15.08	23.78	-86.7	-6.67	40.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	78.79	21.13	0.0	86.67	100.0						
Cycle 1 Day 22	212	78.55	20.58	6.7	83.33	100.0	210	-1.49	15.70	-53.3	0.00	46.7
Cycle 2 Day 1	231	81.13	19.06	13.3	86.67	100.0	225	1.69	17.92	-60.0	0.00	60.0
Cycle 2 Day 22	185	81.66	18.41	0.0	86.67	100.0	181	1.73	18.69	-66.7	0.00	53.3
Cycle 3 Day 1	204	82.45	18.57	0.0	86.67	100.0	198	2.66	18.70	-73.3	0.00	66.7
Cycle 3 Day 22	156	83.12	16.86	13.3	86.67	100.0	149	1.52	15.88	-53.3	0.00	53.3
Cycle 4 Day 1	171	82.26	19.00	6.7	86.67	100.0	163	1.47	19.25	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	80.15	20.86	0.0	86.67	100.0	127	-1.52	19.68	-80.0	0.00	66.7
Cycle 5 Day 1	147	81.63	18.06	0.0	86.67	100.0	143	0.37	18.79	-60.0	0.00	66.7
Cycle 5 Day 22	120	82.44	17.98	20.0	86.67	100.0	113	-0.12	19.90	-60.0	0.00	53.3
Cycle 6 Day 1	122	82.02	16.68	33.3	86.67	100.0	117	-1.42	19.14	-66.7	0.00	66.7
Cycle 6 Day 22	93	83.30	16.47	26.7	86.67	100.0	89	-0.60	15.72	-46.7	0.00	40.0
Cycle 7 Day 1	91	84.32	16.40	33.3	86.67	100.0	88	-0.68	15.53	-66.7	0.00	33.3
Cycle 7 Day 22	66	85.96	13.89	40.0	86.67	100.0	64	1.56	18.16	-60.0	0.00	60.0
Cycle 8 Day 1	73	86.30	14.57	40.0	86.67	100.0	72	0.74	16.24	-40.0	0.00	66.7
Cycle 8 Day 22	56	85.83	13.15	46.7	86.67	100.0	54	0.62	17.48	-46.7	0.00	66.7
Cycle 9 Day 1	53	87.30	14.52	40.0	86.67	100.0	51	0.78	18.07	-60.0	0.00	53.3
Cycle 9 Day 22	46	87.68	13.70	46.7	93.33	100.0	44	2.12	17.48	-53.3	0.00	53.3
Cycle 10 Day 1	47	88.94	15.56	20.0	93.33	100.0	45	0.15	15.14	-60.0	0.00	46.7
Cycle 10 Day 22	35	85.90	19.92	13.3	93.33	100.0	34	-3.53	18.15	-66.7	0.00	26.7
Cycle 11 Day 1	37	87.93	15.14	40.0	93.33	100.0	35	-2.67	13.74	-60.0	0.00	26.7
Cycle 11 Day 22	22	84.24	20.42	20.0	90.00	100.0	20	-6.67	14.99	-46.7	0.00	13.3
Cycle 12 Day 1	32	86.67	15.15	53.3	90.00	100.0	30	-4.22	12.44	-46.7	0.00	13.3
Cycle 12 Day 22	20	84.00	16.95	53.3	90.00	100.0	18	-5.19	11.56	-26.7	-3.33	6.7
Cycle 13 Day 1	25	83.73	19.54	40.0	86.67	100.0	24	-8.06	16.68	-60.0	0.00	13.3
Cycle 13 Day 22	15	84.44	18.63	46.7	93.33	100.0	14	-8.57	16.42	-53.3	-3.33	6.7
Cycle 14 Day 1	23	88.12	11.88	66.7	86.67	100.0	22	-2.73	8.40	-20.0	0.00	13.3
Cycle 14 Day 22	13	83.08	16.91	40.0	86.67	100.0	12	-6.11	11.53	-33.3	-3.33	6.7
Cycle 15 Day 1	19	82.11	18.20	46.7	86.67	100.0	19	-8.07	15.33	-53.3	0.00	6.7
Cycle 16 Day 1	11	80.00	20.87	40.0	80.00	100.0	11	-9.09	20.28	-60.0	0.00	13.3
Cycle 17 Day 1	10	82.00	19.13	46.7	83.33	100.0	10	-6.67	14.74	-40.0	0.00	6.7
Study Disc 1	137	72.99	26.24	0.0	80.00	100.0	133	-4.81	22.64	-86.7	0.00	53.3
Study Disc 2	10	58.00	35.14	0.0	60.00	100.0	10	-23.33	36.14	-80.0	-23.33	26.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	76.21	19.66	6.7	80.00	100.0	79	-7.93	22.92	-86.7	-6.67	40.0
90 D SFU Z/P	71	71.64	26.92	0.0	80.00	100.0	70	-12.29	27.56	-100.0	-6.67	53.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	74.77	27.56	0.0	83.33	100.0						
Cycle 1 Day 22	187	70.77	26.40	0.0	66.67	100.0	177	-6.78	25.09	-100.0	0.00	66.7
Cycle 2 Day 1	217	75.42	25.81	0.0	83.33	100.0	207	-0.64	26.78	-83.3	0.00	83.3
Cycle 2 Day 22	157	75.58	23.38	0.0	83.33	100.0	150	-1.67	25.82	-66.7	0.00	100.0
Cycle 3 Day 1	200	78.42	23.62	0.0	83.33	100.0	190	0.96	28.02	-83.3	0.00	83.3
Cycle 3 Day 22	161	72.88	25.74	0.0	66.67	100.0	152	-3.73	25.96	-66.7	0.00	66.7
Cycle 4 Day 1	178	76.59	24.70	0.0	83.33	100.0	170	-1.18	28.41	-100.0	0.00	83.3
Cycle 4 Day 22	128	76.56	21.06	16.7	66.67	100.0	123	-2.98	28.39	-83.3	0.00	83.3
Cycle 5 Day 1	156	73.50	25.18	0.0	66.67	100.0	148	-4.50	29.65	-100.0	0.00	66.7
Cycle 5 Day 22	114	74.71	24.21	0.0	66.67	100.0	107	-2.49	28.67	-66.7	0.00	66.7
Cycle 6 Day 1	125	74.53	23.81	0.0	66.67	100.0	116	-3.30	29.91	-83.3	0.00	83.3
Cycle 6 Day 22	102	72.88	25.47	0.0	66.67	100.0	97	-4.64	29.54	-66.7	0.00	66.7
Cycle 7 Day 1	111	75.38	22.34	0.0	66.67	100.0	105	-5.24	26.79	-100.0	0.00	66.7
Cycle 7 Day 22	80	75.42	18.37	16.7	66.67	100.0	74	-4.50	28.31	-83.3	0.00	83.3
Cycle 8 Day 1	81	79.22	20.33	33.3	83.33	100.0	74	-1.80	28.74	-66.7	0.00	66.7
Cycle 8 Day 22	71	79.81	19.50	16.7	83.33	100.0	66	-2.02	28.12	-83.3	0.00	66.7
Cycle 9 Day 1	73	83.56	18.32	33.3	83.33	100.0	66	3.79	27.24	-66.7	0.00	66.7
Cycle 9 Day 22	54	79.32	17.42	50.0	66.67	100.0	50	-0.67	27.76	-33.3	0.00	66.7
Cycle 10 Day 1	58	78.45	19.50	33.3	83.33	100.0	53	-1.89	28.62	-66.7	0.00	66.7
Cycle 10 Day 22	47	78.01	19.69	33.3	66.67	100.0	44	-3.41	29.55	-66.7	0.00	66.7
Cycle 11 Day 1	50	81.00	19.92	33.3	83.33	100.0	46	-0.72	31.81	-66.7	0.00	83.3
Cycle 11 Day 22	35	76.67	18.17	50.0	66.67	100.0	32	-5.73	27.31	-50.0	0.00	50.0
Cycle 12 Day 1	43	78.29	20.42	16.7	66.67	100.0	39	-4.70	25.92	-50.0	0.00	50.0
Cycle 12 Day 22	32	77.60	18.26	50.0	75.00	100.0	30	-8.89	24.26	-50.0	-8.33	50.0
Cycle 13 Day 1	37	79.73	20.46	33.3	83.33	100.0	34	-3.92	28.15	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	81.86	18.52	33.3	83.33	100.0	31	-6.45	29.08	-66.7	0.00	83.3
Cycle 14 Day 1	31	76.34	23.48	0.0	66.67	100.0	30	-6.67	25.75	-50.0	0.00	50.0
Cycle 14 Day 22	24	79.86	21.41	33.3	83.33	100.0	24	-6.94	27.77	-50.0	0.00	66.7
Cycle 15 Day 1	26	82.05	19.39	33.3	83.33	100.0	26	-2.56	29.70	-66.7	0.00	83.3
Cycle 15 Day 22	22	80.30	25.01	33.3	91.67	100.0	22	-6.82	34.76	-66.7	0.00	100.0
Cycle 16 Day 1	25	80.67	22.91	33.3	100.00	100.0	25	-2.00	33.79	-66.7	0.00	100.0
Cycle 16 Day 22	19	79.82	23.95	33.3	100.00	100.0	19	-3.51	33.60	-50.0	0.00	100.0
Cycle 17 Day 1	19	79.82	26.98	0.0	83.33	100.0	19	-7.89	31.12	-100.0	0.00	50.0
Cycle 17 Day 22	14	77.38	30.39	0.0	91.67	100.0	14	-16.67	30.66	-100.0	0.00	16.7
Cycle 18 Day 1	16	84.38	17.71	50.0	91.67	100.0	16	-5.21	20.83	-33.3	0.00	50.0
Cycle 18 Day 22	11	87.88	16.82	66.7	100.00	100.0	11	-9.09	15.57	-33.3	0.00	0.0
Cycle 19 Day 1	13	89.74	14.50	66.7	100.00	100.0	13	-3.85	20.59	-33.3	0.00	50.0
Cycle 19 Day 22	11	86.36	16.36	66.7	100.00	100.0	11	-13.64	16.36	-33.3	0.00	0.0
Cycle 20 Day 1	13	88.46	15.79	66.7	100.00	100.0	13	-5.13	21.93	-33.3	0.00	50.0
Cycle 21 Day 1	11	92.42	13.67	66.7	100.00	100.0	11	0.00	19.72	-33.3	0.00	50.0
Study Disc 1	132	62.25	31.09	0.0	66.67	100.0	125	-13.47	34.04	-100.0	-16.67	83.3
30 D SFU Z/P	69	60.14	29.04	0.0	66.67	100.0	64	-15.62	29.23	-100.0	-16.67	50.0
90 D SFU Z/P	83	61.45	27.78	0.0	66.67	100.0	80	-15.00	34.74	-100.0	-16.67	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	75.52	28.02	0.0	83.33	100.0						
Cycle 1 Day 22	212	71.62	28.02	0.0	66.67	100.0	210	-4.13	24.10	-83.3	0.00	66.7
Cycle 2 Day 1	231	76.33	26.15	0.0	83.33	100.0	225	0.30	25.92	-100.0	0.00	66.7
Cycle 2 Day 22	185	75.14	26.30	0.0	83.33	100.0	181	-1.20	28.44	-100.0	0.00	83.3
Cycle 3 Day 1	204	78.35	23.06	0.0	83.33	100.0	198	2.19	26.57	-100.0	0.00	100.0
Cycle 3 Day 22	156	76.18	25.41	0.0	83.33	100.0	149	-0.89	25.98	-83.3	0.00	100.0
Cycle 4 Day 1	171	77.97	24.16	0.0	83.33	100.0	163	1.94	26.92	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	74.62	26.09	0.0	66.67	100.0	127	-2.76	24.91	-66.7	0.00	66.7
Cycle 5 Day 1	147	74.26	22.43	0.0	66.67	100.0	143	-3.15	26.68	-83.3	0.00	66.7
Cycle 5 Day 22	120	75.14	24.35	0.0	66.67	100.0	113	-3.10	27.69	-83.3	0.00	66.7
Cycle 6 Day 1	122	73.63	25.07	0.0	66.67	100.0	117	-5.56	26.17	-83.3	0.00	100.0
Cycle 6 Day 22	93	77.06	21.55	16.7	66.67	100.0	89	-2.06	24.72	-50.0	0.00	100.0
Cycle 7 Day 1	91	79.85	23.24	16.7	83.33	100.0	88	-1.70	20.54	-66.7	0.00	66.7
Cycle 7 Day 22	66	79.80	24.02	0.0	83.33	100.0	64	-1.56	20.73	-50.0	0.00	50.0
Cycle 8 Day 1	73	83.11	20.51	33.3	100.00	100.0	72	0.69	21.20	-33.3	0.00	66.7
Cycle 8 Day 22	56	83.93	17.40	33.3	83.33	100.0	54	1.54	19.50	-33.3	0.00	50.0
Cycle 9 Day 1	53	81.76	20.48	33.3	83.33	100.0	51	-1.96	21.51	-33.3	0.00	33.3
Cycle 9 Day 22	46	84.06	18.58	50.0	100.00	100.0	44	0.76	22.72	-50.0	0.00	50.0
Cycle 10 Day 1	47	83.69	22.65	0.0	100.00	100.0	45	-3.33	23.73	-100.0	0.00	50.0
Cycle 10 Day 22	35	83.81	22.68	16.7	100.00	100.0	34	-3.43	23.85	-83.3	0.00	50.0
Cycle 11 Day 1	37	87.39	17.75	33.3	100.00	100.0	35	0.00	20.61	-33.3	0.00	50.0
Cycle 11 Day 22	22	78.03	28.35	0.0	100.00	100.0	20	-11.67	18.02	-50.0	0.00	16.7
Cycle 12 Day 1	32	86.46	16.63	50.0	100.00	100.0	30	-2.22	18.94	-33.3	0.00	33.3
Cycle 12 Day 22	20	81.67	19.42	50.0	83.33	100.0	18	-2.78	15.39	-33.3	0.00	33.3
Cycle 13 Day 1	25	83.33	22.57	33.3	100.00	100.0	24	-4.86	23.81	-66.7	0.00	33.3
Cycle 13 Day 22	15	86.67	18.04	50.0	100.00	100.0	14	0.00	14.62	-33.3	0.00	33.3
Cycle 14 Day 1	23	84.06	16.27	50.0	83.33	100.0	22	-4.55	17.20	-33.3	0.00	33.3
Cycle 14 Day 22	13	78.21	21.93	33.3	83.33	100.0	12	-6.94	19.41	-50.0	0.00	16.7
Cycle 15 Day 1	19	84.21	21.85	33.3	100.00	100.0	19	-5.26	20.83	-66.7	0.00	33.3
Cycle 16 Day 1	11	77.27	21.44	33.3	66.67	100.0	11	-10.61	17.12	-33.3	0.00	16.7
Cycle 17 Day 1	10	80.00	24.60	33.3	91.67	100.0	10	-6.67	14.05	-33.3	0.00	16.7
Study Disc 1	137	64.96	31.26	0.0	66.67	100.0	133	-9.65	30.58	-100.0	0.00	66.7
Study Disc 2	10	55.00	40.86	0.0	66.67	100.0	10	-21.67	34.29	-66.7	-25.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	67.08	26.22	0.0	66.67	100.0	79	-13.08	30.51	-100.0	-16.67	50.0
90 D SFU Z/P	71	62.91	31.27	0.0	66.67	100.0	70	-16.43	27.87	-100.0	-16.67	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	74.64	20.71	0.0	75.00	100.0						
Cycle 1 Day 22	187	75.98	20.91	8.3	75.00	100.0	177	0.85	19.08	-58.3	0.00	66.7
Cycle 2 Day 1	217	79.72	19.64	8.3	83.33	100.0	207	4.55	20.49	-50.0	0.00	83.3
Cycle 2 Day 22	157	81.42	16.56	33.3	83.33	100.0	150	5.78	19.36	-58.3	0.00	66.7
Cycle 3 Day 1	200	82.08	18.32	0.0	83.33	100.0	190	6.27	20.28	-58.3	8.33	83.3
Cycle 3 Day 22	161	78.52	21.50	0.0	83.33	100.0	152	3.62	21.14	-75.0	0.00	91.7
Cycle 4 Day 1	178	81.74	18.32	0.0	83.33	100.0	170	7.40	20.20	-50.0	8.33	91.7
Cycle 4 Day 22	128	79.04	19.81	16.7	83.33	100.0	123	2.71	19.46	-50.0	0.00	58.3
Cycle 5 Day 1	156	79.01	20.42	8.3	83.33	100.0	148	3.89	24.00	-66.7	8.33	91.7
Cycle 5 Day 22	114	79.02	20.12	8.3	83.33	100.0	107	4.60	23.04	-50.0	0.00	66.7
Cycle 6 Day 1	125	80.27	18.74	8.3	83.33	100.0	116	5.03	24.25	-58.3	0.00	83.3
Cycle 6 Day 22	102	81.13	18.50	16.7	83.33	100.0	97	4.64	21.28	-50.0	0.00	83.3
Cycle 7 Day 1	111	81.38	17.94	16.7	83.33	100.0	105	5.24	21.53	-50.0	0.00	83.3
Cycle 7 Day 22	80	80.63	16.97	33.3	83.33	100.0	74	4.50	17.84	-33.3	0.00	58.3
Cycle 8 Day 1	81	81.48	17.18	16.7	83.33	100.0	74	5.29	18.94	-50.0	0.00	58.3
Cycle 8 Day 22	71	82.16	16.92	33.3	83.33	100.0	66	5.43	22.29	-58.3	0.00	58.3
Cycle 9 Day 1	73	80.25	20.58	0.0	83.33	100.0	66	6.69	22.94	-66.7	8.33	66.7
Cycle 9 Day 22	54	79.48	17.41	33.3	79.17	100.0	50	5.83	21.45	-41.7	0.00	58.3
Cycle 10 Day 1	58	81.03	17.99	33.3	83.33	100.0	53	6.76	20.55	-33.3	8.33	66.7
Cycle 10 Day 22	47	82.62	14.42	50.0	83.33	100.0	44	5.87	17.39	-33.3	0.00	41.7
Cycle 11 Day 1	50	83.17	16.71	33.3	91.67	100.0	46	7.61	17.55	-33.3	8.33	33.3
Cycle 11 Day 22	35	83.57	16.85	41.7	83.33	100.0	32	9.11	16.85	-33.3	8.33	41.7
Cycle 12 Day 1	43	83.91	16.10	41.7	83.33	100.0	39	8.97	16.93	-33.3	8.33	50.0
Cycle 12 Day 22	32	79.95	16.65	50.0	83.33	100.0	30	2.78	17.42	-25.0	0.00	50.0
Cycle 13 Day 1	37	82.88	16.31	50.0	91.67	100.0	34	5.64	20.79	-25.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	83.33	15.21	50.0	83.33	100.0	31	2.69	15.57	-33.3	0.00	25.0
Cycle 14 Day 1	31	78.76	20.95	8.3	83.33	100.0	30	3.33	18.13	-41.7	0.00	33.3
Cycle 14 Day 22	24	82.64	17.36	50.0	83.33	100.0	24	3.12	19.48	-33.3	0.00	50.0
Cycle 15 Day 1	26	84.29	14.21	50.0	83.33	100.0	26	5.45	17.47	-33.3	4.17	33.3
Cycle 15 Day 22	22	81.06	16.90	41.7	83.33	100.0	22	2.65	15.93	-33.3	0.00	41.7
Cycle 16 Day 1	25	86.33	15.57	58.3	91.67	100.0	25	8.00	20.48	-33.3	8.33	50.0
Cycle 16 Day 22	19	83.33	18.00	41.7	91.67	100.0	19	7.89	16.31	-25.0	8.33	41.7
Cycle 17 Day 1	19	80.70	25.01	0.0	83.33	100.0	19	5.26	30.58	-91.7	16.67	41.7
Cycle 17 Day 22	14	85.12	22.45	33.3	95.83	100.0	14	8.33	25.94	-58.3	8.33	50.0
Cycle 18 Day 1	16	85.94	13.51	58.3	83.33	100.0	16	13.54	18.97	-25.0	16.67	41.7
Cycle 18 Day 22	11	88.64	11.35	66.7	91.67	100.0	11	12.12	17.23	-8.3	16.67	41.7
Cycle 19 Day 1	13	92.95	10.12	66.7	100.00	100.0	13	19.23	18.44	-8.3	16.67	50.0
Cycle 19 Day 22	11	87.12	13.10	66.7	91.67	100.0	11	9.85	24.10	-25.0	0.00	50.0
Cycle 20 Day 1	13	92.95	10.12	66.7	100.00	100.0	13	16.03	17.17	-8.3	16.67	41.7
Cycle 21 Day 1	11	92.42	12.05	66.7	100.00	100.0	11	15.15	17.41	-8.3	8.33	41.7
Study Disc 1	132	71.40	22.89	0.0	75.00	100.0	125	-2.47	21.59	-66.7	0.00	66.7
30 D SFU Z/P	69	71.74	22.79	8.3	75.00	100.0	64	-2.73	22.32	-75.0	0.00	41.7
90 D SFU Z/P	83	75.00	20.20	16.7	75.00	100.0	80	-1.98	22.98	-66.7	0.00	50.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	73.45	21.16	0.0	75.00	100.0						
Cycle 1 Day 22	212	78.69	20.54	8.3	83.33	100.0	210	3.33	15.96	-50.0	0.00	58.3
Cycle 2 Day 1	231	80.74	18.95	0.0	83.33	100.0	225	6.15	17.93	-66.7	8.33	66.7
Cycle 2 Day 22	185	79.59	19.01	8.3	83.33	100.0	181	5.85	18.69	-58.3	0.00	58.3
Cycle 3 Day 1	204	83.58	17.37	8.3	83.33	100.0	198	9.43	18.44	-75.0	8.33	83.3
Cycle 3 Day 22	156	83.44	19.00	8.3	91.67	100.0	149	9.06	19.35	-75.0	8.33	58.3
Cycle 4 Day 1	171	83.14	17.17	16.7	83.33	100.0	163	8.13	18.86	-58.3	8.33	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	80.30	18.71	8.3	83.33	100.0	127	6.69	21.00	-91.7	0.00	83.3
Cycle 5 Day 1	147	79.54	18.99	16.7	83.33	100.0	143	5.65	20.11	-58.3	0.00	75.0
Cycle 5 Day 22	120	78.61	20.09	8.3	83.33	100.0	113	2.88	18.39	-50.0	0.00	66.7
Cycle 6 Day 1	122	79.85	19.28	16.7	83.33	100.0	117	5.34	17.90	-50.0	8.33	83.3
Cycle 6 Day 22	93	81.63	17.96	25.0	83.33	100.0	89	7.77	18.33	-33.3	8.33	75.0
Cycle 7 Day 1	91	82.51	17.96	25.0	83.33	100.0	88	8.81	19.18	-41.7	8.33	91.7
Cycle 7 Day 22	66	82.20	15.67	41.7	83.33	100.0	64	7.94	19.50	-33.3	4.17	75.0
Cycle 8 Day 1	73	84.47	18.65	8.3	91.67	100.0	72	9.14	17.87	-58.3	8.33	58.3
Cycle 8 Day 22	56	84.08	17.64	33.3	91.67	100.0	54	7.87	19.11	-41.7	4.17	58.3
Cycle 9 Day 1	53	86.01	14.96	41.7	91.67	100.0	51	8.50	16.96	-25.0	8.33	58.3
Cycle 9 Day 22	46	85.14	15.70	33.3	91.67	100.0	44	7.39	20.19	-41.7	0.00	58.3
Cycle 10 Day 1	47	86.70	15.41	41.7	91.67	100.0	45	8.70	19.21	-33.3	8.33	58.3
Cycle 10 Day 22	35	86.19	14.14	50.0	91.67	100.0	34	8.82	21.80	-33.3	8.33	58.3
Cycle 11 Day 1	37	86.26	14.86	33.3	91.67	100.0	35	8.10	21.24	-41.7	8.33	58.3
Cycle 11 Day 22	22	82.95	18.09	33.3	83.33	100.0	20	5.00	22.03	-33.3	8.33	58.3
Cycle 12 Day 1	32	83.07	15.91	33.3	83.33	100.0	30	3.33	18.39	-41.7	0.00	41.7
Cycle 12 Day 22	20	81.25	14.27	41.7	83.33	100.0	18	2.78	19.17	-33.3	8.33	25.0
Cycle 13 Day 1	25	83.00	18.86	33.3	91.67	100.0	24	1.74	21.42	-41.7	0.00	41.7
Cycle 13 Day 22	15	81.11	16.20	41.7	83.33	100.0	14	0.00	18.20	-33.3	8.33	25.0
Cycle 14 Day 1	23	83.33	17.77	41.7	83.33	100.0	22	2.65	20.31	-41.7	4.17	33.3
Cycle 14 Day 22	13	78.85	17.88	33.3	83.33	100.0	12	-3.47	22.60	-41.7	-8.33	25.0
Cycle 15 Day 1	19	79.82	18.49	33.3	75.00	100.0	19	-0.44	20.87	-41.7	0.00	25.0
Cycle 16 Day 1	11	75.76	23.70	33.3	75.00	100.0	11	-9.09	23.11	-41.7	-8.33	25.0
Cycle 17 Day 1	10	82.50	22.03	41.7	95.83	100.0	10	-2.50	20.43	-33.3	0.00	25.0
Study Disc 1	137	71.05	25.63	0.0	75.00	100.0	133	-2.94	22.57	-50.0	0.00	58.3
Study Disc 2	10	62.50	29.98	8.3	75.00	100.0	10	-10.83	29.67	-50.0	-12.50	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	75.51	19.91	8.3	75.00	100.0	79	-1.37	19.40	-50.0	0.00	41.7
90 D SFU Z/P	71	70.42	24.27	0.0	75.00	100.0	70	-4.76	24.52	-66.7	-8.33	58.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	87.48	17.62	0.0	100.00	100.0						
Cycle 1 Day 22	187	86.10	17.19	33.3	83.33	100.0	177	-3.01	18.04	-50.0	0.00	100.0
Cycle 2 Day 1	217	87.86	17.31	16.7	100.00	100.0	207	-0.16	19.57	-50.0	0.00	100.0
Cycle 2 Day 22	157	88.11	16.35	16.7	100.00	100.0	150	-1.00	16.75	-50.0	0.00	33.3
Cycle 3 Day 1	200	88.25	17.35	0.0	100.00	100.0	190	-0.61	20.67	-66.7	0.00	100.0
Cycle 3 Day 22	161	85.09	17.54	33.3	83.33	100.0	152	-3.07	18.83	-50.0	0.00	50.0
Cycle 4 Day 1	178	88.39	15.22	33.3	100.00	100.0	170	0.10	19.82	-66.7	0.00	83.3
Cycle 4 Day 22	128	84.24	19.99	16.7	83.33	100.0	123	-5.28	21.59	-83.3	0.00	66.7
Cycle 5 Day 1	156	84.51	19.41	16.7	83.33	100.0	148	-3.83	21.13	-83.3	0.00	50.0
Cycle 5 Day 22	114	84.50	20.41	16.7	100.00	100.0	107	-3.89	23.07	-83.3	0.00	83.3
Cycle 6 Day 1	125	82.53	19.61	0.0	83.33	100.0	116	-5.17	24.32	-100.0	0.00	100.0
Cycle 6 Day 22	102	85.78	20.09	0.0	100.00	100.0	97	-2.06	23.97	-83.3	0.00	100.0
Cycle 7 Day 1	111	86.64	16.02	33.3	100.00	100.0	105	-2.06	18.73	-50.0	0.00	66.7
Cycle 7 Day 22	80	87.29	16.40	33.3	100.00	100.0	74	-1.35	17.39	-50.0	0.00	66.7
Cycle 8 Day 1	81	86.21	18.03	16.7	100.00	100.0	74	-2.48	20.95	-83.3	0.00	50.0
Cycle 8 Day 22	71	88.50	16.81	33.3	100.00	100.0	66	1.01	21.85	-50.0	0.00	100.0
Cycle 9 Day 1	73	84.70	19.59	0.0	83.33	100.0	66	-1.26	21.14	-50.0	0.00	66.7
Cycle 9 Day 22	54	84.26	16.95	33.3	83.33	100.0	50	-2.33	21.82	-50.0	0.00	66.7
Cycle 10 Day 1	58	85.06	15.51	50.0	83.33	100.0	53	-0.63	23.56	-33.3	0.00	100.0
Cycle 10 Day 22	47	87.59	14.93	50.0	100.00	100.0	44	-2.27	18.18	-33.3	0.00	66.7
Cycle 11 Day 1	50	87.67	17.11	33.3	100.00	100.0	46	-1.09	16.63	-33.3	0.00	33.3
Cycle 11 Day 22	35	85.71	16.74	50.0	100.00	100.0	32	-3.13	16.63	-33.3	0.00	33.3
Cycle 12 Day 1	43	87.21	14.92	50.0	100.00	100.0	39	-1.71	18.26	-50.0	0.00	33.3
Cycle 12 Day 22	32	88.02	14.19	66.7	100.00	100.0	30	-1.11	19.04	-33.3	0.00	33.3
Cycle 13 Day 1	37	88.29	14.63	66.7	100.00	100.0	34	0.49	19.02	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	88.24	14.52	66.7	100.00	100.0	31	-1.61	18.93	-33.3	0.00	33.3
Cycle 14 Day 1	31	85.48	18.63	33.3	100.00	100.0	30	0.00	15.78	-33.3	0.00	33.3
Cycle 14 Day 22	24	84.03	17.36	50.0	83.33	100.0	24	-2.78	22.34	-33.3	0.00	33.3
Cycle 15 Day 1	26	85.90	16.79	50.0	91.67	100.0	26	-1.92	20.18	-50.0	0.00	33.3
Cycle 15 Day 22	22	87.12	17.01	50.0	100.00	100.0	22	0.76	18.17	-33.3	0.00	33.3
Cycle 16 Day 1	25	88.00	14.84	50.0	100.00	100.0	25	1.33	17.95	-33.3	0.00	33.3
Cycle 16 Day 22	19	87.72	16.52	50.0	100.00	100.0	19	2.63	19.45	-33.3	0.00	33.3
Cycle 17 Day 1	19	85.96	20.23	33.3	100.00	100.0	19	2.63	23.74	-66.7	0.00	33.3
Cycle 17 Day 22	14	86.90	19.81	50.0	100.00	100.0	14	0.00	23.57	-50.0	0.00	33.3
Cycle 18 Day 1	16	90.63	13.57	66.7	100.00	100.0	16	6.25	19.12	-33.3	0.00	33.3
Cycle 18 Day 22	11	90.91	13.67	66.7	100.00	100.0	11	3.03	20.84	-33.3	0.00	33.3
Cycle 19 Day 1	13	94.87	10.51	66.7	100.00	100.0	13	6.41	18.68	-33.3	0.00	33.3
Cycle 19 Day 22	11	90.91	13.67	66.7	100.00	100.0	11	1.52	22.92	-33.3	0.00	33.3
Cycle 20 Day 1	13	93.59	10.84	66.7	100.00	100.0	13	2.56	17.80	-33.3	0.00	33.3
Cycle 21 Day 1	11	92.42	11.46	66.7	100.00	100.0	11	0.00	16.67	-33.3	0.00	33.3
Study Disc 1	132	79.04	22.99	0.0	83.33	100.0	125	-8.13	23.15	-100.0	0.00	50.0
30 D SFU Z/P	69	78.74	23.72	0.0	83.33	100.0	64	-10.16	24.78	-100.0	0.00	50.0
90 D SFU Z/P	83	75.90	22.43	16.7	83.33	100.0	80	-12.29	21.50	-83.3	-8.33	33.3
Placebo + mFOLFOX6 (N=282)												
Baseline	258	86.69	18.35	16.7	100.00	100.0						
Cycle 1 Day 22	212	87.11	17.67	16.7	100.00	100.0	210	-0.32	14.49	-33.3	0.00	66.7
Cycle 2 Day 1	231	88.24	19.03	0.0	100.00	100.0	225	0.30	15.98	-66.7	0.00	66.7
Cycle 2 Day 22	185	87.21	17.16	16.7	100.00	100.0	181	-1.10	15.38	-50.0	0.00	33.3
Cycle 3 Day 1	204	87.83	17.75	16.7	100.00	100.0	198	-0.17	16.19	-83.3	0.00	33.3
Cycle 3 Day 22	156	89.32	15.95	33.3	100.00	100.0	149	-0.11	13.49	-33.3	0.00	33.3
Cycle 4 Day 1	171	87.33	17.11	33.3	100.00	100.0	163	-1.64	15.85	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	88.01	17.15	33.3	100.00	100.0	127	-1.84	16.16	-50.0	0.00	50.0
Cycle 5 Day 1	147	85.37	17.22	33.3	83.33	100.0	143	-3.61	17.37	-66.7	0.00	83.3
Cycle 5 Day 22	120	87.08	16.80	33.3	100.00	100.0	113	-3.39	16.08	-50.0	0.00	66.7
Cycle 6 Day 1	122	86.61	18.14	16.7	100.00	100.0	117	-3.13	17.22	-66.7	0.00	66.7
Cycle 6 Day 22	93	89.78	15.93	33.3	100.00	100.0	89	-0.37	15.07	-50.0	0.00	33.3
Cycle 7 Day 1	91	85.71	18.01	16.7	83.33	100.0	88	-2.65	16.93	-33.3	0.00	83.3
Cycle 7 Day 22	66	88.64	17.58	33.3	100.00	100.0	64	-2.08	12.42	-33.3	0.00	33.3
Cycle 8 Day 1	73	87.44	15.90	33.3	83.33	100.0	72	-3.01	14.35	-50.0	0.00	33.3
Cycle 8 Day 22	56	85.71	18.65	33.3	100.00	100.0	54	-6.48	17.56	-66.7	0.00	33.3
Cycle 9 Day 1	53	89.31	16.37	33.3	100.00	100.0	51	-2.29	13.75	-50.0	0.00	16.7
Cycle 9 Day 22	46	90.94	14.79	50.0	100.00	100.0	44	0.76	15.23	-50.0	0.00	33.3
Cycle 10 Day 1	47	89.01	15.26	33.3	100.00	100.0	45	-2.22	14.91	-50.0	0.00	33.3
Cycle 10 Day 22	35	88.10	19.63	33.3	100.00	100.0	34	-4.41	17.56	-66.7	0.00	33.3
Cycle 11 Day 1	37	88.29	16.13	50.0	100.00	100.0	35	-3.81	16.21	-50.0	0.00	33.3
Cycle 11 Day 22	22	92.42	16.04	33.3	100.00	100.0	20	-0.83	16.64	-50.0	0.00	33.3
Cycle 12 Day 1	32	90.10	16.86	33.3	100.00	100.0	30	-2.22	14.99	-50.0	0.00	33.3
Cycle 12 Day 22	20	86.67	14.91	50.0	83.33	100.0	18	-3.70	16.72	-33.3	0.00	16.7
Cycle 13 Day 1	25	88.00	18.33	33.3	100.00	100.0	24	-4.17	19.19	-50.0	0.00	16.7
Cycle 13 Day 22	15	88.89	20.57	33.3	100.00	100.0	14	-3.57	16.25	-50.0	0.00	16.7
Cycle 14 Day 1	23	85.51	19.66	33.3	100.00	100.0	22	-5.30	18.82	-66.7	0.00	16.7
Cycle 14 Day 22	13	83.33	20.41	33.3	83.33	100.0	12	-8.33	13.30	-33.3	-8.33	16.7
Cycle 15 Day 1	19	89.47	17.75	33.3	100.00	100.0	19	-1.75	13.49	-33.3	0.00	16.7
Cycle 16 Day 1	11	80.30	23.35	50.0	100.00	100.0	11	-13.64	20.84	-50.0	0.00	16.7
Cycle 17 Day 1	10	83.33	23.57	33.3	91.67	100.0	10	-8.33	18.00	-50.0	0.00	16.7
Study Disc 1	137	79.56	23.13	0.0	83.33	100.0	133	-7.14	22.03	-100.0	0.00	50.0
Study Disc 2	10	68.33	32.82	0.0	75.00	100.0	10	-18.33	31.87	-83.3	-8.33	16.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	83.13	16.98	33.3	83.33	100.0	79	-6.33	16.94	-50.0	0.00	33.3
90 D SFU Z/P	71	81.46	21.00	16.7	83.33	100.0	70	-7.62	20.20	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	75.36	25.77	0.0	83.33	100.0						
Cycle 1 Day 22	187	74.06	26.72	0.0	66.67	100.0	177	-3.11	24.13	-83.3	0.00	100.0
Cycle 2 Day 1	217	76.73	23.29	0.0	83.33	100.0	207	-0.32	24.24	-66.7	0.00	100.0
Cycle 2 Day 22	157	75.48	22.21	0.0	66.67	100.0	150	-2.44	23.04	-66.7	0.00	66.7
Cycle 3 Day 1	200	78.08	24.76	0.0	83.33	100.0	190	0.53	25.31	-66.7	0.00	66.7
Cycle 3 Day 22	161	71.84	25.43	0.0	66.67	100.0	152	-5.70	25.09	-83.3	0.00	50.0
Cycle 4 Day 1	178	78.37	22.59	16.7	83.33	100.0	170	0.20	24.86	-66.7	0.00	83.3
Cycle 4 Day 22	128	77.08	22.04	33.3	66.67	100.0	123	-0.95	25.28	-66.7	0.00	66.7
Cycle 5 Day 1	156	75.96	25.84	0.0	83.33	100.0	148	-1.80	29.17	-100.0	0.00	83.3
Cycle 5 Day 22	114	77.05	23.92	0.0	83.33	100.0	107	-0.47	27.23	-83.3	0.00	100.0
Cycle 6 Day 1	125	76.53	23.39	0.0	83.33	100.0	116	-0.57	24.57	-66.7	0.00	100.0
Cycle 6 Day 22	102	79.74	21.45	0.0	83.33	100.0	97	1.03	24.63	-66.7	0.00	66.7
Cycle 7 Day 1	111	77.48	20.06	0.0	66.67	100.0	105	-1.43	23.70	-66.7	0.00	83.3
Cycle 7 Day 22	80	76.88	20.80	16.7	66.67	100.0	74	0.45	25.28	-66.7	0.00	83.3
Cycle 8 Day 1	81	79.63	21.25	16.7	83.33	100.0	74	0.00	19.70	-50.0	0.00	50.0
Cycle 8 Day 22	71	80.75	21.02	0.0	83.33	100.0	66	0.76	19.71	-33.3	0.00	50.0
Cycle 9 Day 1	73	81.51	21.07	0.0	83.33	100.0	66	2.02	20.98	-50.0	0.00	50.0
Cycle 9 Day 22	54	82.41	17.56	33.3	83.33	100.0	50	2.67	19.15	-33.3	0.00	50.0
Cycle 10 Day 1	58	82.76	22.72	0.0	100.00	100.0	53	2.20	21.94	-66.7	0.00	33.3
Cycle 10 Day 22	47	81.56	20.92	0.0	83.33	100.0	44	-0.38	19.85	-33.3	0.00	33.3
Cycle 11 Day 1	50	85.00	18.21	33.3	91.67	100.0	46	2.90	20.58	-33.3	0.00	66.7
Cycle 11 Day 22	35	79.05	16.83	33.3	66.67	100.0	32	-3.12	21.35	-33.3	0.00	50.0
Cycle 12 Day 1	43	84.11	19.23	33.3	100.00	100.0	39	2.56	18.55	-33.3	0.00	33.3
Cycle 12 Day 22	32	79.17	25.40	0.0	83.33	100.0	30	-3.33	21.62	-50.0	0.00	33.3
Cycle 13 Day 1	37	81.08	19.71	33.3	83.33	100.0	34	0.49	19.46	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	83.33	20.92	33.3	100.00	100.0	31	0.00	23.57	-66.7	0.00	33.3
Cycle 14 Day 1	31	80.65	25.49	0.0	100.00	100.0	30	-1.11	20.03	-50.0	0.00	33.3
Cycle 14 Day 22	24	82.64	20.55	33.3	100.00	100.0	24	-2.08	20.45	-33.3	0.00	33.3
Cycle 15 Day 1	26	81.41	23.25	33.3	91.67	100.0	26	-1.92	26.38	-66.7	0.00	33.3
Cycle 15 Day 22	22	84.85	21.77	33.3	100.00	100.0	22	3.03	19.68	-33.3	0.00	33.3
Cycle 16 Day 1	25	85.33	20.59	33.3	100.00	100.0	25	1.33	23.53	-50.0	0.00	33.3
Cycle 16 Day 22	19	82.46	20.39	33.3	100.00	100.0	19	1.75	22.84	-33.3	0.00	33.3
Cycle 17 Day 1	19	79.82	25.81	0.0	83.33	100.0	19	-0.88	31.17	-100.0	0.00	33.3
Cycle 17 Day 22	14	76.19	20.37	33.3	66.67	100.0	14	-8.33	24.24	-66.7	0.00	33.3
Cycle 18 Day 1	16	84.38	16.63	66.7	91.67	100.0	16	2.08	20.07	-33.3	0.00	33.3
Cycle 18 Day 22	11	84.85	17.41	66.7	100.00	100.0	11	0.00	19.72	-33.3	0.00	33.3
Cycle 19 Day 1	13	87.18	16.88	66.7	100.00	100.0	13	3.85	20.59	-33.3	0.00	33.3
Cycle 19 Day 22	11	86.36	16.36	66.7	100.00	100.0	11	0.00	12.91	-16.7	0.00	33.3
Cycle 20 Day 1	13	89.74	16.01	66.7	100.00	100.0	13	6.41	19.88	-33.3	0.00	33.3
Cycle 21 Day 1	11	92.42	13.67	66.7	100.00	100.0	11	9.09	20.23	-33.3	0.00	33.3
Study Disc 1	132	65.78	30.15	0.0	66.67	100.0	125	-10.67	29.66	-83.3	0.00	66.7
30 D SFU Z/P	69	65.46	29.05	0.0	66.67	100.0	64	-13.54	31.55	-100.0	0.00	33.3
90 D SFU Z/P	83	68.67	26.72	0.0	66.67	100.0	80	-10.83	30.36	-83.3	-16.67	50.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	73.26	27.18	0.0	75.00	100.0						
Cycle 1 Day 22	212	73.98	26.52	0.0	83.33	100.0	210	0.48	23.05	-66.7	0.00	100.0
Cycle 2 Day 1	231	77.13	23.93	0.0	83.33	100.0	225	3.11	25.69	-66.7	0.00	100.0
Cycle 2 Day 22	185	77.03	24.12	0.0	83.33	100.0	181	2.76	27.47	-83.3	0.00	100.0
Cycle 3 Day 1	204	75.57	25.05	0.0	83.33	100.0	198	2.44	26.78	-100.0	0.00	83.3
Cycle 3 Day 22	156	77.46	21.74	16.7	83.33	100.0	149	3.80	25.86	-66.7	0.00	83.3
Cycle 4 Day 1	171	78.07	24.29	0.0	83.33	100.0	163	5.62	23.88	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	76.39	21.99	0.0	83.33	100.0	127	2.49	22.13	-66.7	0.00	66.7
Cycle 5 Day 1	147	74.49	25.38	0.0	83.33	100.0	143	0.82	28.82	-100.0	0.00	100.0
Cycle 5 Day 22	120	76.94	23.98	0.0	83.33	100.0	113	0.74	27.04	-100.0	0.00	100.0
Cycle 6 Day 1	122	76.23	23.66	0.0	66.67	100.0	117	0.14	26.40	-83.3	0.00	83.3
Cycle 6 Day 22	93	80.29	20.99	16.7	83.33	100.0	89	3.75	28.51	-66.7	0.00	100.0
Cycle 7 Day 1	91	80.40	22.17	16.7	83.33	100.0	88	1.52	22.97	-50.0	0.00	100.0
Cycle 7 Day 22	66	83.59	20.98	0.0	100.00	100.0	64	6.51	23.50	-33.3	0.00	100.0
Cycle 8 Day 1	73	83.79	20.97	16.7	100.00	100.0	72	4.63	21.34	-33.3	0.00	66.7
Cycle 8 Day 22	56	83.93	17.40	33.3	83.33	100.0	54	3.70	23.27	-33.3	0.00	66.7
Cycle 9 Day 1	53	85.85	17.72	33.3	100.00	100.0	51	5.56	23.49	-33.3	0.00	66.7
Cycle 9 Day 22	46	84.42	17.36	33.3	83.33	100.0	44	5.68	26.15	-33.3	0.00	66.7
Cycle 10 Day 1	47	84.04	20.25	33.3	100.00	100.0	45	1.85	27.35	-66.7	0.00	66.7
Cycle 10 Day 22	35	82.38	20.19	33.3	83.33	100.0	34	1.47	29.12	-50.0	0.00	100.0
Cycle 11 Day 1	37	87.39	17.75	33.3	100.00	100.0	35	6.19	22.90	-33.3	0.00	66.7
Cycle 11 Day 22	22	81.06	18.75	33.3	83.33	100.0	20	-3.33	17.61	-33.3	0.00	33.3
Cycle 12 Day 1	32	84.90	18.14	33.3	91.67	100.0	30	1.11	23.13	-50.0	0.00	66.7
Cycle 12 Day 22	20	85.00	16.13	50.0	83.33	100.0	18	2.78	16.42	-16.7	0.00	33.3
Cycle 13 Day 1	25	90.67	15.28	50.0	100.00	100.0	24	5.56	24.41	-33.3	0.00	66.7
Cycle 13 Day 22	15	87.78	17.21	50.0	100.00	100.0	14	7.14	26.73	-33.3	0.00	66.7
Cycle 14 Day 1	23	87.68	14.41	66.7	100.00	100.0	22	3.03	24.47	-33.3	0.00	66.7
Cycle 14 Day 22	13	83.33	18.00	50.0	83.33	100.0	12	1.39	20.67	-33.3	0.00	33.3
Cycle 15 Day 1	19	84.21	22.55	33.3	100.00	100.0	19	-3.51	20.47	-33.3	0.00	33.3
Cycle 16 Day 1	11	87.88	16.82	66.7	100.00	100.0	11	4.55	30.81	-33.3	0.00	66.7
Cycle 17 Day 1	10	85.00	18.34	50.0	91.67	100.0	10	0.00	33.33	-50.0	0.00	66.7
Study Disc 1	137	68.61	28.80	0.0	66.67	100.0	133	-3.38	23.37	-100.0	0.00	50.0
Study Disc 2	10	60.00	40.22	0.0	66.67	100.0	10	-13.33	42.89	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	72.02	23.54	0.0	66.67	100.0	79	-3.38	26.06	-66.7	0.00	66.7
90 D SFU Z/P	71	66.90	28.24	0.0	66.67	100.0	70	-7.14	28.31	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	31.13	23.94	0.0	33.33	100.0						
Cycle 1 Day 22	187	38.21	25.01	0.0	33.33	100.0	177	8.47	23.12	-66.7	0.00	100.0
Cycle 2 Day 1	217	32.92	23.10	0.0	33.33	100.0	207	3.81	22.20	-77.8	0.00	66.7
Cycle 2 Day 22	157	32.41	21.27	0.0	33.33	100.0	150	4.00	22.75	-66.7	0.00	66.7
Cycle 3 Day 1	200	30.50	21.86	0.0	33.33	100.0	190	2.11	23.61	-100.0	0.00	77.8
Cycle 3 Day 22	161	37.27	23.78	0.0	33.33	100.0	152	8.48	23.15	-44.4	11.11	77.8
Cycle 4 Day 1	178	30.40	22.14	0.0	33.33	88.9	170	1.70	25.04	-77.8	0.00	66.7
Cycle 4 Day 22	128	33.33	20.78	0.0	33.33	88.9	123	5.96	24.03	-88.9	0.00	66.7
Cycle 5 Day 1	156	33.62	23.91	0.0	33.33	100.0	148	4.95	26.85	-77.8	0.00	77.8
Cycle 5 Day 22	114	32.75	23.37	0.0	33.33	100.0	107	5.30	27.06	-77.8	0.00	66.7
Cycle 6 Day 1	125	29.42	23.50	0.0	33.33	100.0	116	2.20	25.85	-77.8	0.00	77.8
Cycle 6 Day 22	102	29.63	21.17	0.0	33.33	88.9	97	2.52	24.66	-100.0	0.00	66.7
Cycle 7 Day 1	111	27.03	18.99	0.0	33.33	100.0	105	0.74	22.02	-88.9	0.00	66.7
Cycle 7 Day 22	80	29.17	18.66	0.0	33.33	77.8	74	2.70	20.46	-66.7	0.00	55.6
Cycle 8 Day 1	81	26.20	21.39	0.0	33.33	100.0	74	0.15	24.43	-66.7	0.00	66.7
Cycle 8 Day 22	71	25.35	20.59	0.0	33.33	100.0	66	-0.34	22.30	-66.7	0.00	66.7
Cycle 9 Day 1	73	24.35	20.43	0.0	33.33	100.0	66	-3.37	22.81	-66.7	0.00	66.7
Cycle 9 Day 22	54	27.98	20.22	0.0	27.78	77.8	50	-0.44	22.56	-66.7	0.00	33.3
Cycle 10 Day 1	58	26.25	20.57	0.0	27.78	88.9	53	-0.42	24.06	-66.7	0.00	66.7
Cycle 10 Day 22	47	27.66	18.08	0.0	22.22	77.8	44	2.53	22.20	-66.7	0.00	44.4
Cycle 11 Day 1	50	23.11	18.08	0.0	22.22	55.6	46	-2.42	20.68	-33.3	0.00	55.6
Cycle 11 Day 22	35	25.08	19.31	0.0	22.22	77.8	32	-1.04	18.80	-33.3	0.00	44.4
Cycle 12 Day 1	43	24.81	17.46	0.0	22.22	77.8	39	-0.57	18.72	-44.4	0.00	33.3
Cycle 12 Day 22	32	27.08	16.92	0.0	33.33	55.6	30	4.07	16.11	-33.3	0.00	33.3
Cycle 13 Day 1	37	27.33	16.69	0.0	22.22	66.7	34	3.92	19.89	-44.4	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	26.80	16.89	0.0	22.22	55.6	31	5.38	20.06	-33.3	11.11	33.3
Cycle 14 Day 1	31	29.39	21.76	0.0	22.22	100.0	30	3.70	20.29	-44.4	0.00	55.6
Cycle 14 Day 22	24	26.85	18.22	0.0	33.33	66.7	24	3.70	21.65	-44.4	11.11	44.4
Cycle 15 Day 1	26	28.63	23.97	0.0	33.33	100.0	26	7.26	25.52	-33.3	11.11	88.9
Cycle 15 Day 22	22	27.27	15.98	0.0	27.78	55.6	22	5.05	19.62	-44.4	11.11	44.4
Cycle 16 Day 1	25	24.44	19.25	0.0	22.22	66.7	25	0.44	22.33	-44.4	0.00	55.6
Cycle 16 Day 22	19	26.32	18.96	0.0	33.33	55.6	19	1.17	20.59	-44.4	0.00	33.3
Cycle 17 Day 1	19	28.65	25.21	0.0	22.22	100.0	19	5.26	24.39	-22.2	0.00	77.8
Cycle 17 Day 22	14	27.78	19.85	0.0	27.78	66.7	14	6.35	18.34	-22.2	5.56	44.4
Cycle 18 Day 1	16	23.61	15.65	0.0	22.22	55.6	16	-0.69	18.80	-33.3	0.00	44.4
Cycle 18 Day 22	11	18.18	12.45	11.1	11.11	44.4	11	-3.03	15.78	-33.3	0.00	22.2
Cycle 19 Day 1	13	15.38	11.60	0.0	11.11	33.3	13	-5.98	19.57	-44.4	-11.11	22.2
Cycle 19 Day 22	11	17.17	13.48	0.0	22.22	33.3	11	-3.03	19.93	-33.3	0.00	22.2
Cycle 20 Day 1	13	19.66	12.13	0.0	22.22	33.3	13	-0.85	19.49	-33.3	0.00	22.2
Cycle 21 Day 1	11	16.16	12.54	0.0	22.22	33.3	11	-3.03	13.23	-22.2	0.00	22.2
Study Disc 1	132	43.10	28.14	0.0	33.33	100.0	125	12.18	27.49	-55.6	11.11	88.9
30 D SFU Z/P	69	44.44	25.42	0.0	44.44	100.0	64	9.90	26.50	-44.4	11.11	66.7
90 D SFU Z/P	83	43.11	25.94	0.0	44.44	100.0	80	12.78	29.43	-33.3	5.56	88.9
Placebo + mFOLFOX6 (N=282)												
Baseline	258	32.69	23.71	0.0	33.33	100.0						
Cycle 1 Day 22	212	36.11	25.04	0.0	33.33	100.0	210	4.50	20.34	-55.6	0.00	66.7
Cycle 2 Day 1	231	30.25	22.89	0.0	33.33	100.0	225	-1.48	22.30	-88.9	0.00	66.7
Cycle 2 Day 22	185	31.71	23.36	0.0	33.33	100.0	181	-0.06	21.90	-55.6	0.00	66.7
Cycle 3 Day 1	204	29.19	20.54	0.0	33.33	100.0	198	-2.13	21.92	-55.6	0.00	77.8
Cycle 3 Day 22	156	29.70	21.35	0.0	33.33	100.0	149	-0.37	21.47	-66.7	0.00	55.6
Cycle 4 Day 1	171	28.72	21.04	0.0	33.33	100.0	163	-1.30	23.34	-77.8	0.00	55.6

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	29.12	23.08	0.0	33.33	100.0	127	-1.49	22.89	-55.6	0.00	77.8
Cycle 5 Day 1	147	30.08	21.53	0.0	33.33	88.9	143	0.39	24.86	-55.6	0.00	88.9
Cycle 5 Day 22	120	29.91	21.74	0.0	33.33	100.0	113	2.06	25.31	-66.7	0.00	66.7
Cycle 6 Day 1	122	29.33	19.59	0.0	33.33	77.8	117	2.09	23.20	-55.6	0.00	66.7
Cycle 6 Day 22	93	26.76	18.98	0.0	33.33	77.8	89	-0.62	21.47	-66.7	0.00	44.4
Cycle 7 Day 1	91	23.93	20.01	0.0	22.22	88.9	88	-2.40	20.53	-55.6	0.00	33.3
Cycle 7 Day 22	66	25.42	18.57	0.0	27.78	66.7	64	-1.39	20.62	-55.6	0.00	33.3
Cycle 8 Day 1	73	22.98	20.81	0.0	22.22	77.8	72	-1.08	22.85	-55.6	0.00	77.8
Cycle 8 Day 22	56	23.21	19.10	0.0	22.22	66.7	54	-1.85	22.92	-44.4	0.00	66.7
Cycle 9 Day 1	53	19.29	18.89	0.0	11.11	66.7	51	-4.58	20.75	-44.4	0.00	33.3
Cycle 9 Day 22	46	22.22	17.99	0.0	22.22	66.7	44	-3.54	21.40	-55.6	0.00	33.3
Cycle 10 Day 1	47	17.02	18.51	0.0	11.11	66.7	45	-5.43	21.14	-44.4	0.00	66.7
Cycle 10 Day 22	35	21.90	21.64	0.0	22.22	66.7	34	-1.31	20.43	-33.3	0.00	55.6
Cycle 11 Day 1	37	17.72	20.19	0.0	11.11	66.7	35	-2.54	20.54	-44.4	0.00	44.4
Cycle 11 Day 22	22	21.72	25.08	0.0	16.67	77.8	20	0.56	20.54	-33.3	0.00	33.3
Cycle 12 Day 1	32	22.57	21.77	0.0	16.67	66.7	30	2.59	20.77	-33.3	0.00	44.4
Cycle 12 Day 22	20	27.22	25.61	0.0	27.78	66.7	18	3.70	18.67	-33.3	0.00	33.3
Cycle 13 Day 1	25	25.33	23.47	0.0	22.22	55.6	24	6.48	20.70	-44.4	5.56	55.6
Cycle 13 Day 22	15	24.44	23.83	0.0	22.22	66.7	14	3.97	17.76	-33.3	5.56	33.3
Cycle 14 Day 1	23	22.22	18.65	0.0	33.33	55.6	22	0.51	18.93	-33.3	0.00	33.3
Cycle 14 Day 22	13	29.06	21.05	0.0	33.33	66.7	12	4.63	15.32	-22.2	0.00	33.3
Cycle 15 Day 1	19	26.90	23.22	0.0	22.22	66.7	19	7.60	21.93	-44.4	11.11	44.4
Cycle 16 Day 1	11	31.31	20.98	0.0	33.33	55.6	11	14.14	12.26	-11.1	11.11	33.3
Cycle 17 Day 1	10	31.11	23.89	0.0	27.78	66.7	10	12.22	19.91	-22.2	22.22	44.4
Study Disc 1	137	39.09	27.52	0.0	33.33	100.0	133	5.01	27.27	-55.6	0.00	66.7
Study Disc 2	10	51.11	34.43	0.0	44.44	100.0	10	20.00	36.59	-33.3	33.33	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	36.63	21.11	0.0	33.33	88.9	79	6.05	25.27	-55.6	11.11	77.8
90 D SFU Z/P	71	41.78	24.38	0.0	33.33	100.0	70	12.38	25.56	-33.3	11.11	77.8

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	30.90	24.41	0.0	33.33	100.0						
	Cycle 1 Day 22	125	34.58	24.12	0.0	33.33	100.0	117	6.93	22.06	-66.7	0.00	100.0
	Cycle 2 Day 1	138	30.76	22.19	0.0	33.33	100.0	130	2.22	19.59	-77.8	0.00	55.6
	Cycle 2 Day 22	103	29.88	22.28	0.0	33.33	100.0	97	3.09	21.44	-66.7	0.00	44.4
	Cycle 3 Day 1	125	28.80	22.09	0.0	33.33	88.9	117	2.75	21.73	-100.0	0.00	66.7
	Cycle 3 Day 22	97	34.82	24.93	0.0	33.33	100.0	90	8.40	22.98	-44.4	11.11	77.8
	Cycle 4 Day 1	112	29.07	22.53	0.0	33.33	88.9	104	2.67	23.40	-77.8	0.00	66.7
	Cycle 4 Day 22	84	33.60	21.54	0.0	33.33	88.9	79	7.45	25.14	-88.9	11.11	66.7
	Cycle 5 Day 1	101	33.77	24.89	0.0	33.33	100.0	94	6.97	26.82	-77.8	0.00	77.8
	Cycle 5 Day 22	70	33.17	24.70	0.0	33.33	100.0	64	6.25	25.80	-77.8	0.00	66.7
	Cycle 6 Day 1	75	28.89	23.61	0.0	33.33	100.0	67	4.48	24.70	-77.8	0.00	55.6
	Cycle 6 Day 22	64	28.47	21.03	0.0	33.33	77.8	60	4.26	24.81	-100.0	0.00	66.7
	Cycle 7 Day 1	70	26.51	20.40	0.0	33.33	100.0	64	3.12	22.87	-88.9	0.00	66.7
	Cycle 7 Day 22	53	29.77	19.34	0.0	33.33	77.8	47	4.96	22.32	-66.7	0.00	55.6
	Cycle 8 Day 1	54	27.37	22.19	0.0	33.33	100.0	47	2.36	25.37	-66.7	0.00	66.7
	Cycle 8 Day 22	44	24.24	22.26	0.0	22.22	100.0	39	0.28	22.58	-33.3	0.00	66.7
	Cycle 9 Day 1	46	24.88	22.00	0.0	33.33	100.0	39	-1.71	23.99	-66.7	0.00	66.7
	Cycle 9 Day 22	32	30.56	22.93	0.0	33.33	77.8	28	2.78	23.74	-66.7	0.00	33.3
	Cycle 10 Day 1	36	30.56	22.75	0.0	33.33	88.9	31	5.38	26.58	-66.7	0.00	66.7
	Cycle 10 Day 22	30	25.19	19.56	0.0	22.22	77.8	27	0.82	23.86	-66.7	0.00	44.4
	Cycle 11 Day 1	33	23.91	19.27	0.0	22.22	55.6	29	0.77	22.41	-33.3	0.00	55.6
	Cycle 11 Day 22	23	27.05	20.87	0.0	33.33	77.8	20	1.11	20.68	-33.3	0.00	44.4
	Cycle 12 Day 1	26	27.35	18.39	0.0	27.78	77.8	22	1.01	20.26	-33.3	0.00	33.3
	Cycle 12 Day 22	18	27.78	18.77	0.0	33.33	55.6	16	4.17	18.54	-33.3	0.00	33.3
	Cycle 13 Day 1	21	26.98	17.77	0.0	22.22	66.7	18	4.32	22.27	-44.4	5.56	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	20	23.33	18.70	0.0	22.22	55.6	17	1.31	21.47	-33.3	0.00	33.3
	Cycle 14 Day 1	16	30.56	27.67	0.0	22.22	100.0	15	2.96	22.01	-44.4	11.11	33.3
	Cycle 14 Day 22	15	20.74	19.64	0.0	22.22	66.7	15	-2.96	24.66	-44.4	0.00	44.4
	Cycle 15 Day 1	14	23.81	21.29	0.0	22.22	55.6	14	2.38	20.52	-33.3	11.11	33.3
	Cycle 15 Day 22	15	25.93	15.53	0.0	22.22	55.6	15	2.96	19.91	-44.4	11.11	33.3
	Cycle 16 Day 1	13	17.95	15.41	0.0	22.22	44.4	13	-7.69	20.98	-44.4	0.00	22.2
	Cycle 16 Day 22	13	24.79	16.45	0.0	22.22	55.6	13	-1.71	22.15	-44.4	11.11	22.2
	Cycle 17 Day 1	12	26.85	20.90	0.0	22.22	77.8	12	3.70	20.29	-22.2	0.00	33.3
	Cycle 18 Day 1	10	18.89	14.86	0.0	11.11	44.4	10	-4.44	17.53	-33.3	0.00	22.2
	Study Disc 1	86	44.57	28.39	0.0	33.33	100.0	79	13.92	26.48	-44.4	11.11	88.9
	30 D SFU Z/P	44	44.44	26.25	0.0	44.44	100.0	40	9.72	26.41	-44.4	11.11	66.7
	90 D SFU Z/P	49	40.82	29.17	0.0	33.33	100.0	47	11.35	32.56	-33.3	0.00	88.9
	Placebo + mFOLFOX6 (N=175)												
	Baseline	160	30.00	23.14	0.0	33.33	100.0						
	Cycle 1 Day 22	138	33.98	24.34	0.0	33.33	100.0	136	5.72	19.92	-44.4	0.00	66.7
	Cycle 2 Day 1	151	29.80	22.75	0.0	33.33	100.0	145	0.77	19.67	-55.6	0.00	44.4
	Cycle 2 Day 22	128	30.12	22.49	0.0	33.33	100.0	124	0.99	18.03	-44.4	0.00	44.4
	Cycle 3 Day 1	130	28.12	20.15	0.0	33.33	77.8	125	0.18	18.56	-55.6	0.00	55.6
	Cycle 3 Day 22	105	29.63	22.94	0.0	33.33	100.0	100	1.33	21.03	-66.7	0.00	55.6
	Cycle 4 Day 1	109	28.44	22.65	0.0	22.22	100.0	102	1.20	22.76	-77.8	0.00	55.6
	Cycle 4 Day 22	87	29.25	24.09	0.0	33.33	100.0	83	0.54	23.79	-55.6	0.00	77.8
	Cycle 5 Day 1	93	28.08	21.33	0.0	33.33	88.9	90	0.37	23.46	-55.6	0.00	88.9
	Cycle 5 Day 22	83	27.98	20.26	0.0	33.33	66.7	77	2.60	23.36	-55.6	0.00	66.7
	Cycle 6 Day 1	74	28.83	20.39	0.0	33.33	77.8	70	3.97	22.70	-55.6	0.00	66.7
	Cycle 6 Day 22	61	25.32	19.68	0.0	33.33	77.8	58	-1.15	22.96	-66.7	0.00	44.4
	Cycle 7 Day 1	58	21.07	19.38	0.0	22.22	66.7	55	-2.22	22.06	-55.6	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	40	21.94	18.40	0.0	22.22	66.7	38	-1.75	22.60	-55.6	0.00	33.3
	Cycle 8 Day 1	45	20.49	19.95	0.0	22.22	66.7	44	-1.77	23.59	-55.6	0.00	55.6
	Cycle 8 Day 22	34	22.22	17.94	0.0	22.22	66.7	32	-2.78	22.75	-44.4	0.00	44.4
	Cycle 9 Day 1	33	20.20	20.50	0.0	11.11	66.7	31	-2.51	22.72	-44.4	0.00	33.3
	Cycle 9 Day 22	28	21.03	17.46	0.0	22.22	66.7	26	-3.85	23.71	-55.6	0.00	33.3
	Cycle 10 Day 1	26	14.53	17.99	0.0	5.56	55.6	24	-5.56	19.66	-44.4	0.00	33.3
	Cycle 10 Day 22	21	20.11	21.84	0.0	22.22	66.7	20	-1.67	19.84	-33.3	-5.56	33.3
	Cycle 11 Day 1	22	15.66	19.60	0.0	11.11	66.7	20	-2.78	19.70	-44.4	0.00	33.3
	Cycle 11 Day 22	13	18.80	24.17	0.0	11.11	66.7	11	3.03	19.93	-22.2	0.00	33.3
	Cycle 12 Day 1	17	20.92	23.86	0.0	11.11	66.7	15	4.44	21.74	-33.3	11.11	33.3
	Cycle 12 Day 22	11	25.25	27.71	0.0	22.22	66.7	9	7.41	19.25	-22.2	0.00	33.3
	Cycle 13 Day 1	14	23.02	24.45	0.0	16.67	55.6	13	5.13	17.34	-33.3	11.11	22.2
	Cycle 14 Day 1	11	20.20	20.38	0.0	22.22	44.4	10	-2.22	20.15	-33.3	5.56	22.2
	Study Disc 1	83	36.95	27.11	0.0	33.33	100.0	81	6.58	25.81	-55.6	0.00	66.7
	30 D SFU Z/P	57	35.87	20.03	0.0	33.33	77.8	56	7.54	20.99	-44.4	11.11	55.6
	90 D SFU Z/P	50	40.67	23.82	0.0	33.33	100.0	49	13.15	23.53	-22.2	11.11	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	31.50	23.28	0.0	33.33	88.9						
	Cycle 1 Day 22	62	45.52	25.35	0.0	44.44	100.0	60	11.48	24.97	-44.4	11.11	66.7
	Cycle 2 Day 1	79	36.71	24.29	0.0	33.33	100.0	77	6.49	25.95	-66.7	0.00	66.7
	Cycle 2 Day 22	54	37.24	18.46	0.0	33.33	77.8	53	5.66	25.09	-55.6	0.00	66.7
	Cycle 3 Day 1	75	33.33	21.30	0.0	33.33	100.0	73	1.07	26.46	-66.7	0.00	77.8
	Cycle 3 Day 22	64	40.97	21.58	0.0	38.89	100.0	62	8.60	23.58	-33.3	11.11	66.7
	Cycle 4 Day 1	66	32.66	21.43	0.0	33.33	88.9	66	0.17	27.53	-66.7	0.00	66.7
	Cycle 4 Day 22	44	32.83	19.46	0.0	33.33	77.8	44	3.28	21.91	-55.6	0.00	55.6
	Cycle 5 Day 1	55	33.33	22.22	0.0	33.33	88.9	54	1.44	26.79	-66.7	0.00	66.7
	Cycle 5 Day 22	44	32.07	21.33	0.0	33.33	88.9	43	3.88	29.08	-66.7	0.00	66.7
	Cycle 6 Day 1	50	30.22	23.55	0.0	33.33	100.0	49	-0.91	27.30	-66.7	0.00	77.8
	Cycle 6 Day 22	38	31.58	21.54	0.0	33.33	88.9	37	-0.30	24.50	-55.6	0.00	66.7
	Cycle 7 Day 1	41	27.91	16.50	0.0	33.33	77.8	41	-2.98	20.34	-44.4	0.00	55.6
	Cycle 7 Day 22	27	27.98	17.53	0.0	33.33	66.7	27	-1.23	16.40	-33.3	0.00	33.3
	Cycle 8 Day 1	27	23.87	19.90	0.0	22.22	88.9	27	-3.70	22.65	-44.4	0.00	66.7
	Cycle 8 Day 22	27	27.16	17.79	0.0	33.33	66.7	27	-1.23	22.29	-66.7	0.00	33.3
	Cycle 9 Day 1	27	23.46	17.79	0.0	33.33	55.6	27	-5.76	21.21	-66.7	0.00	44.4
	Cycle 9 Day 22	22	24.24	15.19	0.0	22.22	55.6	22	-4.55	20.76	-55.6	0.00	22.2
	Cycle 10 Day 1	22	19.19	14.21	0.0	22.22	33.3	22	-8.59	17.46	-44.4	-11.11	22.2
	Cycle 10 Day 22	17	32.03	14.64	0.0	33.33	55.6	17	5.23	19.69	-22.2	0.00	44.4
	Cycle 11 Day 1	17	21.57	15.94	0.0	22.22	44.4	17	-7.84	16.56	-33.3	0.00	11.1
	Cycle 11 Day 22	12	21.30	16.04	0.0	22.22	55.6	12	-4.63	15.32	-33.3	-5.56	22.2
	Cycle 12 Day 1	17	20.92	15.66	0.0	22.22	44.4	17	-2.61	16.91	-44.4	0.00	33.3
	Cycle 12 Day 22	14	26.19	14.85	0.0	33.33	44.4	14	3.97	13.51	-22.2	0.00	22.2
	Cycle 13 Day 1	16	27.78	15.71	0.0	27.78	66.7	16	3.47	17.55	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	14	31.75	12.97	0.0	33.33	55.6	14	10.32	17.68	-33.3	11.11	33.3
	Cycle 14 Day 1	15	28.15	13.84	0.0	22.22	66.7	15	4.44	19.15	-33.3	0.00	55.6
	Cycle 15 Day 1	12	34.26	26.57	0.0	33.33	100.0	12	12.96	30.27	-11.1	0.00	88.9
	Cycle 16 Day 1	12	31.48	21.10	0.0	33.33	66.7	12	9.26	21.10	-22.2	0.00	55.6
	Study Disc 1	46	40.34	27.75	0.0	33.33	100.0	46	9.18	29.19	-55.6	5.56	66.7
	30 D SFU Z/P	25	44.44	24.43	0.0	44.44	88.9	24	10.19	27.20	-44.4	11.11	66.7
	90 D SFU Z/P	34	46.41	20.37	11.1	44.44	88.9	33	14.81	24.64	-22.2	11.11	66.7
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	37.07	24.09	0.0	33.33	100.0						
	Cycle 1 Day 22	74	40.09	26.00	0.0	33.33	100.0	74	2.25	21.05	-55.6	0.00	44.4
	Cycle 2 Day 1	80	31.11	23.28	0.0	33.33	100.0	80	-5.56	26.04	-88.9	0.00	66.7
	Cycle 2 Day 22	57	35.28	25.03	0.0	33.33	100.0	57	-2.34	28.62	-55.6	0.00	66.7
	Cycle 3 Day 1	74	31.08	21.21	0.0	33.33	100.0	73	-6.09	26.39	-55.6	-11.11	77.8
	Cycle 3 Day 22	51	29.85	17.85	0.0	33.33	66.7	49	-3.85	22.17	-66.7	0.00	33.3
	Cycle 4 Day 1	62	29.21	18.02	0.0	33.33	77.8	61	-5.46	23.88	-55.6	0.00	55.6
	Cycle 4 Day 22	45	28.89	21.24	0.0	33.33	88.9	44	-5.30	20.82	-55.6	0.00	33.3
	Cycle 5 Day 1	54	33.54	21.64	0.0	33.33	88.9	53	0.42	27.30	-55.6	0.00	55.6
	Cycle 5 Day 22	37	34.23	24.48	0.0	33.33	100.0	36	0.93	29.38	-66.7	0.00	66.7
	Cycle 6 Day 1	48	30.09	18.47	0.0	33.33	77.8	47	-0.71	23.90	-55.6	0.00	55.6
	Cycle 6 Day 22	32	29.51	17.54	0.0	33.33	77.8	31	0.36	18.70	-44.4	0.00	33.3
	Cycle 7 Day 1	33	28.96	20.40	0.0	22.22	88.9	33	-2.69	18.01	-44.4	0.00	22.2
	Cycle 7 Day 22	26	30.77	17.86	0.0	33.33	66.7	26	-0.85	17.76	-55.6	0.00	22.2
	Cycle 8 Day 1	28	26.98	21.90	0.0	22.22	77.8	28	0.00	22.02	-44.4	0.00	77.8
	Cycle 8 Day 22	22	24.75	21.12	0.0	27.78	66.7	22	-0.51	23.63	-33.3	0.00	66.7
	Cycle 9 Day 1	20	17.78	16.28	0.0	16.67	44.4	20	-7.78	17.33	-44.4	-11.11	22.2
	Cycle 9 Day 22	18	24.07	19.15	0.0	22.22	66.7	18	-3.09	18.20	-44.4	0.00	22.2

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	21	20.11	19.12	0.0	22.22	66.7	21	-5.29	23.21	-33.3	-11.11	66.7
	Cycle 10 Day 22	14	24.60	21.87	0.0	22.22	55.6	14	-0.79	21.99	-33.3	0.00	55.6
	Cycle 11 Day 1	15	20.74	21.36	0.0	22.22	66.7	15	-2.22	22.30	-44.4	0.00	44.4
	Cycle 12 Day 1	15	24.44	19.79	0.0	22.22	66.7	15	0.74	20.34	-33.3	0.00	44.4
	Cycle 13 Day 1	11	28.28	22.97	0.0	33.33	55.6	11	8.08	24.89	-44.4	0.00	55.6
	Cycle 14 Day 1	12	24.07	17.62	0.0	33.33	55.6	12	2.78	18.43	-33.3	0.00	33.3
	Cycle 15 Day 1	10	24.44	20.82	0.0	22.22	55.6	10	3.33	22.25	-44.4	5.56	33.3
	Study Disc 1	54	42.39	28.07	0.0	33.33	100.0	52	2.56	29.49	-55.6	0.00	66.7
	30 D SFU Z/P	24	38.43	23.85	0.0	33.33	88.9	23	2.42	33.83	-55.6	0.00	77.8
	90 D SFU Z/P	21	44.44	26.06	0.0	33.33	100.0	21	10.58	30.32	-33.3	11.11	77.8

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	15.37	23.90	0.0	0.00	100.0						
Cycle 1 Day 22	187	23.08	22.28	0.0	16.67	100.0	177	9.13	23.77	-66.7	16.67	83.3
Cycle 2 Day 1	217	17.51	19.66	0.0	16.67	100.0	207	3.38	25.90	-83.3	0.00	100.0
Cycle 2 Day 22	157	17.62	20.08	0.0	16.67	83.3	150	4.33	23.76	-66.7	0.00	83.3
Cycle 3 Day 1	200	14.83	19.04	0.0	0.00	83.3	190	0.53	27.43	-100.0	0.00	66.7
Cycle 3 Day 22	161	18.32	21.43	0.0	16.67	100.0	152	4.61	24.28	-66.7	0.00	66.7
Cycle 4 Day 1	178	14.51	18.75	0.0	0.00	100.0	170	0.00	26.46	-83.3	0.00	83.3
Cycle 4 Day 22	128	14.32	17.84	0.0	16.67	83.3	123	2.30	25.46	-83.3	0.00	66.7
Cycle 5 Day 1	156	12.61	18.00	0.0	0.00	100.0	148	0.11	22.71	-66.7	0.00	66.7
Cycle 5 Day 22	114	13.16	20.26	0.0	0.00	100.0	107	2.34	20.02	-66.7	0.00	66.7
Cycle 6 Day 1	125	10.40	17.15	0.0	0.00	100.0	116	-2.16	18.97	-66.7	0.00	50.0
Cycle 6 Day 22	102	10.13	16.44	0.0	0.00	66.7	97	-0.52	22.37	-66.7	0.00	50.0
Cycle 7 Day 1	111	7.66	13.06	0.0	0.00	66.7	105	-2.86	18.98	-66.7	0.00	50.0
Cycle 7 Day 22	80	11.04	13.24	0.0	0.00	50.0	74	2.93	18.58	-66.7	0.00	50.0
Cycle 8 Day 1	81	7.61	12.65	0.0	0.00	50.0	74	-1.35	17.83	-66.7	0.00	33.3
Cycle 8 Day 22	71	11.27	15.11	0.0	0.00	66.7	66	-0.76	21.37	-66.7	0.00	50.0
Cycle 9 Day 1	73	7.31	15.21	0.0	0.00	83.3	66	-4.80	19.12	-66.7	0.00	33.3
Cycle 9 Day 22	54	10.80	15.91	0.0	0.00	66.7	50	1.00	19.46	-66.7	0.00	33.3
Cycle 10 Day 1	58	9.77	15.31	0.0	0.00	66.7	53	0.31	19.47	-66.7	0.00	50.0
Cycle 10 Day 22	47	10.28	13.26	0.0	0.00	50.0	44	0.76	21.25	-66.7	0.00	33.3
Cycle 11 Day 1	50	7.00	13.51	0.0	0.00	66.7	46	-1.81	18.33	-66.7	0.00	50.0
Cycle 11 Day 22	35	10.48	15.70	0.0	0.00	66.7	32	1.04	19.83	-66.7	0.00	33.3
Cycle 12 Day 1	43	6.98	12.72	0.0	0.00	50.0	39	-2.14	19.56	-66.7	0.00	50.0
Cycle 12 Day 22	32	9.38	15.80	0.0	0.00	66.7	30	0.00	20.99	-66.7	0.00	50.0
Cycle 13 Day 1	37	8.56	15.53	0.0	0.00	66.7	34	-1.96	21.23	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	8.82	16.53	0.0	0.00	66.7	31	0.54	22.97	-66.7	0.00	50.0
Cycle 14 Day 1	31	7.53	19.17	0.0	0.00	100.0	30	-5.00	20.13	-66.7	0.00	33.3
Cycle 14 Day 22	24	8.33	14.74	0.0	0.00	50.0	24	-4.86	27.57	-66.7	0.00	50.0
Cycle 15 Day 1	26	7.05	12.63	0.0	0.00	33.3	26	-1.28	21.56	-66.7	0.00	33.3
Cycle 15 Day 22	22	8.33	12.33	0.0	0.00	33.3	22	-3.79	24.09	-66.7	0.00	33.3
Cycle 16 Day 1	25	4.00	8.71	0.0	0.00	33.3	25	-8.67	22.11	-66.7	0.00	33.3
Cycle 16 Day 22	19	13.16	21.21	0.0	0.00	66.7	19	-1.75	34.20	-66.7	0.00	66.7
Cycle 17 Day 1	19	2.63	6.24	0.0	0.00	16.7	19	-9.65	20.27	-66.7	0.00	16.7
Cycle 17 Day 22	14	10.71	15.48	0.0	0.00	33.3	14	-2.38	24.33	-66.7	0.00	33.3
Cycle 18 Day 1	16	3.13	6.72	0.0	0.00	16.7	16	-10.42	24.25	-66.7	0.00	16.7
Cycle 18 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	0.00	22.36	-50.0	0.00	33.3
Cycle 19 Day 1	13	3.85	7.31	0.0	0.00	16.7	13	-5.13	18.49	-50.0	0.00	16.7
Cycle 19 Day 22	11	6.06	11.24	0.0	0.00	33.3	11	-4.55	21.20	-50.0	0.00	16.7
Cycle 20 Day 1	13	3.85	7.31	0.0	0.00	16.7	13	-2.56	16.45	-50.0	0.00	16.7
Cycle 21 Day 1	11	4.55	7.78	0.0	0.00	16.7	11	3.03	6.74	0.0	0.00	16.7
Study Disc 1	132	19.07	24.46	0.0	16.67	100.0	125	5.33	27.57	-66.7	0.00	100.0
30 D SFU Z/P	69	18.60	24.84	0.0	16.67	100.0	64	5.47	24.85	-66.7	0.00	66.7
90 D SFU Z/P	83	12.65	19.75	0.0	0.00	100.0	80	0.42	22.50	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	17.18	24.33	0.0	0.00	100.0						
Cycle 1 Day 22	212	19.10	21.78	0.0	16.67	100.0	210	2.70	23.19	-83.3	0.00	66.7
Cycle 2 Day 1	231	12.77	18.37	0.0	0.00	100.0	225	-3.70	23.85	-100.0	0.00	83.3
Cycle 2 Day 22	185	17.12	19.69	0.0	16.67	100.0	181	0.83	26.25	-83.3	0.00	100.0
Cycle 3 Day 1	204	10.62	15.66	0.0	0.00	66.7	198	-5.13	23.70	-100.0	0.00	66.7
Cycle 3 Day 22	156	13.57	17.43	0.0	16.67	83.3	149	-1.68	28.19	-100.0	0.00	83.3
Cycle 4 Day 1	171	10.23	17.36	0.0	0.00	100.0	163	-4.19	23.74	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	11.62	18.75	0.0	0.00	100.0	127	-3.41	25.57	-100.0	0.00	100.0
Cycle 5 Day 1	147	8.39	15.77	0.0	0.00	83.3	143	-6.88	23.84	-100.0	0.00	83.3
Cycle 5 Day 22	120	9.17	17.13	0.0	0.00	83.3	113	-5.90	22.15	-83.3	0.00	66.7
Cycle 6 Day 1	122	9.84	19.84	0.0	0.00	100.0	117	-3.56	24.35	-83.3	0.00	83.3
Cycle 6 Day 22	93	8.42	16.23	0.0	0.00	100.0	89	-5.43	24.59	-83.3	0.00	66.7
Cycle 7 Day 1	91	6.23	13.75	0.0	0.00	100.0	88	-5.11	20.74	-83.3	0.00	83.3
Cycle 7 Day 22	66	6.31	10.85	0.0	0.00	50.0	64	-5.99	22.49	-83.3	0.00	33.3
Cycle 8 Day 1	73	5.94	11.24	0.0	0.00	50.0	72	-3.94	16.90	-66.7	0.00	50.0
Cycle 8 Day 22	56	7.14	10.94	0.0	0.00	33.3	54	-4.63	22.99	-83.3	0.00	33.3
Cycle 9 Day 1	53	7.55	14.82	0.0	0.00	66.7	51	-4.25	25.13	-83.3	0.00	50.0
Cycle 9 Day 22	46	5.80	8.76	0.0	0.00	33.3	44	-5.68	23.00	-83.3	0.00	16.7
Cycle 10 Day 1	47	5.32	11.05	0.0	0.00	50.0	45	-5.19	20.04	-83.3	0.00	50.0
Cycle 10 Day 22	35	8.57	13.63	0.0	0.00	50.0	34	-3.92	26.61	-83.3	0.00	50.0
Cycle 11 Day 1	37	6.31	15.39	0.0	0.00	66.7	35	-3.33	22.43	-83.3	0.00	50.0
Cycle 11 Day 22	22	4.55	9.17	0.0	0.00	33.3	20	-5.83	27.19	-83.3	0.00	33.3
Cycle 12 Day 1	32	8.33	12.70	0.0	0.00	50.0	30	-1.67	26.39	-83.3	0.00	50.0
Cycle 12 Day 22	20	10.83	11.18	0.0	16.67	33.3	18	-2.78	28.15	-83.3	8.33	16.7
Cycle 13 Day 1	25	6.67	9.62	0.0	0.00	33.3	24	-2.78	25.85	-83.3	0.00	33.3
Cycle 13 Day 22	15	8.89	10.67	0.0	0.00	33.3	14	-5.95	27.43	-83.3	0.00	16.7
Cycle 14 Day 1	23	10.14	14.86	0.0	0.00	50.0	22	-0.76	24.92	-83.3	0.00	50.0
Cycle 14 Day 22	13	11.54	18.49	0.0	0.00	66.7	12	-2.78	27.37	-83.3	0.00	16.7
Cycle 15 Day 1	19	4.39	7.54	0.0	0.00	16.7	19	-5.26	25.49	-83.3	0.00	16.7
Cycle 16 Day 1	11	12.12	21.20	0.0	0.00	66.7	11	10.61	22.70	-16.7	0.00	66.7
Cycle 17 Day 1	10	5.00	8.05	0.0	0.00	16.7	10	3.33	10.54	-16.7	0.00	16.7
Study Disc 1	137	15.82	24.20	0.0	0.00	100.0	133	-1.25	26.64	-83.3	0.00	83.3
Study Disc 2	10	25.00	23.90	0.0	16.67	66.7	10	0.00	31.43	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	16.67	22.05	0.0	16.67	100.0	79	-2.32	27.05	-100.0	0.00	66.7
90 D SFU Z/P	71	12.21	19.10	0.0	0.00	66.7	70	-6.90	28.59	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	25.68	25.51	0.0	16.67	100.0						
Cycle 1 Day 22	187	22.01	21.40	0.0	16.67	100.0	177	-2.54	23.40	-66.7	0.00	66.7
Cycle 2 Day 1	217	17.97	22.44	0.0	16.67	100.0	207	-6.36	24.77	-83.3	0.00	83.3
Cycle 2 Day 22	157	16.03	18.77	0.0	16.67	83.3	150	-7.67	24.47	-100.0	0.00	66.7
Cycle 3 Day 1	200	14.75	18.39	0.0	8.33	100.0	190	-9.12	25.92	-100.0	0.00	66.7
Cycle 3 Day 22	161	16.67	18.82	0.0	16.67	83.3	152	-8.44	24.71	-100.0	0.00	50.0
Cycle 4 Day 1	178	15.07	18.38	0.0	16.67	66.7	170	-9.31	24.46	-83.3	0.00	50.0
Cycle 4 Day 22	128	15.23	17.12	0.0	16.67	66.7	123	-5.69	23.94	-66.7	0.00	50.0
Cycle 5 Day 1	156	16.88	20.12	0.0	16.67	83.3	148	-5.86	27.00	-83.3	0.00	66.7
Cycle 5 Day 22	114	15.50	19.55	0.0	0.00	83.3	107	-6.23	24.61	-66.7	0.00	66.7
Cycle 6 Day 1	125	15.33	19.12	0.0	16.67	100.0	116	-5.75	25.83	-66.7	0.00	100.0
Cycle 6 Day 22	102	16.01	19.33	0.0	16.67	83.3	97	-4.64	23.66	-66.7	0.00	50.0
Cycle 7 Day 1	111	14.71	18.08	0.0	16.67	83.3	105	-5.24	23.94	-66.7	0.00	66.7
Cycle 7 Day 22	80	16.87	17.89	0.0	16.67	66.7	74	-2.93	23.79	-66.7	0.00	50.0
Cycle 8 Day 1	81	16.67	19.72	0.0	16.67	83.3	74	-2.70	25.44	-66.7	0.00	66.7
Cycle 8 Day 22	71	14.08	17.05	0.0	0.00	66.7	66	-6.31	22.03	-66.7	0.00	33.3
Cycle 9 Day 1	73	14.84	17.69	0.0	0.00	66.7	66	-6.31	20.62	-66.7	0.00	50.0
Cycle 9 Day 22	54	17.59	18.43	0.0	16.67	83.3	50	-4.67	23.82	-66.7	0.00	33.3
Cycle 10 Day 1	58	17.24	17.65	0.0	16.67	66.7	53	-2.20	17.91	-50.0	0.00	33.3
Cycle 10 Day 22	47	18.44	18.47	0.0	16.67	66.7	44	1.14	21.98	-50.0	0.00	50.0
Cycle 11 Day 1	50	13.33	17.82	0.0	0.00	66.7	46	-5.80	21.15	-50.0	0.00	50.0
Cycle 11 Day 22	35	12.38	16.83	0.0	0.00	50.0	32	-4.17	19.40	-50.0	0.00	33.3
Cycle 12 Day 1	43	15.89	17.04	0.0	16.67	66.7	39	-2.99	18.29	-33.3	0.00	33.3
Cycle 12 Day 22	32	18.23	17.64	0.0	16.67	66.7	30	1.67	15.38	-33.3	0.00	33.3
Cycle 13 Day 1	37	14.86	14.58	0.0	16.67	50.0	34	-0.98	17.86	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	15.20	15.55	0.0	16.67	50.0	31	1.61	16.86	-33.3	0.00	33.3
Cycle 14 Day 1	31	16.67	21.08	0.0	16.67	83.3	30	-1.11	22.29	-33.3	0.00	66.7
Cycle 14 Day 22	24	11.81	14.31	0.0	8.33	50.0	24	-3.47	17.71	-33.3	0.00	33.3
Cycle 15 Day 1	26	14.10	18.07	0.0	0.00	66.7	26	-0.64	20.27	-33.3	0.00	66.7
Cycle 15 Day 22	22	12.12	15.59	0.0	0.00	50.0	22	-3.79	20.53	-50.0	0.00	33.3
Cycle 16 Day 1	25	16.67	17.35	0.0	16.67	66.7	25	0.67	23.31	-50.0	0.00	66.7
Cycle 16 Day 22	19	14.91	19.95	0.0	0.00	66.7	19	-5.26	21.55	-50.0	0.00	33.3
Cycle 17 Day 1	19	19.30	25.01	0.0	16.67	100.0	19	5.26	29.94	-50.0	0.00	100.0
Cycle 17 Day 22	14	15.48	21.15	0.0	0.00	66.7	14	2.38	26.03	-33.3	0.00	66.7
Cycle 18 Day 1	16	11.46	14.55	0.0	0.00	33.3	16	-5.21	22.54	-50.0	0.00	33.3
Cycle 18 Day 22	11	12.12	13.10	0.0	16.67	33.3	11	-1.52	21.67	-50.0	0.00	16.7
Cycle 19 Day 1	13	7.69	12.94	0.0	0.00	33.3	13	-5.13	21.93	-50.0	0.00	33.3
Cycle 19 Day 22	11	18.18	13.85	0.0	16.67	33.3	11	4.55	18.40	-33.3	0.00	33.3
Cycle 20 Day 1	13	8.97	12.94	0.0	0.00	33.3	13	-5.13	21.93	-33.3	0.00	33.3
Cycle 21 Day 1	11	7.58	11.46	0.0	0.00	33.3	11	-4.55	22.47	-33.3	-16.67	33.3
Study Disc 1	132	27.02	26.50	0.0	25.00	100.0	125	0.27	25.92	-66.7	0.00	83.3
30 D SFU Z/P	69	29.47	24.78	0.0	33.33	83.3	64	2.34	29.68	-66.7	0.00	83.3
90 D SFU Z/P	83	29.52	29.37	0.0	33.33	100.0	80	4.37	28.90	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	26.61	25.13	0.0	16.67	100.0						
Cycle 1 Day 22	212	20.28	20.84	0.0	16.67	83.3	210	-5.48	19.23	-66.7	0.00	50.0
Cycle 2 Day 1	231	16.38	20.50	0.0	16.67	100.0	225	-9.19	21.93	-100.0	0.00	83.3
Cycle 2 Day 22	185	16.22	22.55	0.0	0.00	100.0	181	-9.21	23.27	-83.3	0.00	100.0
Cycle 3 Day 1	204	15.60	19.86	0.0	0.00	100.0	198	-9.18	22.56	-66.7	0.00	66.7
Cycle 3 Day 22	156	17.20	22.59	0.0	0.00	100.0	149	-7.61	22.13	-66.7	0.00	50.0
Cycle 4 Day 1	171	13.74	20.32	0.0	0.00	100.0	163	-9.41	21.68	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	15.66	21.38	0.0	0.00	100.0	127	-8.01	22.99	-66.7	0.00	66.7
Cycle 5 Day 1	147	16.67	21.10	0.0	16.67	100.0	143	-6.53	23.41	-66.7	0.00	100.0
Cycle 5 Day 22	120	19.17	24.03	0.0	16.67	100.0	113	-5.90	24.49	-66.7	0.00	83.3
Cycle 6 Day 1	122	17.35	23.51	0.0	0.00	100.0	117	-5.13	24.51	-66.7	0.00	66.7
Cycle 6 Day 22	93	14.52	20.45	0.0	0.00	83.3	89	-8.99	18.98	-50.0	0.00	33.3
Cycle 7 Day 1	91	11.90	20.38	0.0	0.00	83.3	88	-8.33	19.08	-66.7	0.00	33.3
Cycle 7 Day 22	66	12.12	18.62	0.0	0.00	83.3	64	-7.55	19.68	-66.7	0.00	33.3
Cycle 8 Day 1	73	11.64	20.54	0.0	0.00	100.0	72	-8.33	17.91	-66.7	0.00	33.3
Cycle 8 Day 22	56	10.71	19.70	0.0	0.00	100.0	54	-9.26	15.41	-50.0	0.00	33.3
Cycle 9 Day 1	53	10.38	19.67	0.0	0.00	100.0	51	-9.15	19.24	-50.0	0.00	50.0
Cycle 9 Day 22	46	14.86	19.32	0.0	8.33	83.3	44	-5.30	20.89	-50.0	0.00	33.3
Cycle 10 Day 1	47	13.48	21.04	0.0	0.00	100.0	45	-3.33	24.52	-33.3	0.00	100.0
Cycle 10 Day 22	35	12.38	19.11	0.0	0.00	66.7	34	-5.88	22.05	-50.0	0.00	66.7
Cycle 11 Day 1	37	8.56	16.02	0.0	0.00	66.7	35	-7.14	17.29	-33.3	0.00	33.3
Cycle 11 Day 22	22	10.61	25.48	0.0	0.00	100.0	20	-5.83	17.33	-50.0	0.00	16.7
Cycle 12 Day 1	32	13.02	17.32	0.0	0.00	66.7	30	-2.78	15.83	-33.3	0.00	33.3
Cycle 12 Day 22	20	13.33	23.94	0.0	0.00	83.3	18	-10.19	18.20	-50.0	0.00	16.7
Cycle 13 Day 1	25	12.00	17.69	0.0	0.00	66.7	24	-2.08	19.85	-33.3	0.00	50.0
Cycle 13 Day 22	15	8.89	12.39	0.0	0.00	33.3	14	-5.95	19.18	-33.3	0.00	33.3
Cycle 14 Day 1	23	8.70	14.10	0.0	0.00	50.0	22	-4.55	17.95	-33.3	0.00	33.3
Cycle 14 Day 22	13	10.26	12.80	0.0	0.00	33.3	12	-11.11	17.88	-33.3	0.00	16.7
Cycle 15 Day 1	19	16.67	22.91	0.0	0.00	66.7	19	2.63	21.70	-33.3	0.00	66.7
Cycle 16 Day 1	11	13.64	24.52	0.0	0.00	66.7	11	-4.55	23.68	-33.3	0.00	50.0
Cycle 17 Day 1	10	11.67	22.29	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	16.7
Study Disc 1	137	29.44	27.21	0.0	33.33	100.0	133	1.13	29.46	-66.7	0.00	83.3
Study Disc 2	10	33.33	23.57	0.0	33.33	66.7	10	18.33	22.84	0.0	8.33	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	28.19	25.50	0.0	33.33	100.0	79	6.75	27.02	-50.0	0.00	66.7
90 D SFU Z/P	71	27.46	28.47	0.0	16.67	100.0	70	6.90	31.53	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Asia	Zolbetuximab + mFOLFOX6 (N= 88)												
	Baseline	84	16.67	22.26	0.0	8.33	100.0						
	Cycle 1 Day 22	65	18.46	21.47	0.0	16.67	66.7	64	3.13	20.11	-33.3	0.00	66.7
	Cycle 2 Day 1	78	15.60	22.04	0.0	0.00	100.0	76	-1.97	21.42	-66.7	0.00	83.3
	Cycle 2 Day 22	61	13.66	18.64	0.0	0.00	66.7	60	-4.44	21.23	-66.7	0.00	66.7
	Cycle 3 Day 1	77	13.20	15.37	0.0	0.00	50.0	75	-4.67	18.90	-66.7	0.00	50.0
	Cycle 3 Day 22	61	14.48	16.80	0.0	16.67	66.7	59	-3.67	19.34	-66.7	0.00	33.3
	Cycle 4 Day 1	68	12.75	15.54	0.0	0.00	50.0	66	-6.57	21.46	-83.3	0.00	50.0
	Cycle 4 Day 22	55	15.76	16.17	0.0	16.67	50.0	55	0.61	20.28	-66.7	0.00	50.0
	Cycle 5 Day 1	65	16.92	19.43	0.0	16.67	83.3	64	-0.52	24.48	-66.7	0.00	66.7
	Cycle 5 Day 22	47	15.60	19.48	0.0	16.67	83.3	47	1.06	20.38	-50.0	0.00	66.7
	Cycle 6 Day 1	52	19.23	21.99	0.0	16.67	100.0	51	2.94	25.54	-50.0	0.00	100.0
	Cycle 6 Day 22	41	18.29	17.40	0.0	16.67	50.0	41	5.69	18.11	-50.0	0.00	50.0
	Cycle 7 Day 1	46	17.75	19.05	0.0	16.67	83.3	45	4.81	21.50	-66.7	0.00	66.7
	Cycle 7 Day 22	35	22.86	19.84	0.0	33.33	66.7	35	9.05	21.14	-50.0	0.00	50.0
	Cycle 8 Day 1	38	20.61	21.38	0.0	16.67	83.3	37	5.86	24.28	-50.0	0.00	66.7
	Cycle 8 Day 22	29	16.67	17.82	0.0	16.67	66.7	29	2.87	17.29	-33.3	0.00	33.3
	Cycle 9 Day 1	32	14.06	15.90	0.0	0.00	33.3	31	0.54	15.20	-50.0	0.00	33.3
	Cycle 9 Day 22	25	19.33	14.17	0.0	16.67	33.3	25	6.67	20.97	-66.7	0.00	33.3
	Cycle 10 Day 1	28	17.26	16.66	0.0	16.67	50.0	27	4.32	15.04	-33.3	0.00	33.3
	Cycle 10 Day 22	22	16.67	19.25	0.0	0.00	50.0	22	6.82	18.30	-33.3	0.00	33.3
	Cycle 11 Day 1	24	18.06	18.98	0.0	16.67	66.7	23	5.80	18.54	-33.3	0.00	50.0
	Cycle 11 Day 22	20	13.33	16.75	0.0	0.00	50.0	20	3.33	16.75	-16.7	0.00	33.3
	Cycle 12 Day 1	21	15.87	17.06	0.0	16.67	50.0	20	5.00	14.41	-33.3	0.00	33.3
	Cycle 12 Day 22	18	15.74	16.64	0.0	8.33	33.3	18	4.63	15.97	-16.7	0.00	33.3
	Cycle 13 Day 1	22	16.67	13.61	0.0	16.67	33.3	21	5.56	16.94	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	20	16.67	17.10	0.0	16.67	50.0	20	5.83	17.33	-33.3	0.00	33.3
	Cycle 14 Day 1	17	12.75	12.54	0.0	16.67	33.3	17	0.98	17.15	-33.3	0.00	33.3
	Cycle 14 Day 22	15	14.44	16.51	0.0	16.67	50.0	15	3.33	12.91	-16.7	0.00	33.3
	Cycle 15 Day 1	14	15.48	16.62	0.0	8.33	33.3	14	4.76	12.10	-16.7	0.00	33.3
	Cycle 15 Day 22	14	16.67	17.30	0.0	16.67	50.0	14	4.76	18.98	-50.0	0.00	33.3
	Cycle 16 Day 1	15	20.00	19.11	0.0	16.67	66.7	15	7.78	24.29	-50.0	0.00	66.7
	Cycle 16 Day 22	13	15.38	20.93	0.0	0.00	66.7	13	1.28	18.59	-50.0	0.00	33.3
	Cycle 17 Day 1	14	21.43	27.29	0.0	16.67	100.0	14	10.71	31.76	-50.0	0.00	100.0
	Cycle 17 Day 22	11	16.67	22.36	0.0	0.00	66.7	11	7.58	23.99	-16.7	0.00	66.7
	Cycle 18 Day 1	11	12.12	15.08	0.0	0.00	33.3	11	-1.52	24.10	-50.0	0.00	33.3
	Study Disc 1	52	24.68	25.46	0.0	25.00	100.0	51	2.94	28.62	-66.7	0.00	83.3
	30 D SFU Z/P	28	30.36	25.28	0.0	33.33	83.3	27	7.41	31.46	-33.3	0.00	83.3
	90 D SFU Z/P	38	30.26	30.72	0.0	25.00	100.0	37	7.66	32.77	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N= 89)												
	Baseline	87	21.26	19.96	0.0	16.67	83.3						
	Cycle 1 Day 22	77	13.85	16.31	0.0	16.67	66.7	76	-7.24	17.71	-50.0	0.00	33.3
	Cycle 2 Day 1	82	11.99	14.88	0.0	0.00	50.0	81	-9.67	18.04	-50.0	0.00	33.3
	Cycle 2 Day 22	64	11.98	15.84	0.0	0.00	66.7	63	-9.26	22.75	-83.3	0.00	50.0
	Cycle 3 Day 1	70	12.86	17.30	0.0	0.00	66.7	70	-9.05	20.79	-50.0	0.00	50.0
	Cycle 3 Day 22	56	11.61	16.49	0.0	0.00	83.3	56	-11.90	21.49	-66.7	0.00	33.3
	Cycle 4 Day 1	59	11.30	17.63	0.0	0.00	100.0	59	-9.89	19.36	-50.0	0.00	33.3
	Cycle 4 Day 22	41	8.13	11.86	0.0	0.00	33.3	41	-12.60	18.92	-50.0	-16.67	33.3
	Cycle 5 Day 1	46	11.59	14.85	0.0	0.00	50.0	46	-8.33	20.41	-50.0	0.00	50.0
	Cycle 5 Day 22	39	17.95	21.76	0.0	16.67	83.3	39	-1.28	27.14	-50.0	0.00	83.3
	Cycle 6 Day 1	40	13.75	19.20	0.0	0.00	66.7	40	-5.00	22.71	-50.0	0.00	50.0
	Cycle 6 Day 22	30	8.89	12.93	0.0	0.00	33.3	30	-9.44	17.88	-33.3	-8.33	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 1	30	7.22	10.43	0.0	0.00	33.3	30	-8.89	17.36	-33.3	0.00	33.3
	Cycle 7 Day 22	23	10.14	13.98	0.0	0.00	33.3	23	-6.52	21.17	-50.0	0.00	33.3
	Cycle 8 Day 1	24	6.25	10.78	0.0	0.00	33.3	24	-11.81	15.13	-33.3	0.00	0.0
	Cycle 8 Day 22	16	5.21	10.03	0.0	0.00	33.3	16	-9.38	19.21	-33.3	-8.33	33.3
	Cycle 9 Day 1	16	5.21	10.03	0.0	0.00	33.3	16	-12.50	19.72	-50.0	-8.33	16.7
	Cycle 9 Day 22	12	12.50	12.56	0.0	16.67	33.3	12	-5.56	21.71	-33.3	0.00	33.3
	Cycle 10 Day 1	14	15.48	27.32	0.0	0.00	100.0	14	-4.76	36.06	-33.3	-8.33	100.0
	Cycle 10 Day 22	12	13.89	19.89	0.0	8.33	66.7	12	-6.94	31.35	-50.0	-16.67	66.7
	Cycle 11 Day 1	11	9.09	11.46	0.0	0.00	33.3	11	-10.61	20.10	-33.3	-16.67	33.3
	Study Disc 1	60	25.56	26.66	0.0	16.67	100.0	60	3.61	30.55	-66.7	0.00	83.3
	30 D SFU Z/P	38	22.37	20.97	0.0	16.67	66.7	37	3.60	27.54	-50.0	0.00	66.7
	90 D SFU Z/P	34	24.02	23.28	0.0	16.67	83.3	33	6.06	30.57	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Non-Asia	Zolbetuximab + mFOLFOX6 (N=195)												
	Baseline	173	30.06	25.90	0.0	33.33	100.0						
	Cycle 1 Day 22	122	23.91	21.21	0.0	16.67	100.0	113	-5.75	24.58	-66.7	0.00	66.7
	Cycle 2 Day 1	139	19.30	22.63	0.0	16.67	100.0	131	-8.91	26.25	-83.3	0.00	66.7
	Cycle 2 Day 22	96	17.53	18.79	0.0	16.67	83.3	90	-9.81	26.31	-100.0	0.00	33.3
	Cycle 3 Day 1	123	15.72	20.05	0.0	16.67	100.0	115	-12.03	29.33	-100.0	-16.67	66.7
	Cycle 3 Day 22	100	18.00	19.92	0.0	16.67	83.3	93	-11.47	27.25	-100.0	-16.67	50.0
	Cycle 4 Day 1	110	16.52	19.87	0.0	16.67	66.7	104	-11.06	26.13	-83.3	0.00	50.0
	Cycle 4 Day 22	73	14.84	17.91	0.0	16.67	66.7	68	-10.78	25.56	-66.7	-8.33	50.0
	Cycle 5 Day 1	91	16.85	20.71	0.0	0.00	66.7	84	-9.92	28.24	-83.3	0.00	66.7
	Cycle 5 Day 22	67	15.42	19.74	0.0	0.00	66.7	60	-11.94	26.23	-66.7	-8.33	50.0
	Cycle 6 Day 1	73	12.56	16.38	0.0	0.00	66.7	65	-12.56	24.12	-66.7	-16.67	33.3
	Cycle 6 Day 22	61	14.48	20.52	0.0	0.00	83.3	56	-12.20	24.51	-66.7	-16.67	33.3
	Cycle 7 Day 1	65	12.56	17.19	0.0	0.00	66.7	60	-12.78	23.04	-66.7	-16.67	33.3
	Cycle 7 Day 22	45	12.22	14.82	0.0	0.00	50.0	39	-13.68	20.90	-66.7	0.00	16.7
	Cycle 8 Day 1	43	13.18	17.65	0.0	0.00	66.7	37	-11.26	23.91	-66.7	0.00	50.0
	Cycle 8 Day 22	42	12.30	16.49	0.0	0.00	66.7	37	-13.51	22.85	-66.7	0.00	16.7
	Cycle 9 Day 1	41	15.45	19.15	0.0	16.67	66.7	35	-12.38	22.99	-66.7	-16.67	50.0
	Cycle 9 Day 22	29	16.09	21.59	0.0	0.00	83.3	25	-16.00	21.24	-66.7	-16.67	16.7
	Cycle 10 Day 1	30	17.22	18.82	0.0	16.67	66.7	26	-8.97	18.40	-50.0	0.00	33.3
	Cycle 10 Day 22	25	20.00	18.00	0.0	16.67	66.7	22	-4.55	24.22	-50.0	0.00	50.0
	Cycle 11 Day 1	26	8.97	15.80	0.0	0.00	66.7	23	-17.39	17.03	-50.0	-16.67	16.7
	Cycle 11 Day 22	15	11.11	17.44	0.0	0.00	50.0	12	-16.67	17.41	-50.0	-16.67	0.0
	Cycle 12 Day 1	22	15.91	17.43	0.0	16.67	66.7	19	-11.40	18.47	-33.3	-16.67	33.3
	Cycle 12 Day 22	14	21.43	18.98	0.0	16.67	66.7	12	-2.78	13.91	-33.3	0.00	16.7
	Cycle 13 Day 1	15	12.22	16.02	0.0	0.00	50.0	13	-11.54	14.25	-33.3	-16.67	16.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	14	13.10	13.36	0.0	16.67	33.3	11	-6.06	13.48	-33.3	0.00	16.7
	Cycle 14 Day 1	14	21.43	28.06	0.0	8.33	83.3	13	-3.85	28.18	-33.3	-16.67	66.7
	Cycle 15 Day 1	12	12.50	20.26	0.0	0.00	66.7	12	-6.94	26.07	-33.3	-16.67	66.7
	Cycle 16 Day 1	10	11.67	13.72	0.0	8.33	33.3	10	-10.00	17.92	-33.3	-16.67	16.7
	Study Disc 1	80	28.54	27.20	0.0	25.00	100.0	74	-1.58	23.92	-50.0	0.00	50.0
	30 D SFU Z/P	41	28.86	24.73	0.0	33.33	66.7	37	-1.35	28.16	-66.7	0.00	66.7
	90 D SFU Z/P	45	28.89	28.52	0.0	33.33	100.0	43	1.55	25.15	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=193)												
	Baseline	171	29.34	27.03	0.0	33.33	100.0						
	Cycle 1 Day 22	135	23.95	22.27	0.0	16.67	83.3	134	-4.48	20.04	-66.7	0.00	50.0
	Cycle 2 Day 1	149	18.79	22.70	0.0	16.67	100.0	144	-8.91	23.89	-100.0	0.00	83.3
	Cycle 2 Day 22	121	18.46	25.17	0.0	16.67	100.0	118	-9.18	23.63	-66.7	0.00	100.0
	Cycle 3 Day 1	134	17.04	20.99	0.0	16.67	100.0	128	-9.24	23.55	-66.7	0.00	66.7
	Cycle 3 Day 22	100	20.33	24.91	0.0	16.67	100.0	93	-5.02	22.22	-66.7	0.00	50.0
	Cycle 4 Day 1	112	15.03	21.57	0.0	0.00	100.0	104	-9.13	22.98	-66.7	0.00	50.0
	Cycle 4 Day 22	91	19.05	23.78	0.0	16.67	100.0	86	-5.81	24.49	-66.7	0.00	66.7
	Cycle 5 Day 1	101	18.98	23.10	0.0	16.67	100.0	97	-5.67	24.75	-66.7	0.00	100.0
	Cycle 5 Day 22	81	19.75	25.15	0.0	16.67	100.0	74	-8.33	22.79	-66.7	0.00	66.7
	Cycle 6 Day 1	82	19.11	25.27	0.0	0.00	100.0	77	-5.19	25.54	-66.7	0.00	66.7
	Cycle 6 Day 22	63	17.20	22.79	0.0	0.00	83.3	59	-8.76	19.66	-50.0	0.00	33.3
	Cycle 7 Day 1	61	14.21	23.54	0.0	0.00	83.3	58	-8.05	20.05	-66.7	0.00	33.3
	Cycle 7 Day 22	43	13.18	20.75	0.0	0.00	83.3	41	-8.13	19.05	-66.7	0.00	33.3
	Cycle 8 Day 1	49	14.29	23.57	0.0	0.00	100.0	48	-6.60	19.06	-66.7	0.00	33.3
	Cycle 8 Day 22	40	12.92	22.16	0.0	0.00	100.0	38	-9.21	13.81	-50.0	0.00	16.7
	Cycle 9 Day 1	37	12.61	22.36	0.0	0.00	100.0	35	-7.62	19.11	-50.0	0.00	50.0
	Cycle 9 Day 22	34	15.69	21.30	0.0	0.00	83.3	32	-5.21	20.93	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	33	12.63	18.18	0.0	0.00	66.7	31	-2.69	17.79	-33.3	0.00	33.3
	Cycle 10 Day 22	23	11.59	19.09	0.0	0.00	66.7	22	-5.30	15.76	-33.3	0.00	16.7
	Cycle 11 Day 1	26	8.33	17.80	0.0	0.00	66.7	24	-5.56	16.05	-33.3	0.00	33.3
	Cycle 11 Day 22	16	14.58	29.11	0.0	0.00	100.0	14	-1.19	13.81	-33.3	0.00	16.7
	Cycle 12 Day 1	23	13.04	18.77	0.0	0.00	66.7	21	-1.59	13.85	-33.3	0.00	33.3
	Cycle 12 Day 22	14	19.05	26.84	0.0	8.33	83.3	12	-1.39	11.14	-16.7	0.00	16.7
	Cycle 13 Day 1	17	13.73	20.61	0.0	0.00	66.7	16	3.13	18.48	-33.3	0.00	50.0
	Cycle 13 Day 22	10	11.67	13.72	0.0	8.33	33.3	9	1.85	15.47	-16.7	0.00	33.3
	Cycle 14 Day 1	15	10.00	16.43	0.0	0.00	50.0	14	1.19	15.28	-33.3	0.00	33.3
	Cycle 15 Day 1	13	10.26	19.88	0.0	0.00	66.7	13	0.00	13.61	-33.3	0.00	16.7
	Study Disc 1	77	32.47	27.43	0.0	33.33	100.0	73	-0.91	28.58	-66.7	0.00	66.7
	30 D SFU Z/P	43	33.33	28.17	0.0	33.33	100.0	42	9.52	26.58	-33.3	0.00	66.7
	90 D SFU Z/P	37	30.63	32.52	0.0	16.67	100.0	37	7.66	32.77	-50.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	13.23	22.97	0.0	0.00	100.0						
Cycle 1 Day 22	187	14.44	21.85	0.0	0.00	100.0	177	1.88	22.67	-66.7	0.00	100.0
Cycle 2 Day 1	217	12.60	20.41	0.0	0.00	66.7	207	0.48	20.90	-100.0	0.00	66.7
Cycle 2 Day 22	157	10.40	17.64	0.0	0.00	100.0	150	-0.67	20.96	-66.7	0.00	66.7
Cycle 3 Day 1	200	11.33	19.89	0.0	0.00	100.0	190	0.35	24.24	-100.0	0.00	66.7
Cycle 3 Day 22	161	13.25	20.17	0.0	0.00	100.0	152	1.32	21.32	-66.7	0.00	33.3
Cycle 4 Day 1	178	11.42	21.27	0.0	0.00	100.0	170	-0.20	23.36	-100.0	0.00	66.7
Cycle 4 Day 22	128	11.46	19.37	0.0	0.00	100.0	123	2.71	20.29	-66.7	0.00	66.7
Cycle 5 Day 1	156	11.97	18.53	0.0	0.00	66.7	148	2.25	20.82	-66.7	0.00	66.7
Cycle 5 Day 22	114	10.82	18.55	0.0	0.00	66.7	107	1.56	21.66	-100.0	0.00	66.7
Cycle 6 Day 1	125	11.73	19.52	0.0	0.00	66.7	116	0.86	23.45	-100.0	0.00	66.7
Cycle 6 Day 22	102	10.13	18.04	0.0	0.00	66.7	97	0.34	21.24	-100.0	0.00	66.7
Cycle 7 Day 1	111	12.61	19.62	0.0	0.00	100.0	105	3.49	21.64	-33.3	0.00	100.0
Cycle 7 Day 22	80	11.25	19.80	0.0	0.00	66.7	74	4.50	19.37	-33.3	0.00	66.7
Cycle 8 Day 1	81	9.05	17.49	0.0	0.00	100.0	74	2.70	20.46	-33.3	0.00	100.0
Cycle 8 Day 22	71	9.39	16.12	0.0	0.00	66.7	66	2.02	18.38	-66.7	0.00	33.3
Cycle 9 Day 1	73	10.96	17.62	0.0	0.00	66.7	66	2.53	18.77	-66.7	0.00	33.3
Cycle 9 Day 22	54	9.88	15.36	0.0	0.00	33.3	50	2.00	24.66	-100.0	0.00	33.3
Cycle 10 Day 1	58	10.92	19.13	0.0	0.00	100.0	53	3.14	26.36	-100.0	0.00	100.0
Cycle 10 Day 22	47	8.51	16.25	0.0	0.00	66.7	44	3.03	17.34	-33.3	0.00	33.3
Cycle 11 Day 1	50	6.00	14.58	0.0	0.00	66.7	46	0.00	17.21	-33.3	0.00	66.7
Cycle 11 Day 22	35	6.67	15.76	0.0	0.00	66.7	32	3.13	17.68	-33.3	0.00	66.7
Cycle 12 Day 1	43	11.63	19.08	0.0	0.00	66.7	39	6.84	13.64	0.0	0.00	33.3
Cycle 12 Day 22	32	8.33	14.66	0.0	0.00	33.3	30	4.44	14.47	-33.3	0.00	33.3
Cycle 13 Day 1	37	9.91	15.45	0.0	0.00	33.3	34	5.88	15.29	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	7.84	14.35	0.0	0.00	33.3	31	5.38	15.15	-33.3	0.00	33.3
Cycle 14 Day 1	31	8.60	14.83	0.0	0.00	33.3	30	3.33	13.42	-33.3	0.00	33.3
Cycle 14 Day 22	24	6.94	13.83	0.0	0.00	33.3	24	2.78	13.61	-33.3	0.00	33.3
Cycle 15 Day 1	26	7.69	14.32	0.0	0.00	33.3	26	2.56	13.07	-33.3	0.00	33.3
Cycle 15 Day 22	22	4.55	11.71	0.0	0.00	33.3	22	0.00	10.29	-33.3	0.00	33.3
Cycle 16 Day 1	25	8.00	14.53	0.0	0.00	33.3	25	2.67	13.33	-33.3	0.00	33.3
Cycle 16 Day 22	19	7.02	13.96	0.0	0.00	33.3	19	1.75	13.49	-33.3	0.00	33.3
Cycle 17 Day 1	19	12.28	16.52	0.0	0.00	33.3	19	5.26	12.49	0.0	0.00	33.3
Cycle 17 Day 22	14	11.90	21.11	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	66.7
Cycle 18 Day 1	16	10.42	15.96	0.0	0.00	33.3	16	2.08	14.75	-33.3	0.00	33.3
Cycle 18 Day 22	11	15.15	22.92	0.0	0.00	66.7	11	12.12	22.47	0.0	0.00	66.7
Cycle 19 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	5.13	12.52	0.0	0.00	33.3
Cycle 19 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Cycle 20 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	2.56	9.25	0.0	0.00	33.3
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
Study Disc 1	132	20.20	27.55	0.0	0.00	100.0	125	7.47	28.36	-66.7	0.00	100.0
30 D SFU Z/P	69	20.77	28.64	0.0	0.00	100.0	64	4.69	25.10	-66.7	0.00	66.7
90 D SFU Z/P	83	26.10	29.01	0.0	33.33	100.0	80	13.75	30.79	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	13.70	23.20	0.0	0.00	100.0						
Cycle 1 Day 22	212	12.89	24.10	0.0	0.00	100.0	210	1.43	22.19	-66.7	0.00	100.0
Cycle 2 Day 1	231	11.69	19.98	0.0	0.00	100.0	225	0.59	20.88	-100.0	0.00	100.0
Cycle 2 Day 22	185	11.53	19.94	0.0	0.00	100.0	181	0.18	21.52	-66.7	0.00	66.7
Cycle 3 Day 1	204	12.25	19.49	0.0	0.00	100.0	198	1.01	20.13	-66.7	0.00	66.7
Cycle 3 Day 22	156	12.39	23.10	0.0	0.00	100.0	149	2.24	21.10	-66.7	0.00	66.7
Cycle 4 Day 1	171	12.48	20.46	0.0	0.00	100.0	163	1.43	21.07	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	11.11	19.61	0.0	0.00	100.0	127	0.26	20.36	-66.7	0.00	66.7
Cycle 5 Day 1	147	10.88	19.96	0.0	0.00	100.0	143	0.00	23.74	-66.7	0.00	100.0
Cycle 5 Day 22	120	11.67	19.16	0.0	0.00	66.7	113	1.77	22.20	-100.0	0.00	66.7
Cycle 6 Day 1	122	13.66	20.89	0.0	0.00	100.0	117	3.70	22.22	-66.7	0.00	66.7
Cycle 6 Day 22	93	11.11	18.61	0.0	0.00	66.7	89	1.50	21.27	-66.7	0.00	66.7
Cycle 7 Day 1	91	9.52	17.42	0.0	0.00	66.7	88	-1.52	20.16	-100.0	0.00	33.3
Cycle 7 Day 22	66	7.07	17.06	0.0	0.00	100.0	64	-2.08	18.66	-66.7	0.00	33.3
Cycle 8 Day 1	73	9.13	17.80	0.0	0.00	66.7	72	0.00	21.67	-66.7	0.00	66.7
Cycle 8 Day 22	56	7.14	15.19	0.0	0.00	66.7	54	-3.09	18.62	-66.7	0.00	33.3
Cycle 9 Day 1	53	8.81	17.48	0.0	0.00	66.7	51	-2.61	19.82	-66.7	0.00	33.3
Cycle 9 Day 22	46	7.25	15.58	0.0	0.00	66.7	44	-2.27	19.55	-66.7	0.00	33.3
Cycle 10 Day 1	47	9.22	17.99	0.0	0.00	66.7	45	0.00	17.41	-66.7	0.00	33.3
Cycle 10 Day 22	35	8.57	20.36	0.0	0.00	66.7	34	2.94	17.15	-33.3	0.00	66.7
Cycle 11 Day 1	37	5.41	14.73	0.0	0.00	66.7	35	-0.95	12.75	-33.3	0.00	33.3
Cycle 11 Day 22	22	6.06	16.70	0.0	0.00	66.7	20	1.67	13.13	-33.3	0.00	33.3
Cycle 12 Day 1	32	8.33	18.93	0.0	0.00	66.7	30	2.22	14.99	-33.3	0.00	33.3
Cycle 12 Day 22	20	13.33	25.13	0.0	0.00	100.0	18	5.56	17.15	-33.3	0.00	33.3
Cycle 13 Day 1	25	12.00	23.33	0.0	0.00	100.0	24	5.56	16.05	-33.3	0.00	33.3
Cycle 13 Day 22	15	11.11	27.22	0.0	0.00	100.0	14	2.38	15.82	-33.3	0.00	33.3
Cycle 14 Day 1	23	8.70	18.03	0.0	0.00	66.7	22	3.03	17.55	-33.3	0.00	33.3
Cycle 14 Day 22	13	12.82	21.68	0.0	0.00	66.7	12	2.78	17.16	-33.3	0.00	33.3
Cycle 15 Day 1	19	8.77	18.73	0.0	0.00	66.7	19	3.51	18.90	-33.3	0.00	33.3
Cycle 16 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	6.06	13.48	0.0	0.00	33.3
Cycle 17 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
Study Disc 1	137	20.68	27.16	0.0	0.00	100.0	133	7.77	27.49	-66.7	0.00	100.0
Study Disc 2	10	33.33	38.49	0.0	33.33	100.0	10	16.67	36.00	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	15.64	21.79	0.0	0.00	100.0	79	5.91	20.51	-66.7	0.00	100.0
90 D SFU Z/P	71	20.66	26.65	0.0	0.00	100.0	70	12.86	27.97	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	27.50	28.50	0.0	33.33	100.0						
Cycle 1 Day 22	187	24.96	26.91	0.0	33.33	100.0	177	0.00	27.52	-100.0	0.00	66.7
Cycle 2 Day 1	217	22.43	25.44	0.0	33.33	100.0	207	-4.03	29.92	-100.0	0.00	66.7
Cycle 2 Day 22	157	19.53	24.18	0.0	0.00	100.0	150	-5.33	29.18	-100.0	0.00	66.7
Cycle 3 Day 1	200	16.83	24.56	0.0	0.00	100.0	190	-8.42	30.85	-100.0	0.00	100.0
Cycle 3 Day 22	161	20.91	23.52	0.0	33.33	100.0	152	-5.26	27.69	-100.0	0.00	66.7
Cycle 4 Day 1	178	15.17	20.07	0.0	0.00	100.0	170	-10.59	29.55	-100.0	0.00	66.7
Cycle 4 Day 22	128	16.93	21.73	0.0	0.00	100.0	123	-5.42	31.47	-100.0	0.00	100.0
Cycle 5 Day 1	156	19.66	24.50	0.0	0.00	100.0	148	-5.41	32.31	-100.0	0.00	100.0
Cycle 5 Day 22	114	17.84	24.36	0.0	0.00	100.0	107	-5.92	32.64	-100.0	0.00	66.7
Cycle 6 Day 1	125	19.73	26.47	0.0	0.00	100.0	116	-4.89	31.16	-100.0	0.00	100.0
Cycle 6 Day 22	102	18.63	22.29	0.0	0.00	100.0	97	-3.78	29.61	-100.0	0.00	66.7
Cycle 7 Day 1	111	16.82	21.02	0.0	0.00	66.7	105	-6.03	28.03	-100.0	0.00	66.7
Cycle 7 Day 22	80	17.50	21.20	0.0	0.00	100.0	74	-4.95	24.48	-66.7	0.00	66.7
Cycle 8 Day 1	81	16.05	22.43	0.0	0.00	100.0	74	-5.86	26.67	-66.7	0.00	66.7
Cycle 8 Day 22	71	17.84	22.42	0.0	0.00	100.0	66	-4.55	24.73	-66.7	0.00	33.3
Cycle 9 Day 1	73	15.98	24.29	0.0	0.00	100.0	66	-6.06	27.37	-66.7	0.00	66.7
Cycle 9 Day 22	54	14.81	23.05	0.0	0.00	100.0	50	-5.33	31.84	-66.7	0.00	100.0
Cycle 10 Day 1	58	17.24	19.98	0.0	0.00	66.7	53	-3.77	25.03	-66.7	0.00	33.3
Cycle 10 Day 22	47	9.93	15.41	0.0	0.00	33.3	44	-6.06	24.14	-66.7	0.00	33.3
Cycle 11 Day 1	50	14.00	19.15	0.0	0.00	66.7	46	-3.62	23.55	-33.3	0.00	66.7
Cycle 11 Day 22	35	12.38	18.23	0.0	0.00	66.7	32	-4.17	22.00	-33.3	0.00	33.3
Cycle 12 Day 1	43	13.95	18.16	0.0	0.00	66.7	39	-2.56	24.64	-33.3	0.00	66.7
Cycle 12 Day 22	32	15.62	20.71	0.0	0.00	66.7	30	1.11	22.29	-33.3	0.00	33.3
Cycle 13 Day 1	37	14.41	18.49	0.0	0.00	66.7	34	-2.94	30.00	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	8.82	14.93	0.0	0.00	33.3	31	-5.38	25.96	-66.7	0.00	33.3
Cycle 14 Day 1	31	12.90	22.24	0.0	0.00	100.0	30	-6.67	23.81	-66.7	0.00	33.3
Cycle 14 Day 22	24	11.11	16.05	0.0	0.00	33.3	24	-2.78	25.85	-66.7	0.00	33.3
Cycle 15 Day 1	26	14.10	16.79	0.0	0.00	33.3	26	-1.28	24.00	-33.3	0.00	33.3
Cycle 15 Day 22	22	10.61	15.89	0.0	0.00	33.3	22	-6.06	24.42	-66.7	0.00	33.3
Cycle 16 Day 1	25	12.00	16.33	0.0	0.00	33.3	25	-5.33	26.67	-66.7	0.00	33.3
Cycle 16 Day 22	19	12.28	16.52	0.0	0.00	33.3	19	-8.77	24.45	-66.7	0.00	33.3
Cycle 17 Day 1	19	17.54	28.04	0.0	0.00	100.0	19	-3.51	36.67	-66.7	0.00	100.0
Cycle 17 Day 22	14	14.29	21.54	0.0	0.00	66.7	14	-4.76	28.81	-33.3	0.00	66.7
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	-18.75	27.13	-66.7	-16.67	33.3
Cycle 18 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	-12.12	30.81	-66.7	0.00	33.3
Cycle 19 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-17.95	29.24	-66.7	0.00	33.3
Cycle 19 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-18.18	31.14	-66.7	0.00	33.3
Cycle 20 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-15.38	32.25	-66.7	0.00	33.3
Cycle 21 Day 1	11	12.12	16.82	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
Study Disc 1	132	25.00	27.44	0.0	33.33	100.0	125	-1.60	31.35	-100.0	0.00	66.7
30 D SFU Z/P	69	25.12	25.82	0.0	33.33	100.0	64	-0.52	28.79	-66.7	0.00	66.7
90 D SFU Z/P	83	29.32	28.70	0.0	33.33	100.0	80	2.92	29.62	-100.0	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	29.59	28.64	0.0	33.33	100.0						
Cycle 1 Day 22	212	23.58	25.54	0.0	33.33	100.0	210	-3.81	29.28	-100.0	0.00	66.7
Cycle 2 Day 1	231	21.07	25.61	0.0	0.00	100.0	225	-6.22	29.73	-100.0	0.00	100.0
Cycle 2 Day 22	185	19.46	22.91	0.0	0.00	100.0	181	-8.84	28.68	-100.0	0.00	66.7
Cycle 3 Day 1	204	16.83	23.74	0.0	0.00	100.0	198	-10.27	30.98	-100.0	0.00	66.7
Cycle 3 Day 22	156	18.38	24.04	0.0	0.00	100.0	149	-10.07	31.17	-100.0	0.00	66.7
Cycle 4 Day 1	171	14.42	21.08	0.0	0.00	100.0	163	-11.86	30.47	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	16.92	21.99	0.0	0.00	100.0	127	-11.55	29.21	-100.0	0.00	100.0
Cycle 5 Day 1	147	17.91	24.14	0.0	0.00	100.0	143	-8.62	34.19	-100.0	0.00	66.7
Cycle 5 Day 22	120	19.44	23.10	0.0	0.00	100.0	113	-6.19	29.39	-100.0	0.00	66.7
Cycle 6 Day 1	122	19.13	24.96	0.0	0.00	100.0	117	-7.98	31.15	-66.7	0.00	66.7
Cycle 6 Day 22	93	16.49	21.77	0.0	0.00	100.0	89	-12.36	30.31	-100.0	0.00	66.7
Cycle 7 Day 1	91	16.12	21.87	0.0	0.00	66.7	88	-10.61	27.93	-66.7	0.00	66.7
Cycle 7 Day 22	66	15.66	22.81	0.0	0.00	100.0	64	-12.50	24.12	-66.7	0.00	33.3
Cycle 8 Day 1	73	18.26	23.60	0.0	0.00	100.0	72	-8.33	30.00	-66.7	0.00	100.0
Cycle 8 Day 22	56	13.10	19.78	0.0	0.00	66.7	54	-15.43	25.67	-66.7	0.00	33.3
Cycle 9 Day 1	53	16.35	22.29	0.0	0.00	100.0	51	-13.73	25.97	-66.7	0.00	33.3
Cycle 9 Day 22	46	15.22	21.89	0.0	0.00	66.7	44	-14.39	31.66	-100.0	0.00	33.3
Cycle 10 Day 1	47	20.57	28.28	0.0	0.00	100.0	45	-8.15	34.20	-66.7	0.00	100.0
Cycle 10 Day 22	35	20.95	26.92	0.0	0.00	100.0	34	-10.78	29.27	-66.7	0.00	33.3
Cycle 11 Day 1	37	13.51	21.46	0.0	0.00	66.7	35	-13.33	25.82	-66.7	0.00	33.3
Cycle 11 Day 22	22	15.15	22.37	0.0	0.00	66.7	20	-11.67	29.17	-66.7	0.00	33.3
Cycle 12 Day 1	32	15.62	20.71	0.0	0.00	66.7	30	-12.22	26.96	-66.7	0.00	33.3
Cycle 12 Day 22	20	26.67	23.20	0.0	33.33	66.7	18	-7.41	21.56	-33.3	0.00	33.3
Cycle 13 Day 1	25	21.33	21.26	0.0	33.33	66.7	24	-6.94	19.61	-33.3	0.00	33.3
Cycle 13 Day 22	15	24.44	23.46	0.0	33.33	66.7	14	-9.52	20.37	-33.3	0.00	33.3
Cycle 14 Day 1	23	21.74	23.80	0.0	33.33	66.7	22	-6.06	28.43	-66.7	0.00	66.7
Cycle 14 Day 22	13	25.64	24.17	0.0	33.33	66.7	12	-5.56	23.92	-33.3	0.00	33.3
Cycle 15 Day 1	19	22.81	24.98	0.0	33.33	66.7	19	-1.75	26.00	-33.3	0.00	66.7
Cycle 16 Day 1	11	21.21	26.97	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
Cycle 17 Day 1	10	20.00	28.11	0.0	0.00	66.7	10	6.67	21.08	-33.3	0.00	33.3
Study Disc 1	137	26.52	26.24	0.0	33.33	100.0	133	-3.76	32.22	-100.0	0.00	100.0
Study Disc 2	10	50.00	39.28	0.0	33.33	100.0	10	6.67	40.98	-66.7	16.67	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	27.16	27.44	0.0	33.33	100.0	79	-2.53	33.66	-100.0	0.00	66.7
90 D SFU Z/P	71	30.05	33.88	0.0	33.33	100.0	70	-1.43	40.30	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	32.81	32.14	0.0	33.33	100.0						
Cycle 1 Day 22	187	39.22	29.45	0.0	33.33	100.0	177	9.04	33.05	-66.7	0.00	100.0
Cycle 2 Day 1	217	27.19	28.20	0.0	33.33	100.0	207	-4.99	36.01	-100.0	0.00	100.0
Cycle 2 Day 22	157	31.00	27.76	0.0	33.33	100.0	150	-1.33	34.08	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.33	26.46	0.0	33.33	100.0	190	-8.07	34.53	-100.0	0.00	100.0
Cycle 3 Day 22	161	34.78	30.36	0.0	33.33	100.0	152	2.19	35.71	-100.0	0.00	100.0
Cycle 4 Day 1	178	26.78	30.70	0.0	33.33	100.0	170	-6.08	38.49	-100.0	0.00	100.0
Cycle 4 Day 22	128	32.81	28.98	0.0	33.33	100.0	123	1.90	38.01	-100.0	0.00	100.0
Cycle 5 Day 1	156	27.35	29.20	0.0	33.33	100.0	148	-3.83	35.96	-100.0	0.00	100.0
Cycle 5 Day 22	114	26.02	30.32	0.0	33.33	100.0	107	-1.25	36.32	-66.7	0.00	100.0
Cycle 6 Day 1	125	22.40	28.33	0.0	0.00	100.0	116	-6.03	37.20	-100.0	0.00	100.0
Cycle 6 Day 22	102	24.18	28.59	0.0	16.67	100.0	97	-6.53	38.38	-100.0	0.00	66.7
Cycle 7 Day 1	111	18.92	25.27	0.0	0.00	100.0	105	-10.79	35.35	-100.0	0.00	100.0
Cycle 7 Day 22	80	20.00	23.48	0.0	16.67	100.0	74	-7.66	37.24	-100.0	0.00	100.0
Cycle 8 Day 1	81	20.58	28.66	0.0	0.00	100.0	74	-9.01	34.59	-100.0	0.00	100.0
Cycle 8 Day 22	71	22.54	25.68	0.0	33.33	100.0	66	-8.59	36.66	-100.0	0.00	100.0
Cycle 9 Day 1	73	18.72	25.45	0.0	0.00	100.0	66	-13.64	35.07	-100.0	0.00	100.0
Cycle 9 Day 22	54	20.37	29.26	0.0	0.00	100.0	50	-11.33	42.38	-100.0	0.00	66.7
Cycle 10 Day 1	58	18.97	28.69	0.0	0.00	100.0	53	-10.06	40.08	-100.0	0.00	100.0
Cycle 10 Day 22	47	24.11	26.65	0.0	33.33	100.0	44	-4.55	40.41	-100.0	0.00	100.0
Cycle 11 Day 1	50	14.67	23.48	0.0	0.00	100.0	46	-13.77	38.22	-66.7	0.00	100.0
Cycle 11 Day 22	35	17.14	24.75	0.0	0.00	100.0	32	-8.33	33.87	-100.0	0.00	66.7
Cycle 12 Day 1	43	22.48	27.91	0.0	33.33	100.0	39	-8.55	35.64	-100.0	0.00	100.0
Cycle 12 Day 22	32	25.00	25.40	0.0	33.33	100.0	30	2.22	34.94	-66.7	0.00	100.0
Cycle 13 Day 1	37	18.92	26.69	0.0	0.00	100.0	34	-5.88	33.30	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	16.67	24.96	0.0	0.00	100.0	31	-3.23	35.85	-66.7	0.00	100.0
Cycle 14 Day 1	31	19.35	28.25	0.0	0.00	100.0	30	-6.67	35.45	-66.7	0.00	100.0
Cycle 14 Day 22	24	20.83	27.47	0.0	0.00	100.0	24	0.00	39.32	-66.7	0.00	100.0
Cycle 15 Day 1	26	21.79	29.73	0.0	0.00	100.0	26	0.00	37.71	-66.7	0.00	100.0
Cycle 15 Day 22	22	21.21	31.78	0.0	0.00	100.0	22	0.00	43.64	-66.7	0.00	100.0
Cycle 16 Day 1	25	13.33	16.67	0.0	0.00	33.3	25	-12.00	25.24	-66.7	0.00	33.3
Cycle 16 Day 22	19	28.07	33.82	0.0	33.33	100.0	19	3.51	36.67	-66.7	0.00	66.7
Cycle 17 Day 1	19	17.54	25.74	0.0	0.00	100.0	19	-8.77	33.04	-66.7	0.00	66.7
Cycle 17 Day 22	14	28.57	31.64	0.0	33.33	100.0	14	2.38	33.24	-66.7	0.00	66.7
Cycle 18 Day 1	16	16.67	21.08	0.0	0.00	66.7	16	-12.50	31.91	-66.7	-16.67	66.7
Cycle 18 Day 22	11	18.18	22.92	0.0	0.00	66.7	11	3.03	23.35	-33.3	0.00	33.3
Cycle 19 Day 1	13	15.38	25.88	0.0	0.00	66.7	13	-7.69	19.97	-33.3	0.00	33.3
Cycle 19 Day 22	11	15.15	22.92	0.0	0.00	66.7	11	-3.03	23.35	-33.3	0.00	33.3
Cycle 20 Day 1	13	17.95	25.88	0.0	0.00	66.7	13	-2.56	28.74	-33.3	0.00	66.7
Cycle 21 Day 1	11	21.21	34.23	0.0	0.00	100.0	11	0.00	21.08	-33.3	0.00	33.3
Study Disc 1	132	38.13	33.75	0.0	33.33	100.0	125	2.93	36.91	-100.0	0.00	100.0
30 D SFU Z/P	69	40.58	33.76	0.0	33.33	100.0	64	4.69	31.91	-66.7	0.00	66.7
90 D SFU Z/P	83	30.12	30.63	0.0	33.33	100.0	80	-4.17	36.12	-100.0	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	32.17	31.44	0.0	33.33	100.0						
Cycle 1 Day 22	212	33.96	31.79	0.0	33.33	100.0	210	4.13	33.00	-100.0	0.00	100.0
Cycle 2 Day 1	231	22.22	27.39	0.0	0.00	100.0	225	-8.00	31.74	-100.0	0.00	100.0
Cycle 2 Day 22	185	30.27	29.64	0.0	33.33	100.0	181	0.18	35.57	-100.0	0.00	100.0
Cycle 3 Day 1	204	21.41	25.29	0.0	16.67	100.0	198	-8.75	31.18	-100.0	0.00	100.0
Cycle 3 Day 22	156	26.71	26.07	0.0	33.33	100.0	149	-2.68	30.39	-100.0	0.00	66.7
Cycle 4 Day 1	171	20.47	24.59	0.0	0.00	100.0	163	-7.36	34.35	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	24.49	26.00	0.0	33.33	100.0	127	-4.99	31.17	-100.0	0.00	66.7
Cycle 5 Day 1	147	20.41	24.19	0.0	0.00	100.0	143	-7.93	30.12	-100.0	0.00	33.3
Cycle 5 Day 22	120	20.28	23.79	0.0	0.00	100.0	113	-6.19	30.39	-100.0	0.00	66.7
Cycle 6 Day 1	122	21.04	25.78	0.0	0.00	100.0	117	-5.41	32.15	-100.0	0.00	66.7
Cycle 6 Day 22	93	18.64	22.77	0.0	0.00	100.0	89	-8.61	30.37	-66.7	0.00	66.7
Cycle 7 Day 1	91	12.45	19.66	0.0	0.00	100.0	88	-10.61	28.83	-100.0	0.00	33.3
Cycle 7 Day 22	66	13.64	22.63	0.0	0.00	100.0	64	-10.94	30.32	-66.7	0.00	66.7
Cycle 8 Day 1	73	11.87	18.73	0.0	0.00	66.7	72	-9.26	26.96	-66.7	0.00	33.3
Cycle 8 Day 22	56	17.86	21.99	0.0	0.00	66.7	54	-4.32	28.99	-66.7	0.00	66.7
Cycle 9 Day 1	53	15.72	23.21	0.0	0.00	100.0	51	-4.58	32.67	-66.7	0.00	100.0
Cycle 9 Day 22	46	15.94	19.55	0.0	0.00	66.7	44	-3.79	26.13	-66.7	0.00	33.3
Cycle 10 Day 1	47	12.06	18.94	0.0	0.00	66.7	45	-5.93	26.86	-66.7	0.00	33.3
Cycle 10 Day 22	35	18.10	23.35	0.0	0.00	66.7	34	-0.98	32.29	-66.7	0.00	66.7
Cycle 11 Day 1	37	11.71	19.59	0.0	0.00	66.7	35	-4.76	25.75	-66.7	0.00	66.7
Cycle 11 Day 22	22	9.09	18.35	0.0	0.00	66.7	20	-13.33	34.88	-66.7	0.00	33.3
Cycle 12 Day 1	32	12.50	22.00	0.0	0.00	66.7	30	-6.67	29.56	-66.7	0.00	66.7
Cycle 12 Day 22	20	18.33	22.88	0.0	0.00	66.7	18	-7.41	31.43	-66.7	0.00	33.3
Cycle 13 Day 1	25	13.33	21.52	0.0	0.00	66.7	24	-4.17	31.57	-66.7	0.00	66.7
Cycle 13 Day 22	15	26.67	22.54	0.0	33.33	66.7	14	7.14	29.75	-33.3	0.00	66.7
Cycle 14 Day 1	23	18.84	22.08	0.0	0.00	66.7	22	1.52	28.13	-33.3	0.00	66.7
Cycle 14 Day 22	13	20.51	25.60	0.0	0.00	66.7	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 15 Day 1	19	14.04	20.23	0.0	0.00	66.7	19	-3.51	26.98	-66.7	0.00	66.7
Cycle 16 Day 1	11	12.12	16.82	0.0	0.00	33.3	11	-6.06	25.03	-33.3	0.00	33.3
Cycle 17 Day 1	10	16.67	23.57	0.0	0.00	66.7	10	-3.33	24.60	-33.3	0.00	33.3
Study Disc 1	137	30.90	33.97	0.0	33.33	100.0	133	-1.00	37.14	-100.0	0.00	100.0
Study Disc 2	10	30.00	36.68	0.0	16.67	100.0	10	0.00	44.44	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	29.63	30.28	0.0	33.33	100.0	79	2.53	33.24	-100.0	0.00	66.7
90 D SFU Z/P	71	34.74	31.08	0.0	33.33	100.0	70	7.62	38.98	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	19.33	28.15	0.0	0.00	100.0						
Cycle 1 Day 22	187	25.13	28.99	0.0	33.33	100.0	177	8.66	32.96	-100.0	0.00	100.0
Cycle 2 Day 1	217	19.51	26.71	0.0	0.00	100.0	207	-0.48	33.25	-100.0	0.00	100.0
Cycle 2 Day 22	157	15.71	23.44	0.0	0.00	100.0	150	-2.89	31.12	-100.0	0.00	66.7
Cycle 3 Day 1	200	14.33	22.79	0.0	0.00	100.0	190	-5.09	31.29	-100.0	0.00	100.0
Cycle 3 Day 22	161	18.01	24.72	0.0	0.00	100.0	152	-2.85	28.18	-100.0	0.00	66.7
Cycle 4 Day 1	178	16.29	25.85	0.0	0.00	100.0	170	-2.75	32.11	-100.0	0.00	100.0
Cycle 4 Day 22	128	16.41	24.39	0.0	0.00	100.0	123	1.08	31.92	-100.0	0.00	100.0
Cycle 5 Day 1	156	16.03	24.68	0.0	0.00	100.0	148	-2.48	31.13	-100.0	0.00	66.7
Cycle 5 Day 22	114	21.05	28.83	0.0	0.00	100.0	107	2.49	31.62	-100.0	0.00	100.0
Cycle 6 Day 1	125	18.40	27.58	0.0	0.00	100.0	116	-2.30	28.39	-66.7	0.00	100.0
Cycle 6 Day 22	102	15.69	25.13	0.0	0.00	100.0	97	-4.47	27.06	-66.7	0.00	100.0
Cycle 7 Day 1	111	16.82	25.38	0.0	0.00	100.0	105	-3.17	29.79	-66.7	0.00	100.0
Cycle 7 Day 22	80	13.75	22.31	0.0	0.00	100.0	74	-3.15	25.98	-100.0	0.00	66.7
Cycle 8 Day 1	81	14.40	22.94	0.0	0.00	100.0	74	-4.50	27.77	-66.7	0.00	66.7
Cycle 8 Day 22	71	13.62	20.76	0.0	0.00	100.0	66	-7.58	27.30	-100.0	0.00	33.3
Cycle 9 Day 1	73	12.79	20.51	0.0	0.00	100.0	66	-9.09	26.50	-66.7	0.00	33.3
Cycle 9 Day 22	54	17.28	24.00	0.0	0.00	100.0	50	-1.33	33.64	-100.0	0.00	100.0
Cycle 10 Day 1	58	16.67	24.38	0.0	0.00	100.0	53	0.63	31.00	-66.7	0.00	100.0
Cycle 10 Day 22	47	14.18	21.70	0.0	0.00	100.0	44	-0.76	22.14	-66.7	0.00	33.3
Cycle 11 Day 1	50	13.33	19.05	0.0	0.00	66.7	46	0.00	25.34	-66.7	0.00	66.7
Cycle 11 Day 22	35	12.38	18.23	0.0	0.00	66.7	32	-1.04	27.41	-66.7	0.00	66.7
Cycle 12 Day 1	43	13.95	22.10	0.0	0.00	100.0	39	-5.13	22.35	-66.7	0.00	33.3
Cycle 12 Day 22	32	19.79	22.17	0.0	16.67	66.7	30	3.33	30.76	-66.7	0.00	66.7
Cycle 13 Day 1	37	15.32	23.03	0.0	0.00	66.7	34	0.00	28.43	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	12.75	18.38	0.0	0.00	66.7	31	-1.08	29.17	-66.7	0.00	66.7
Cycle 14 Day 1	31	8.60	14.83	0.0	0.00	33.3	30	-6.67	25.37	-66.7	0.00	33.3
Cycle 14 Day 22	24	11.11	21.23	0.0	0.00	66.7	24	-2.78	32.48	-66.7	0.00	66.7
Cycle 15 Day 1	26	11.54	18.72	0.0	0.00	66.7	26	-3.85	27.21	-66.7	0.00	33.3
Cycle 15 Day 22	22	9.09	15.19	0.0	0.00	33.3	22	-4.55	25.81	-66.7	0.00	33.3
Cycle 16 Day 1	25	9.33	15.28	0.0	0.00	33.3	25	-4.00	26.03	-66.7	0.00	33.3
Cycle 16 Day 22	19	14.04	23.08	0.0	0.00	66.7	19	0.00	24.85	-66.7	0.00	33.3
Cycle 17 Day 1	19	10.53	19.41	0.0	0.00	66.7	19	-1.75	28.27	-66.7	0.00	33.3
Cycle 17 Day 22	14	14.29	21.54	0.0	0.00	66.7	14	-2.38	30.56	-66.7	0.00	33.3
Cycle 18 Day 1	16	10.42	15.96	0.0	0.00	33.3	16	-6.25	27.81	-66.7	0.00	33.3
Cycle 18 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	3.03	27.71	-66.7	0.00	33.3
Cycle 19 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	0.00	30.43	-66.7	0.00	33.3
Cycle 19 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-3.03	27.71	-66.7	0.00	33.3
Cycle 20 Day 1	13	12.82	16.88	0.0	0.00	33.3	13	0.00	30.43	-66.7	0.00	33.3
Cycle 21 Day 1	11	15.15	17.41	0.0	0.00	33.3	11	0.00	33.33	-66.7	0.00	33.3
Study Disc 1	132	22.98	28.87	0.0	0.00	100.0	125	1.07	37.61	-100.0	0.00	100.0
30 D SFU Z/P	69	24.15	29.08	0.0	33.33	100.0	64	1.56	33.30	-100.0	0.00	66.7
90 D SFU Z/P	83	16.47	24.07	0.0	0.00	100.0	80	-5.00	34.82	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	19.64	28.39	0.0	0.00	100.0						
Cycle 1 Day 22	212	23.27	28.91	0.0	0.00	100.0	210	4.44	29.91	-66.7	0.00	100.0
Cycle 2 Day 1	231	17.32	25.97	0.0	0.00	100.0	225	-2.37	32.80	-100.0	0.00	100.0
Cycle 2 Day 22	185	20.18	25.80	0.0	0.00	100.0	181	0.37	31.23	-66.7	0.00	100.0
Cycle 3 Day 1	204	15.85	23.03	0.0	0.00	100.0	198	-2.53	30.40	-100.0	0.00	100.0
Cycle 3 Day 22	156	19.02	24.28	0.0	0.00	100.0	149	-0.89	31.70	-100.0	0.00	100.0
Cycle 4 Day 1	171	15.79	22.09	0.0	0.00	66.7	163	-1.02	28.79	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	18.94	23.00	0.0	0.00	100.0	127	2.10	29.02	-100.0	0.00	100.0
Cycle 5 Day 1	147	17.23	23.52	0.0	0.00	100.0	143	-1.40	30.86	-100.0	0.00	100.0
Cycle 5 Day 22	120	15.83	22.02	0.0	0.00	100.0	113	-2.06	26.83	-66.7	0.00	33.3
Cycle 6 Day 1	122	16.12	25.07	0.0	0.00	100.0	117	0.28	28.53	-100.0	0.00	66.7
Cycle 6 Day 22	93	13.98	21.04	0.0	0.00	66.7	89	-3.75	29.91	-100.0	0.00	66.7
Cycle 7 Day 1	91	12.09	21.95	0.0	0.00	100.0	88	-3.79	27.88	-66.7	0.00	100.0
Cycle 7 Day 22	66	11.11	18.80	0.0	0.00	66.7	64	-5.21	31.55	-100.0	0.00	66.7
Cycle 8 Day 1	73	12.79	21.96	0.0	0.00	100.0	72	-1.85	26.77	-66.7	0.00	100.0
Cycle 8 Day 22	56	10.71	19.18	0.0	0.00	66.7	54	-3.70	24.80	-100.0	0.00	33.3
Cycle 9 Day 1	53	13.84	23.96	0.0	0.00	100.0	51	-0.65	27.07	-66.7	0.00	100.0
Cycle 9 Day 22	46	13.77	24.92	0.0	0.00	100.0	44	-0.76	29.19	-66.7	0.00	100.0
Cycle 10 Day 1	47	12.77	24.63	0.0	0.00	100.0	45	2.22	26.01	-33.3	0.00	100.0
Cycle 10 Day 22	35	16.19	27.26	0.0	0.00	100.0	34	5.88	27.79	-33.3	0.00	100.0
Cycle 11 Day 1	37	15.32	28.97	0.0	0.00	100.0	35	7.62	29.25	-33.3	0.00	100.0
Cycle 11 Day 22	22	16.67	24.67	0.0	0.00	100.0	20	6.67	23.20	-33.3	0.00	66.7
Cycle 12 Day 1	32	18.75	28.00	0.0	0.00	100.0	30	10.00	30.51	-33.3	0.00	100.0
Cycle 12 Day 22	20	30.00	32.26	0.0	33.33	100.0	18	18.52	34.72	-33.3	0.00	100.0
Cycle 13 Day 1	25	21.33	31.74	0.0	0.00	100.0	24	11.11	34.98	-33.3	0.00	100.0
Cycle 13 Day 22	15	24.44	32.04	0.0	0.00	100.0	14	11.90	38.36	-33.3	0.00	100.0
Cycle 14 Day 1	23	23.19	33.99	0.0	0.00	100.0	22	13.64	38.02	-33.3	0.00	100.0
Cycle 14 Day 22	13	28.21	26.69	0.0	33.33	66.7	12	11.11	35.77	-33.3	0.00	66.7
Cycle 15 Day 1	19	22.81	27.34	0.0	0.00	66.7	19	12.28	31.84	-33.3	0.00	66.7
Cycle 16 Day 1	11	27.27	41.68	0.0	0.00	100.0	11	12.12	40.20	-33.3	0.00	100.0
Cycle 17 Day 1	10	16.67	23.57	0.0	0.00	66.7	10	6.67	26.29	-33.3	0.00	66.7
Study Disc 1	137	18.49	24.23	0.0	0.00	100.0	133	-1.25	30.82	-100.0	0.00	100.0
Study Disc 2	10	23.33	35.31	0.0	0.00	100.0	10	-10.00	35.31	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	21.81	26.44	0.0	0.00	100.0	79	-0.42	33.12	-66.7	0.00	100.0
90 D SFU Z/P	71	18.31	27.48	0.0	0.00	100.0	70	-1.43	29.73	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.91	17.25	0.0	0.00	100.0						
Cycle 1 Day 22	187	12.83	21.06	0.0	0.00	100.0	177	4.90	23.05	-100.0	0.00	100.0
Cycle 2 Day 1	217	13.67	22.74	0.0	0.00	100.0	207	6.28	26.03	-66.7	0.00	100.0
Cycle 2 Day 22	157	11.04	19.39	0.0	0.00	100.0	150	4.67	24.74	-100.0	0.00	100.0
Cycle 3 Day 1	200	9.83	16.30	0.0	0.00	66.7	190	2.11	22.39	-100.0	0.00	66.7
Cycle 3 Day 22	161	10.56	18.04	0.0	0.00	66.7	152	2.19	24.16	-66.7	0.00	66.7
Cycle 4 Day 1	178	8.99	15.66	0.0	0.00	66.7	170	-0.20	22.20	-100.0	0.00	66.7
Cycle 4 Day 22	128	10.42	17.62	0.0	0.00	66.7	123	1.90	23.49	-66.7	0.00	66.7
Cycle 5 Day 1	156	11.97	20.37	0.0	0.00	100.0	148	3.83	24.44	-66.7	0.00	66.7
Cycle 5 Day 22	114	8.19	15.72	0.0	0.00	66.7	107	0.31	20.73	-66.7	0.00	66.7
Cycle 6 Day 1	125	7.20	15.60	0.0	0.00	66.7	116	-2.30	22.72	-100.0	0.00	66.7
Cycle 6 Day 22	102	5.23	12.18	0.0	0.00	33.3	97	-3.44	17.67	-66.7	0.00	33.3
Cycle 7 Day 1	111	6.01	13.63	0.0	0.00	66.7	105	-4.13	20.51	-100.0	0.00	33.3
Cycle 7 Day 22	80	8.75	17.38	0.0	0.00	100.0	74	-0.90	22.05	-66.7	0.00	100.0
Cycle 8 Day 1	81	8.64	15.61	0.0	0.00	66.7	74	-2.25	21.60	-100.0	0.00	33.3
Cycle 8 Day 22	71	5.63	12.58	0.0	0.00	33.3	66	-4.55	22.56	-66.7	0.00	33.3
Cycle 9 Day 1	73	9.13	15.97	0.0	0.00	66.7	66	-2.02	26.72	-100.0	0.00	66.7
Cycle 9 Day 22	54	5.56	14.11	0.0	0.00	66.7	50	-6.00	20.96	-66.7	0.00	33.3
Cycle 10 Day 1	58	8.05	15.68	0.0	0.00	66.7	53	-5.03	25.65	-100.0	0.00	33.3
Cycle 10 Day 22	47	7.80	15.87	0.0	0.00	66.7	44	-3.03	25.74	-66.7	0.00	66.7
Cycle 11 Day 1	50	8.67	17.57	0.0	0.00	66.7	46	-5.80	28.38	-100.0	0.00	66.7
Cycle 11 Day 22	35	5.71	15.09	0.0	0.00	66.7	32	-7.29	20.27	-66.7	0.00	33.3
Cycle 12 Day 1	43	9.30	15.13	0.0	0.00	33.3	39	-2.56	23.43	-66.7	0.00	33.3
Cycle 12 Day 22	32	9.37	15.23	0.0	0.00	33.3	30	-3.33	22.06	-66.7	0.00	33.3
Cycle 13 Day 1	37	6.31	15.39	0.0	0.00	66.7	34	-6.86	29.34	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	6.86	13.68	0.0	0.00	33.3	31	-4.30	22.35	-66.7	0.00	33.3
Cycle 14 Day 1	31	8.60	14.83	0.0	0.00	33.3	30	-4.44	22.71	-66.7	0.00	33.3
Cycle 14 Day 22	24	4.17	11.26	0.0	0.00	33.3	24	-6.94	21.93	-66.7	0.00	33.3
Cycle 15 Day 1	26	5.13	12.26	0.0	0.00	33.3	26	-7.69	19.57	-66.7	0.00	0.0
Cycle 15 Day 22	22	4.55	11.71	0.0	0.00	33.3	22	-7.58	17.61	-66.7	0.00	0.0
Cycle 16 Day 1	25	2.67	9.23	0.0	0.00	33.3	25	-10.67	26.74	-100.0	0.00	33.3
Cycle 16 Day 22	19	7.02	23.78	0.0	0.00	100.0	19	-3.51	29.18	-33.3	0.00	100.0
Cycle 17 Day 1	19	1.75	7.65	0.0	0.00	33.3	19	-14.04	23.08	-66.7	0.00	0.0
Cycle 17 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	-7.14	26.73	-66.7	0.00	33.3
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	-12.50	26.87	-66.7	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 19 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-7.69	24.17	-66.7	0.00	33.3
Cycle 19 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-10.26	21.01	-66.7	0.00	0.0
Cycle 21 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Study Disc 1	132	12.12	22.28	0.0	0.00	100.0	125	3.20	25.90	-66.7	0.00	100.0
30 D SFU Z/P	69	13.04	19.98	0.0	0.00	66.7	64	3.65	25.28	-66.7	0.00	66.7
90 D SFU Z/P	83	13.65	21.49	0.0	0.00	100.0	80	4.58	27.43	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	10.59	19.94	0.0	0.00	100.0						
Cycle 1 Day 22	212	13.21	21.12	0.0	0.00	100.0	210	2.86	24.01	-66.7	0.00	100.0
Cycle 2 Day 1	231	12.99	21.64	0.0	0.00	100.0	225	2.96	22.52	-66.7	0.00	100.0
Cycle 2 Day 22	185	12.25	20.71	0.0	0.00	100.0	181	0.92	22.06	-66.7	0.00	66.7
Cycle 3 Day 1	204	12.42	21.91	0.0	0.00	100.0	198	1.18	24.99	-100.0	0.00	100.0
Cycle 3 Day 22	156	11.97	21.06	0.0	0.00	100.0	149	1.57	24.91	-66.7	0.00	66.7
Cycle 4 Day 1	171	11.50	21.49	0.0	0.00	100.0	163	1.02	24.12	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	10.61	21.13	0.0	0.00	100.0	127	-0.79	25.01	-66.7	0.00	66.7
Cycle 5 Day 1	147	9.30	15.98	0.0	0.00	66.7	143	-1.40	24.98	-100.0	0.00	66.7
Cycle 5 Day 22	120	6.39	13.87	0.0	0.00	66.7	113	-3.83	22.60	-100.0	0.00	66.7
Cycle 6 Day 1	122	9.02	16.62	0.0	0.00	66.7	117	-1.14	24.34	-100.0	0.00	66.7
Cycle 6 Day 22	93	8.60	15.47	0.0	0.00	66.7	89	-1.50	24.05	-100.0	0.00	66.7
Cycle 7 Day 1	91	7.69	14.97	0.0	0.00	66.7	88	-4.17	21.92	-100.0	0.00	33.3
Cycle 7 Day 22	66	5.56	13.82	0.0	0.00	66.7	64	-8.33	23.76	-100.0	0.00	33.3
Cycle 8 Day 1	73	9.13	14.97	0.0	0.00	33.3	72	-2.78	23.57	-100.0	0.00	33.3
Cycle 8 Day 22	56	8.93	16.19	0.0	0.00	66.7	54	-4.32	22.47	-66.7	0.00	66.7
Cycle 9 Day 1	53	9.43	15.16	0.0	0.00	33.3	51	-3.27	19.15	-66.7	0.00	33.3
Cycle 9 Day 22	46	8.70	20.41	0.0	0.00	100.0	44	-4.55	23.40	-66.7	0.00	66.7
Cycle 10 Day 1	47	8.51	16.25	0.0	0.00	66.7	45	-2.96	17.15	-66.7	0.00	33.3
Cycle 10 Day 22	35	8.57	18.69	0.0	0.00	66.7	34	-3.92	17.91	-33.3	0.00	33.3
Cycle 11 Day 1	37	9.01	21.73	0.0	0.00	100.0	35	-0.95	23.55	-66.7	0.00	66.7
Cycle 11 Day 22	22	10.61	23.87	0.0	0.00	100.0	20	1.67	22.88	-66.7	0.00	66.7
Cycle 12 Day 1	32	8.33	16.93	0.0	0.00	66.7	30	-2.22	17.36	-66.7	0.00	33.3
Cycle 12 Day 22	20	10.00	19.04	0.0	0.00	66.7	18	-5.56	20.61	-66.7	0.00	33.3
Cycle 13 Day 1	25	12.00	16.33	0.0	0.00	33.3	24	1.39	26.88	-66.7	0.00	33.3
Cycle 13 Day 22	15	8.89	15.26	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
Cycle 14 Day 1	23	8.70	14.97	0.0	0.00	33.3	22	-4.55	21.32	-66.7	0.00	33.3
Cycle 14 Day 22	13	5.13	12.52	0.0	0.00	33.3	12	-5.56	23.92	-66.7	0.00	33.3
Cycle 15 Day 1	19	5.26	16.72	0.0	0.00	66.7	19	-5.26	22.94	-66.7	0.00	33.3
Cycle 16 Day 1	11	12.12	30.81	0.0	0.00	100.0	11	3.03	37.87	-66.7	0.00	100.0
Cycle 17 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	-3.33	24.60	-66.7	0.00	33.3
Study Disc 1	137	13.87	23.79	0.0	0.00	100.0	133	1.75	25.73	-66.7	0.00	66.7
Study Disc 2	10	6.67	14.05	0.0	0.00	33.3	10	-6.67	26.29	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	12.35	17.83	0.0	0.00	66.7	79	3.38	20.39	-66.7	0.00	33.3
90 D SFU Z/P	71	18.31	28.05	0.0	0.00	100.0	70	8.10	30.26	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	8.63	17.57	0.0	0.00	100.0						
	Cycle 1 Day 22	123	11.65	18.10	0.0	0.00	66.7	117	3.99	22.39	-100.0	0.00	66.7
	Cycle 2 Day 1	137	14.36	23.15	0.0	0.00	100.0	132	6.31	26.09	-66.7	0.00	100.0
	Cycle 2 Day 22	104	11.22	20.04	0.0	0.00	100.0	100	5.00	25.68	-100.0	0.00	100.0
	Cycle 3 Day 1	133	9.27	16.59	0.0	0.00	66.7	127	1.05	22.98	-100.0	0.00	66.7
	Cycle 3 Day 22	107	10.28	17.38	0.0	0.00	66.7	102	1.63	22.68	-66.7	0.00	66.7
	Cycle 4 Day 1	112	8.33	14.50	0.0	0.00	33.3	108	-2.16	21.99	-100.0	0.00	33.3
	Cycle 4 Day 22	85	10.59	18.70	0.0	0.00	66.7	81	2.06	23.18	-66.7	0.00	66.7
	Cycle 5 Day 1	104	13.78	22.09	0.0	0.00	100.0	99	5.72	25.22	-66.7	0.00	66.7
	Cycle 5 Day 22	75	8.44	14.59	0.0	0.00	33.3	70	0.00	19.66	-66.7	0.00	33.3
	Cycle 6 Day 1	81	7.82	16.05	0.0	0.00	66.7	76	-2.19	21.32	-66.7	0.00	66.7
	Cycle 6 Day 22	62	5.38	12.36	0.0	0.00	33.3	59	-3.95	17.60	-66.7	0.00	33.3
	Cycle 7 Day 1	70	7.14	14.90	0.0	0.00	66.7	67	-3.98	18.82	-66.7	0.00	33.3
	Cycle 7 Day 22	56	8.33	14.56	0.0	0.00	33.3	51	-1.31	18.81	-66.7	0.00	33.3
	Cycle 8 Day 1	52	9.62	16.62	0.0	0.00	66.7	48	-0.69	18.82	-66.7	0.00	33.3
	Cycle 8 Day 22	43	3.88	10.81	0.0	0.00	33.3	40	-6.67	20.25	-66.7	0.00	33.3
	Cycle 9 Day 1	40	9.17	15.07	0.0	0.00	33.3	36	-1.85	22.46	-66.7	0.00	33.3
	Cycle 9 Day 22	34	6.86	15.95	0.0	0.00	66.7	31	-4.30	20.62	-66.7	0.00	33.3
	Cycle 10 Day 1	36	10.19	17.49	0.0	0.00	66.7	33	-2.02	21.95	-66.7	0.00	33.3
	Cycle 10 Day 22	31	9.68	17.62	0.0	0.00	66.7	29	-2.30	26.62	-66.7	0.00	66.7
	Cycle 11 Day 1	31	9.68	19.61	0.0	0.00	66.7	29	-4.60	26.31	-66.7	0.00	66.7
	Cycle 11 Day 22	23	7.25	17.28	0.0	0.00	66.7	21	-6.35	17.06	-33.3	0.00	33.3
	Cycle 12 Day 1	24	5.56	12.69	0.0	0.00	33.3	22	-4.55	15.59	-33.3	0.00	33.3
	Cycle 12 Day 22	21	11.11	16.10	0.0	0.00	33.3	19	-1.75	17.48	-33.3	0.00	33.3
	Cycle 13 Day 1	23	7.25	17.28	0.0	0.00	66.7	22	-3.03	22.79	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	22	4.55	11.71	0.0	0.00	33.3	20	-6.67	17.44	-33.3	0.00	33.3
	Cycle 14 Day 1	19	7.02	13.96	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Cycle 14 Day 22	13	2.56	9.25	0.0	0.00	33.3	13	-7.69	14.62	-33.3	0.00	0.0
	Cycle 15 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	-2.08	8.33	-33.3	0.00	0.0
	Cycle 15 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
	Cycle 16 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	-2.08	14.75	-33.3	0.00	33.3
	Cycle 16 Day 22	13	7.69	27.74	0.0	0.00	100.0	13	0.00	33.33	-33.3	0.00	100.0
	Cycle 17 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-6.06	13.48	-33.3	0.00	0.0
	Study Disc 1	89	11.99	21.47	0.0	0.00	100.0	85	2.75	24.78	-66.7	0.00	100.0
	30 D SFU Z/P	44	13.64	20.73	0.0	0.00	66.7	41	4.07	24.94	-33.3	0.00	66.7
	90 D SFU Z/P	52	10.26	18.12	0.0	0.00	66.7	51	1.31	25.79	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	8.54	17.95	0.0	0.00	100.0						
	Cycle 1 Day 22	134	13.18	20.85	0.0	0.00	100.0	132	5.05	23.83	-66.7	0.00	100.0
	Cycle 2 Day 1	148	14.86	23.74	0.0	0.00	100.0	144	6.25	23.97	-66.7	0.00	100.0
	Cycle 2 Day 22	117	12.25	20.81	0.0	0.00	100.0	113	3.54	19.60	-66.7	0.00	66.7
	Cycle 3 Day 1	129	11.89	21.57	0.0	0.00	100.0	126	3.17	24.01	-100.0	0.00	100.0
	Cycle 3 Day 22	102	12.09	19.22	0.0	0.00	66.7	98	2.38	24.05	-66.7	0.00	66.7
	Cycle 4 Day 1	108	10.19	19.04	0.0	0.00	100.0	103	2.91	21.44	-66.7	0.00	66.7
	Cycle 4 Day 22	86	9.30	17.45	0.0	0.00	66.7	83	0.40	22.39	-66.7	0.00	66.7
	Cycle 5 Day 1	95	9.12	16.45	0.0	0.00	66.7	93	0.72	25.05	-100.0	0.00	66.7
	Cycle 5 Day 22	80	5.42	12.37	0.0	0.00	33.3	76	-3.07	19.76	-100.0	0.00	33.3
	Cycle 6 Day 1	81	9.05	16.68	0.0	0.00	66.7	79	1.69	23.20	-100.0	0.00	66.7
	Cycle 6 Day 22	61	7.65	14.13	0.0	0.00	33.3	59	-1.13	22.29	-100.0	0.00	33.3
	Cycle 7 Day 1	61	5.46	12.44	0.0	0.00	33.3	58	-4.02	19.82	-100.0	0.00	33.3
	Cycle 7 Day 22	43	4.65	11.69	0.0	0.00	33.3	41	-8.13	22.09	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 8 Day 1	50	7.33	13.95	0.0	0.00	33.3	49	-2.72	22.40	-100.0	0.00	33.3
	Cycle 8 Day 22	36	8.33	16.67	0.0	0.00	66.7	34	-5.88	25.25	-66.7	0.00	66.7
	Cycle 9 Day 1	33	8.08	14.51	0.0	0.00	33.3	31	-4.30	18.74	-66.7	0.00	33.3
	Cycle 9 Day 22	28	7.14	16.62	0.0	0.00	66.7	26	-6.41	16.38	-33.3	0.00	33.3
	Cycle 10 Day 1	30	8.89	14.99	0.0	0.00	33.3	28	-3.57	18.90	-66.7	0.00	33.3
	Cycle 10 Day 22	23	7.25	17.28	0.0	0.00	66.7	22	-4.55	18.67	-33.3	0.00	33.3
	Cycle 11 Day 1	22	6.06	16.70	0.0	0.00	66.7	20	-3.33	18.42	-66.7	0.00	33.3
	Cycle 11 Day 22	14	9.52	15.63	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Cycle 12 Day 1	18	9.26	15.36	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
	Cycle 12 Day 22	11	9.09	15.57	0.0	0.00	33.3	9	-3.70	11.11	-33.3	0.00	0.0
	Cycle 13 Day 1	13	12.82	16.88	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Cycle 14 Day 1	11	9.09	15.57	0.0	0.00	33.3	10	-6.67	14.05	-33.3	0.00	0.0
	Study Disc 1	88	13.26	22.34	0.0	0.00	100.0	85	3.14	23.92	-66.7	0.00	66.7
	30 D SFU Z/P	46	13.77	18.02	0.0	0.00	66.7	44	8.33	17.79	-33.3	0.00	33.3
	90 D SFU Z/P	41	18.70	29.86	0.0	0.00	100.0	40	12.50	30.84	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	6.59	16.64	0.0	0.00	100.0						
	Cycle 1 Day 22	64	15.10	25.84	0.0	0.00	100.0	60	6.67	24.39	-33.3	0.00	100.0
	Cycle 2 Day 1	80	12.50	22.11	0.0	0.00	100.0	75	6.22	26.11	-66.7	0.00	100.0
	Cycle 2 Day 22	53	10.69	18.23	0.0	0.00	66.7	50	4.00	22.98	-66.7	0.00	66.7
	Cycle 3 Day 1	67	10.95	15.77	0.0	0.00	33.3	63	4.23	21.16	-66.7	0.00	33.3
	Cycle 3 Day 22	54	11.11	19.43	0.0	0.00	66.7	50	3.33	27.15	-66.7	0.00	66.7
	Cycle 4 Day 1	66	10.10	17.51	0.0	0.00	66.7	62	3.23	22.35	-66.7	0.00	66.7
	Cycle 4 Day 22	43	10.08	15.49	0.0	0.00	33.3	42	1.59	24.36	-66.7	0.00	33.3
	Cycle 5 Day 1	52	8.33	16.00	0.0	0.00	66.7	49	0.00	22.57	-66.7	0.00	66.7
	Cycle 5 Day 22	39	7.69	17.87	0.0	0.00	66.7	37	0.90	22.89	-66.7	0.00	66.7
	Cycle 6 Day 1	44	6.06	14.86	0.0	0.00	66.7	40	-2.50	25.47	-100.0	0.00	33.3
	Cycle 6 Day 22	40	5.00	12.05	0.0	0.00	33.3	38	-2.63	17.98	-66.7	0.00	33.3
	Cycle 7 Day 1	41	4.07	11.04	0.0	0.00	33.3	38	-4.39	23.47	-100.0	0.00	33.3
	Cycle 7 Day 22	24	9.72	23.01	0.0	0.00	100.0	23	0.00	28.43	-66.7	0.00	100.0
	Cycle 8 Day 1	29	6.90	13.74	0.0	0.00	33.3	26	-5.13	26.15	-100.0	0.00	33.3
	Cycle 8 Day 22	28	8.33	14.70	0.0	0.00	33.3	26	-1.28	25.79	-66.7	0.00	33.3
	Cycle 9 Day 1	33	9.09	17.23	0.0	0.00	66.7	30	-2.22	31.48	-100.0	0.00	66.7
	Cycle 9 Day 22	20	3.33	10.26	0.0	0.00	33.3	19	-8.77	21.78	-66.7	0.00	33.3
	Cycle 10 Day 1	22	4.55	11.71	0.0	0.00	33.3	20	-10.00	30.78	-100.0	0.00	33.3
	Cycle 10 Day 22	16	4.17	11.39	0.0	0.00	33.3	15	-4.44	24.77	-66.7	0.00	33.3
	Cycle 11 Day 1	19	7.02	13.96	0.0	0.00	33.3	17	-7.84	32.34	-100.0	0.00	33.3
	Cycle 11 Day 22	12	2.78	9.62	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
	Cycle 12 Day 1	19	14.04	16.91	0.0	0.00	33.3	17	0.00	31.18	-66.7	0.00	33.3
	Cycle 12 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	29.13	-66.7	0.00	33.3
	Cycle 13 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	-13.89	38.82	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	12	11.11	16.41	0.0	0.00	33.3	11	0.00	29.81	-66.7	0.00	33.3
	Cycle 14 Day 1	12	11.11	16.41	0.0	0.00	33.3	12	-8.33	32.18	-66.7	0.00	33.3
	Cycle 14 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	29.13	-66.7	0.00	33.3
	Cycle 15 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	-16.67	28.33	-66.7	0.00	0.0
	Study Disc 1	43	12.40	24.15	0.0	0.00	100.0	40	4.17	28.43	-66.7	0.00	66.7
	30 D SFU Z/P	25	12.00	18.95	0.0	0.00	66.7	23	2.90	26.43	-66.7	0.00	66.7
	90 D SFU Z/P	31	19.35	25.49	0.0	0.00	100.0	29	10.34	29.69	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	94	14.18	22.66	0.0	0.00	100.0						
	Cycle 1 Day 22	78	13.25	21.72	0.0	0.00	100.0	78	-0.85	24.01	-66.7	0.00	66.7
	Cycle 2 Day 1	83	9.64	16.89	0.0	0.00	66.7	81	-2.88	18.41	-66.7	0.00	33.3
	Cycle 2 Day 22	68	12.25	20.69	0.0	0.00	66.7	68	-3.43	25.20	-66.7	0.00	66.7
	Cycle 3 Day 1	75	13.33	22.59	0.0	0.00	100.0	72	-2.31	26.43	-66.7	0.00	100.0
	Cycle 3 Day 22	54	11.73	24.36	0.0	0.00	100.0	51	0.00	26.67	-66.7	0.00	66.7
	Cycle 4 Day 1	63	13.76	25.14	0.0	0.00	100.0	60	-2.22	28.03	-66.7	0.00	66.7
	Cycle 4 Day 22	46	13.04	26.74	0.0	0.00	100.0	44	-3.03	29.48	-66.7	0.00	66.7
	Cycle 5 Day 1	52	9.62	15.25	0.0	0.00	33.3	50	-5.33	24.61	-66.7	0.00	33.3
	Cycle 5 Day 22	40	8.33	16.45	0.0	0.00	66.7	37	-5.41	27.79	-66.7	0.00	66.7
	Cycle 6 Day 1	41	8.94	16.71	0.0	0.00	66.7	38	-7.02	25.89	-66.7	0.00	33.3
	Cycle 6 Day 22	32	10.42	17.84	0.0	0.00	66.7	30	-2.22	27.59	-66.7	0.00	66.7
	Cycle 7 Day 1	30	12.22	18.54	0.0	0.00	66.7	30	-4.44	25.87	-66.7	0.00	33.3
	Cycle 7 Day 22	23	7.25	17.28	0.0	0.00	66.7	23	-8.70	27.00	-66.7	0.00	33.3
	Cycle 8 Day 1	23	13.04	16.63	0.0	0.00	33.3	23	-2.90	26.43	-66.7	0.00	33.3
	Cycle 8 Day 22	20	10.00	15.67	0.0	0.00	33.3	20	-1.67	17.01	-66.7	0.00	33.3
	Cycle 9 Day 1	20	11.67	16.31	0.0	0.00	33.3	20	-1.67	20.16	-66.7	0.00	33.3
	Cycle 9 Day 22	18	11.11	25.57	0.0	0.00	100.0	18	-1.85	31.25	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	17	7.84	18.74	0.0	0.00	66.7	17	-1.96	14.29	-33.3	0.00	33.3
	Cycle 10 Day 22	12	11.11	21.71	0.0	0.00	66.7	12	-2.78	17.16	-33.3	0.00	33.3
	Cycle 11 Day 1	15	13.33	27.60	0.0	0.00	100.0	15	2.22	29.46	-66.7	0.00	66.7
	Cycle 12 Day 1	14	7.14	19.30	0.0	0.00	66.7	14	-4.76	22.10	-66.7	0.00	33.3
	Cycle 13 Day 1	12	11.11	16.41	0.0	0.00	33.3	12	0.00	34.82	-66.7	0.00	33.3
	Cycle 14 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-2.78	26.43	-66.7	0.00	33.3
	Cycle 15 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-12.12	26.97	-66.7	0.00	0.0
	Study Disc 1	49	14.97	26.41	0.0	0.00	100.0	48	-0.69	28.76	-66.7	0.00	66.7
	30 D SFU Z/P	35	10.48	17.66	0.0	0.00	66.7	35	-2.86	21.95	-66.7	0.00	33.3
	90 D SFU Z/P	30	17.78	25.87	0.0	0.00	100.0	30	2.22	28.94	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	19.58	28.89	0.0	0.00	100.0						
Cycle 1 Day 22	187	17.83	28.35	0.0	0.00	100.0	177	0.38	24.62	-100.0	0.00	100.0
Cycle 2 Day 1	217	16.90	27.24	0.0	0.00	100.0	207	-1.45	21.86	-66.7	0.00	100.0
Cycle 2 Day 22	157	17.62	26.57	0.0	0.00	100.0	150	-0.67	20.96	-66.7	0.00	100.0
Cycle 3 Day 1	200	17.50	26.09	0.0	0.00	100.0	190	-0.88	22.86	-100.0	0.00	100.0
Cycle 3 Day 22	161	18.84	25.76	0.0	0.00	100.0	152	0.00	21.36	-66.7	0.00	66.7
Cycle 4 Day 1	178	14.23	23.44	0.0	0.00	100.0	170	-2.55	20.51	-66.7	0.00	100.0
Cycle 4 Day 22	128	17.97	25.41	0.0	0.00	100.0	123	-1.90	26.41	-100.0	0.00	66.7
Cycle 5 Day 1	156	18.80	26.28	0.0	0.00	100.0	148	1.13	26.77	-100.0	0.00	100.0
Cycle 5 Day 22	114	22.22	29.30	0.0	0.00	100.0	107	2.49	20.32	-33.3	0.00	66.7
Cycle 6 Day 1	125	19.47	27.17	0.0	0.00	100.0	116	0.00	19.66	-33.3	0.00	66.7
Cycle 6 Day 22	102	16.67	25.58	0.0	0.00	100.0	97	-0.69	18.62	-33.3	0.00	66.7
Cycle 7 Day 1	111	17.72	24.95	0.0	0.00	100.0	105	0.00	21.68	-100.0	0.00	66.7
Cycle 7 Day 22	80	18.75	24.79	0.0	0.00	100.0	74	-0.90	22.05	-100.0	0.00	66.7
Cycle 8 Day 1	81	18.11	24.75	0.0	0.00	100.0	74	0.90	24.03	-100.0	0.00	66.7
Cycle 8 Day 22	71	14.55	23.05	0.0	0.00	100.0	66	-0.51	23.75	-100.0	0.00	33.3
Cycle 9 Day 1	73	15.53	22.96	0.0	0.00	100.0	66	-0.51	22.26	-100.0	0.00	66.7
Cycle 9 Day 22	54	16.05	24.00	0.0	0.00	100.0	50	1.33	21.25	-33.3	0.00	66.7
Cycle 10 Day 1	58	14.94	25.11	0.0	0.00	100.0	53	-0.63	24.01	-100.0	0.00	66.7
Cycle 10 Day 22	47	13.48	22.69	0.0	0.00	100.0	44	-2.27	24.27	-100.0	0.00	33.3
Cycle 11 Day 1	50	10.67	20.69	0.0	0.00	100.0	46	-5.07	22.19	-100.0	0.00	33.3
Cycle 11 Day 22	35	13.33	18.44	0.0	0.00	66.7	32	-4.17	29.02	-100.0	0.00	33.3
Cycle 12 Day 1	43	13.18	23.16	0.0	0.00	100.0	39	-2.56	25.80	-100.0	0.00	33.3
Cycle 12 Day 22	32	15.62	25.38	0.0	0.00	100.0	30	-2.22	27.59	-100.0	0.00	33.3
Cycle 13 Day 1	37	12.61	22.70	0.0	0.00	100.0	34	-4.90	24.80	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	17.65	24.94	0.0	0.00	100.0	31	2.15	28.46	-100.0	0.00	33.3
Cycle 14 Day 1	31	17.20	25.63	0.0	0.00	100.0	30	0.00	24.76	-100.0	0.00	33.3
Cycle 14 Day 22	24	16.67	26.01	0.0	0.00	100.0	24	-1.39	26.88	-100.0	0.00	33.3
Cycle 15 Day 1	26	12.82	25.08	0.0	0.00	100.0	26	-5.13	26.15	-100.0	0.00	33.3
Cycle 15 Day 22	22	12.12	26.32	0.0	0.00	100.0	22	-9.09	29.42	-100.0	0.00	33.3
Cycle 16 Day 1	25	10.67	18.56	0.0	0.00	66.7	25	-5.33	26.67	-100.0	0.00	33.3
Cycle 16 Day 22	19	12.28	19.91	0.0	0.00	66.7	19	-7.02	32.54	-100.0	0.00	33.3
Cycle 17 Day 1	19	15.79	17.10	0.0	0.00	33.3	19	-3.51	31.22	-100.0	0.00	33.3
Cycle 17 Day 22	14	19.05	17.12	0.0	33.33	33.3	14	4.76	17.82	-33.3	0.00	33.3
Cycle 18 Day 1	16	12.50	16.67	0.0	0.00	33.3	16	-2.08	19.12	-33.3	0.00	33.3
Cycle 18 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 19 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 19 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	3.03	17.98	-33.3	0.00	33.3
Cycle 20 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-5.13	18.49	-33.3	0.00	33.3
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3
Study Disc 1	132	23.99	30.07	0.0	0.00	100.0	125	2.67	26.30	-100.0	0.00	66.7
30 D SFU Z/P	69	25.60	32.91	0.0	0.00	100.0	64	3.65	26.64	-33.3	0.00	100.0
90 D SFU Z/P	83	24.50	26.59	0.0	33.33	100.0	80	7.92	23.86	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	18.86	27.38	0.0	0.00	100.0						
Cycle 1 Day 22	212	18.55	26.79	0.0	0.00	100.0	210	-0.48	21.75	-100.0	0.00	66.7
Cycle 2 Day 1	231	17.46	25.02	0.0	0.00	100.0	225	-1.93	24.01	-100.0	0.00	66.7
Cycle 2 Day 22	185	16.22	24.35	0.0	0.00	100.0	181	-1.84	23.76	-66.7	0.00	100.0
Cycle 3 Day 1	204	17.65	24.85	0.0	0.00	100.0	198	-1.85	24.26	-100.0	0.00	100.0
Cycle 3 Day 22	156	19.02	27.59	0.0	0.00	100.0	149	-1.12	22.06	-100.0	0.00	33.3
Cycle 4 Day 1	171	16.37	24.35	0.0	0.00	100.0	163	-3.07	22.77	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	18.43	24.48	0.0	0.00	100.0	127	-0.52	20.13	-66.7	0.00	33.3
Cycle 5 Day 1	147	19.95	29.11	0.0	0.00	100.0	143	0.00	26.83	-100.0	0.00	100.0
Cycle 5 Day 22	120	17.22	24.44	0.0	0.00	100.0	113	-2.06	26.46	-100.0	0.00	100.0
Cycle 6 Day 1	122	18.31	26.80	0.0	0.00	100.0	117	2.28	26.16	-100.0	0.00	66.7
Cycle 6 Day 22	93	16.13	23.37	0.0	0.00	100.0	89	-1.12	25.84	-100.0	0.00	66.7
Cycle 7 Day 1	91	15.38	23.99	0.0	0.00	100.0	88	-1.89	22.24	-100.0	0.00	66.7
Cycle 7 Day 22	66	13.64	23.37	0.0	0.00	100.0	64	-4.17	26.89	-100.0	0.00	33.3
Cycle 8 Day 1	73	15.07	23.60	0.0	0.00	100.0	72	-1.39	21.26	-66.7	0.00	33.3
Cycle 8 Day 22	56	14.88	21.95	0.0	0.00	100.0	54	-0.62	24.65	-66.7	0.00	33.3
Cycle 9 Day 1	53	12.58	24.66	0.0	0.00	100.0	51	-3.92	23.71	-100.0	0.00	33.3
Cycle 9 Day 22	46	13.04	20.46	0.0	0.00	66.7	44	-1.52	28.71	-100.0	0.00	66.7
Cycle 10 Day 1	47	16.31	24.94	0.0	0.00	100.0	45	1.48	26.55	-100.0	0.00	33.3
Cycle 10 Day 22	35	16.19	26.04	0.0	0.00	100.0	34	0.98	29.00	-100.0	0.00	66.7
Cycle 11 Day 1	37	9.91	17.33	0.0	0.00	66.7	35	-2.86	28.44	-100.0	0.00	33.3
Cycle 11 Day 22	22	18.18	28.60	0.0	0.00	100.0	20	6.67	17.44	-33.3	0.00	33.3
Cycle 12 Day 1	32	10.42	23.09	0.0	0.00	100.0	30	2.22	21.32	-33.3	0.00	66.7
Cycle 12 Day 22	20	15.00	27.52	0.0	0.00	100.0	18	1.85	21.30	-33.3	0.00	33.3
Cycle 13 Day 1	25	8.00	22.11	0.0	0.00	100.0	24	0.00	19.66	-33.3	0.00	33.3
Cycle 13 Day 22	15	4.44	11.73	0.0	0.00	33.3	14	-4.76	22.10	-33.3	0.00	33.3
Cycle 14 Day 1	23	11.59	23.80	0.0	0.00	100.0	22	4.55	21.32	-33.3	0.00	33.3
Cycle 14 Day 22	13	10.26	16.01	0.0	0.00	33.3	12	2.78	26.43	-33.3	0.00	33.3
Cycle 15 Day 1	19	12.28	19.91	0.0	0.00	66.7	19	7.02	26.24	-33.3	0.00	66.7
Cycle 16 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
Cycle 17 Day 1	10	10.00	16.10	0.0	0.00	33.3	10	3.33	24.60	-33.3	0.00	33.3
Study Disc 1	137	19.71	25.42	0.0	0.00	100.0	133	0.25	24.45	-66.7	0.00	100.0
Study Disc 2	10	30.00	36.68	0.0	16.67	100.0	10	13.33	47.66	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	19.75	22.84	0.0	0.00	100.0	79	2.95	24.57	-66.7	0.00	66.7
90 D SFU Z/P	71	23.00	29.05	0.0	0.00	100.0	70	4.29	28.89	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 301.1.3004.5.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	163 (57.6%)	148 (52.5%)	
Number of patients censored	120 (42.4%)	134 (47.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.4 [2.3, 4.4]	5.2 [4.2, 6.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.211 [0.966, 1.518]
Log-rank test			
Two-sided stratified log-rank p-value			0.0978

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; 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: 09SEP22

Table 301.1.3004.5.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	105 (58.0)	3.6 [2.4, 5.5]	181	97 (53.6)	4.7 [2.8, 7.5]	1.076 [0.814, 1.421]	0.6119	0.1765
>65 years	102	58 (56.9)	2.8 [1.6, 3.9]	101	51 (50.5)	5.6 [4.4, 11.1]	1.560 [1.068, 2.278]	0.0201	
Sex									
Male	176	93 (52.8)	3.7 [2.2, 5.5]	175	92 (52.6)	5.6 [3.9, 8.0]	1.164 [0.872, 1.553]	0.2992	0.5319
Female	107	70 (65.4)	3.0 [1.4, 3.7]	107	56 (52.3)	4.3 [3.5, 6.6]	1.334 [0.936, 1.901]	0.1126	
Region									
Asia	88	61 (69.3)	3.7 [1.9, 5.8]	89	53 (59.6)	5.6 [2.3, 8.5]	1.136 [0.781, 1.652]	0.5042	0.6909
Non-Asia	195	102 (52.3)	3.0 [2.2, 4.2]	193	95 (49.2)	5.1 [4.1, 6.2]	1.277 [0.965, 1.689]	0.0870	
Number of Organs with Metastatic Sites									
0-2	219	127 (58.0)	3.0 [2.2, 4.6]	219	118 (53.9)	5.3 [4.2, 6.8]	1.232 [0.958, 1.584]	0.1057	0.9878
>=3	64	36 (56.3)	3.7 [1.6, 4.8]	63	30 (47.6)	4.8 [2.3, 10.7]	1.224 [0.751, 1.995]	0.4130	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.6.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	152 (53.7%)	144 (51.1%)	
Number of patients censored	131 (46.3%)	138 (48.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.5 [2.6, 4.6]	6.4 [4.7, 7.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.181 [0.938, 1.487]
Log-rank test			
Two-sided stratified log-rank p-value			0.1549

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; 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: 09SEP22

Table 301.1.3004.6.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	93 (51.4)	3.8 [2.4, 9.7]	181	82 (45.3)	8.1 [6.2, 12.3]	1.243 [0.922, 1.675]	0.1550	0.4491
>65 years	102	59 (57.8)	3.0 [2.1, 3.7]	101	62 (61.4)	4.6 [2.8, 6.5]	1.089 [0.762, 1.558]	0.6317	
Sex									
Male	176	92 (52.3)	3.3 [2.1, 5.1]	175	90 (51.4)	6.5 [4.9, 9.3]	1.230 [0.919, 1.647]	0.1624	0.6944
Female	107	60 (56.1)	3.8 [2.4, 6.9]	107	54 (50.5)	5.6 [2.6, 8.3]	1.080 [0.747, 1.563]	0.6796	
Region									
Asia	88	49 (55.7)	6.0 [3.2, 10.9]	89	44 (49.4)	8.6 [6.9, 12.3]	1.175 [0.780, 1.771]	0.4358	0.9816
Non-Asia	195	103 (52.8)	2.8 [1.6, 3.6]	193	100 (51.8)	4.9 [3.3, 6.4]	1.168 [0.887, 1.539]	0.2669	
Number of Organs with Metastatic Sites									
0-2	219	113 (51.6)	3.6 [2.6, 6.0]	219	110 (50.2)	6.4 [4.2, 8.3]	1.124 [0.864, 1.462]	0.3817	0.4360
>=3	64	39 (60.9)	3.0 [1.6, 3.8]	63	34 (54.0)	6.5 [4.9, 9.4]	1.368 [0.858, 2.182]	0.1906	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.7.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	169 (59.7%)	170 (60.3%)	
Number of patients censored	114 (40.3%)	112 (39.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.3 [1.6, 3.0]	2.8 [2.1, 4.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.062 [0.856, 1.316]
Log-rank test			
Two-sided stratified log-rank p-value			0.5811

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; 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: 09SEP22

Table 301.1.3004.7.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	110 (60.8)	1.7 [1.4, 3.1]	181	107 (59.1)	2.4 [1.9, 4.9]	1.112 [0.852, 1.451]	0.4410	0.6711
>65 years	102	59 (57.8)	2.7 [1.6, 4.3]	101	63 (62.4)	2.8 [1.6, 4.6]	1.001 [0.701, 1.429]	0.9876	
Sex									
Male	176	102 (58.0)	2.3 [1.6, 3.9]	175	110 (62.9)	2.8 [1.8, 4.8]	0.967 [0.738, 1.266]	0.8082	0.2311
Female	107	67 (62.6)	1.6 [1.2, 3.0]	107	60 (56.1)	2.6 [1.9, 5.4]	1.274 [0.899, 1.805]	0.1758	
Region									
Asia	88	59 (67.0)	3.5 [1.4, 5.5]	89	58 (65.2)	3.9 [1.6, 6.7]	1.059 [0.735, 1.524]	0.7636	0.9528
Non-Asia	195	110 (56.4)	1.9 [1.5, 2.8]	193	112 (58.0)	2.6 [1.9, 4.2]	1.070 [0.822, 1.392]	0.6091	
Number of Organs with Metastatic Sites									
0-2	219	126 (57.5)	2.3 [1.5, 3.9]	219	133 (60.7)	3.0 [2.1, 4.7]	1.013 [0.794, 1.293]	0.9209	0.3470
>=3	64	43 (67.2)	1.7 [1.4, 3.0]	63	37 (58.7)	2.6 [1.0, 5.1]	1.301 [0.835, 2.028]	0.2402	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.8.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	123 (43.5%)	112 (39.7%)	
Number of patients censored	160 (56.5%)	170 (60.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.4 [5.1, 13.1]	11.1 [8.5, 15.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.182 [0.912, 1.531]
Log-rank test			
Two-sided stratified log-rank p-value			0.2093

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; 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: 09SEP22

Table 301.1.3004.8.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	76 (42.0)	8.5 [5.3, NC]	181	68 (37.6)	12.3 [8.6, 15.4]	1.119 [0.805, 1.555]	0.5043	0.6163
>65 years	102	47 (46.1)	5.3 [2.8, 13.1]	101	44 (43.6)	9.3 [5.8, 18.3]	1.291 [0.854, 1.952]	0.2233	
Sex									
Male	176	74 (42.0)	7.4 [5.1, 16.5]	175	74 (42.3)	11.0 [8.0, 15.1]	1.082 [0.783, 1.494]	0.6337	0.4060
Female	107	49 (45.8)	5.8 [3.3, 19.6]	107	38 (35.5)	13.6 [6.3, 18.6]	1.352 [0.881, 2.075]	0.1673	
Region									
Asia	88	40 (45.5)	10.7 [5.5, NC]	89	40 (44.9)	12.3 [8.0, 15.1]	0.880 [0.563, 1.377]	0.5777	0.1594
Non-Asia	195	83 (42.6)	5.5 [3.6, 13.1]	193	72 (37.3)	11.1 [7.1, 18.3]	1.344 [0.980, 1.844]	0.0660	
Number of Organs with Metastatic Sites									
0-2	219	96 (43.8)	7.4 [5.0, 13.8]	219	89 (40.6)	12.3 [8.1, 15.1]	1.149 [0.860, 1.536]	0.3488	0.7954
>=3	64	27 (42.2)	6.2 [3.3, NC]	63	23 (36.5)	10.4 [6.2, NC]	1.266 [0.724, 2.214]	0.4043	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.9.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	157 (55.5%)	152 (53.9%)	
Number of patients censored	126 (44.5%)	130 (46.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [2.9, 5.2]	5.1 [3.7, 6.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.128 [0.900, 1.413]
Log-rank test			
Two-sided stratified log-rank p-value			0.2962

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; 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: 09SEP22

Table 301.1.3004.9.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	102 (56.4)	4.6 [2.9, 5.7]	181	92 (50.8)	5.7 [3.8, 8.7]	1.197 [0.902, 1.588]	0.2134	0.5756
>65 years	102	55 (53.9)	3.9 [1.6, 5.2]	101	60 (59.4)	3.9 [2.8, 6.7]	1.053 [0.730, 1.518]	0.7816	
Sex									
Male	176	93 (52.8)	4.9 [3.2, 5.8]	175	94 (53.7)	5.1 [3.1, 7.5]	1.046 [0.785, 1.394]	0.7532	0.3352
Female	107	64 (59.8)	2.9 [1.7, 4.6]	107	58 (54.2)	5.1 [2.8, 7.2]	1.323 [0.925, 1.892]	0.1239	
Region									
Asia	88	60 (68.2)	4.1 [2.8, 5.3]	89	53 (59.6)	6.2 [2.4, 8.1]	1.148 [0.792, 1.663]	0.4647	0.9360
Non-Asia	195	97 (49.7)	4.3 [2.3, 5.8]	193	99 (51.3)	4.6 [3.6, 6.8]	1.114 [0.842, 1.474]	0.4527	
Number of Organs with Metastatic Sites									
0-2	219	123 (56.2)	4.3 [2.8, 5.2]	219	122 (55.7)	5.1 [3.3, 7.1]	1.109 [0.864, 1.425]	0.4199	0.7312
>=3	64	34 (53.1)	3.7 [1.6, 6.0]	63	30 (47.6)	5.7 [2.8, 15.1]	1.211 [0.740, 1.983]	0.4463	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.10.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	170 (60.1%)	147 (52.1%)	
Number of patients censored	113 (39.9%)	135 (47.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.6 [2.1, 3.5]	4.6 [2.5, 6.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.287 [1.030, 1.607]
Log-rank test			
Two-sided stratified log-rank p-value			0.0242

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; 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: 09SEP22

Table 301.1.3004.10.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	110 (60.8)	3.0 [2.1, 4.0]	181	89 (49.2)	5.5 [3.1, 9.3]	1.408 [1.064, 1.863]	0.0161	0.2725
>65 years	102	60 (58.8)	2.3 [1.6, 3.7]	101	58 (57.4)	2.6 [1.4, 5.1]	1.094 [0.763, 1.571]	0.6017	
Sex									
Male	176	100 (56.8)	3.0 [2.1, 4.1]	175	93 (53.1)	5.1 [2.8, 7.2]	1.215 [0.916, 1.612]	0.1705	0.4933
Female	107	70 (65.4)	2.4 [1.4, 3.7]	107	54 (50.5)	2.8 [1.5, 6.3]	1.407 [0.986, 2.009]	0.0568	
Region									
Asia	88	53 (60.2)	4.1 [2.4, 5.9]	89	44 (49.4)	6.5 [4.8, 26.3]	1.342 [0.899, 2.004]	0.1508	0.8704
Non-Asia	195	117 (60.0)	2.3 [1.6, 3.0]	193	103 (53.4)	2.8 [1.8, 4.9]	1.265 [0.970, 1.650]	0.0760	
Number of Organs with Metastatic Sites									
0-2	219	131 (59.8)	2.8 [2.1, 3.5]	219	113 (51.6)	4.9 [2.6, 6.2]	1.326 [1.030, 1.707]	0.0268	0.6385
>=3	64	39 (60.9)	2.4 [1.0, 5.1]	63	34 (54.0)	3.2 [1.4, 11.1]	1.135 [0.716, 1.801]	0.5752	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.11.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	189 (66.8%)	176 (62.4%)	
Number of patients censored	94 (33.2%)	106 (37.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.5 [1.2, 1.7]	2.1 [1.4, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.223 [0.993, 1.506]
Log-rank test			
Two-sided stratified log-rank p-value			0.0544

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; 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: 09SEP22

Table 301.1.3004.11.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	121 (66.9)	1.5 [1.0, 2.1]	181	108 (59.7)	2.3 [1.5, 4.2]	1.258 [0.970, 1.632]	0.0831	0.7527
>65 years	102	68 (66.7)	1.5 [1.4, 2.1]	101	68 (67.3)	1.5 [1.0, 3.0]	1.194 [0.850, 1.677]	0.2788	
Sex									
Male	176	116 (65.9)	1.5 [1.4, 2.1]	175	121 (69.1)	1.5 [1.0, 2.3]	1.043 [0.808, 1.347]	0.7031	0.0384
Female	107	73 (68.2)	1.4 [1.0, 2.1]	107	55 (51.4)	3.9 [2.1, 6.1]	1.648 [1.158, 2.345]	0.0050	
Region									
Asia	88	65 (73.9)	1.5 [1.1, 2.4]	89	56 (62.9)	3.9 [1.4, 6.2]	1.385 [0.965, 1.987]	0.0731	0.4185
Non-Asia	195	124 (63.6)	1.5 [1.1, 1.7]	193	120 (62.2)	1.8 [1.2, 2.6]	1.151 [0.894, 1.480]	0.2595	
Number of Organs with Metastatic Sites									
0-2	219	149 (68.0)	1.5 [1.2, 1.7]	219	138 (63.0)	2.1 [1.4, 3.5]	1.251 [0.992, 1.579]	0.0548	0.8067
>=3	64	40 (62.5)	1.6 [0.9, 3.0]	63	38 (60.3)	2.3 [1.0, 6.3]	1.205 [0.763, 1.905]	0.4033	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.12.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	166 (58.7%)	154 (54.6%)	
Number of patients censored	117 (41.3%)	128 (45.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.5 [1.4, 2.3]	3.0 [2.1, 4.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.241 [0.993, 1.550]
Log-rank test			
Two-sided stratified log-rank p-value			0.0550

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; 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: 09SEP22

Table 301.1.3004.12.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	108 (59.7)	1.4 [1.0, 2.4]	181	105 (58.0)	2.2 [1.5, 3.7]	1.115 [0.851, 1.460]	0.4408	0.1851
>65 years	102	58 (56.9)	1.8 [1.5, 3.6]	101	49 (48.5)	7.1 [3.0, 15.4]	1.551 [1.058, 2.273]	0.0220	
Sex									
Male	176	104 (59.1)	1.6 [1.4, 2.8]	175	103 (58.9)	2.8 [2.1, 6.1]	1.187 [0.903, 1.560]	0.2203	0.4733
Female	107	62 (57.9)	1.4 [1.0, 2.6]	107	51 (47.7)	3.5 [1.8, 15.1]	1.378 [0.950, 1.998]	0.0851	
Region									
Asia	88	60 (68.2)	1.6 [1.0, 3.3]	89	58 (65.2)	1.8 [1.0, 6.1]	1.118 [0.778, 1.608]	0.5349	0.4009
Non-Asia	195	106 (54.4)	1.5 [1.4, 2.6]	193	96 (49.7)	3.5 [2.3, 9.0]	1.326 [1.005, 1.749]	0.0461	
Number of Organs with Metastatic Sites									
0-2	219	132 (60.3)	1.5 [1.1, 2.3]	219	119 (54.3)	3.5 [2.1, 7.0]	1.362 [1.062, 1.747]	0.0149	0.1781
>=3	64	34 (53.1)	1.6 [1.4, 13.2]	63	35 (55.6)	2.3 [1.0, 3.7]	0.916 [0.571, 1.470]	0.7243	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.13.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	144 (50.9%)	142 (50.4%)	
Number of patients censored	139 (49.1%)	140 (49.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.5 [3.4, 5.8]	5.5 [4.0, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.141 [0.901, 1.445]
Log-rank test			
Two-sided stratified log-rank p-value			0.2736

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; 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: 09SEP22

Table 301.1.3004.13.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	90 (49.7)	5.1 [3.3, 7.5]	181	84 (46.4)	5.8 [3.7, 12.3]	1.151 [0.855, 1.550]	0.3548	0.8012
>65 years	102	54 (52.9)	3.5 [2.1, 5.7]	101	58 (57.4)	5.1 [3.8, 8.8]	1.101 [0.759, 1.595]	0.6100	
Sex									
Male	176	84 (47.7)	4.5 [3.0, 8.0]	175	93 (53.1)	5.6 [4.4, 8.8]	1.025 [0.763, 1.377]	0.8652	0.2345
Female	107	60 (56.1)	4.2 [2.4, 6.5]	107	49 (45.8)	5.0 [3.1, 14.3]	1.358 [0.930, 1.983]	0.1109	
Region									
Asia	88	54 (61.4)	3.4 [2.1, 5.5]	89	44 (49.4)	9.1 [5.5, 15.1]	1.750 [1.171, 2.614]	0.0057	0.0136
Non-Asia	195	90 (46.2)	5.5 [3.5, 10.4]	193	98 (50.8)	4.6 [3.6, 5.8]	0.900 [0.675, 1.200]	0.4741	
Number of Organs with Metastatic Sites									
0-2	219	110 (50.2)	5.4 [3.5, 7.2]	219	108 (49.3)	5.6 [4.0, 9.3]	1.125 [0.863, 1.468]	0.3845	0.9499
>=3	64	34 (53.1)	3.3 [1.7, 5.6]	63	34 (54.0)	5.5 [2.6, 8.8]	1.182 [0.732, 1.908]	0.4876	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.14.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	132 (46.6%)	126 (44.7%)	
Number of patients censored	151 (53.4%)	156 (55.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.4 [4.0, 8.6]	7.6 [6.0, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.129 [0.883, 1.444]
Log-rank test			
Two-sided stratified log-rank p-value			0.3320

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; 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: 09SEP22

Table 301.1.3004.14.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	87 (48.1)	6.4 [3.3, 9.6]	181	76 (42.0)	8.8 [6.5, 12.3]	1.271 [0.934, 1.730]	0.1269	0.2770
>65 years	102	45 (44.1)	6.5 [3.7, 9.0]	101	50 (49.5)	6.2 [3.1, 8.1]	0.969 [0.648, 1.450]	0.8782	
Sex									
Male	176	78 (44.3)	7.5 [4.4, 10.0]	175	85 (48.6)	7.2 [4.9, 8.8]	0.974 [0.716, 1.324]	0.8623	0.0718
Female	107	54 (50.5)	5.3 [3.1, 9.2]	107	41 (38.3)	10.4 [6.0, NC]	1.545 [1.029, 2.319]	0.0345	
Region									
Asia	88	48 (54.5)	5.6 [3.4, 10.9]	89	46 (51.7)	7.2 [6.0, 11.4]	1.109 [0.739, 1.663]	0.6182	0.8191
Non-Asia	195	84 (43.1)	6.4 [3.7, 9.2]	193	80 (41.5)	8.0 [4.9, 11.5]	1.172 [0.863, 1.592]	0.3104	
Number of Organs with Metastatic Sites									
0-2	219	106 (48.4)	6.0 [4.0, 8.6]	219	101 (46.1)	7.4 [4.9, 8.8]	1.135 [0.864, 1.491]	0.3612	0.7520
>=3	64	26 (40.6)	7.5 [3.0, 19.2]	63	25 (39.7)	10.4 [5.5, NC]	1.242 [0.715, 2.157]	0.4437	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.15.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	127 (44.9%)	126 (44.7%)	
Number of patients censored	156 (55.1%)	156 (55.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.8 [4.5, 8.5]	7.1 [5.0, 10.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.037 [0.809, 1.329]
Log-rank test			
Two-sided stratified log-rank p-value			0.7708

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; 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: 09SEP22

Table 301.1.3004.15.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	86 (47.5)	5.1 [3.4, 8.5]	181	78 (43.1)	7.1 [4.9, 12.3]	1.145 [0.843, 1.557]	0.3853	0.3072
>65 years	102	41 (40.2)	6.0 [4.5, NC]	101	48 (47.5)	6.6 [3.9, 12.2]	0.879 [0.579, 1.335]	0.5474	
Sex									
Male	176	78 (44.3)	5.8 [4.4, 11.8]	175	79 (45.1)	8.1 [4.6, 11.1]	1.064 [0.778, 1.455]	0.6988	0.8978
Female	107	49 (45.8)	5.5 [2.4, 13.7]	107	47 (43.9)	5.3 [4.2, 12.3]	1.007 [0.674, 1.505]	0.9636	
Region									
Asia	88	47 (53.4)	5.8 [3.1, 12.0]	89	43 (48.3)	9.0 [5.2, 12.3]	1.157 [0.764, 1.752]	0.4924	0.5543
Non-Asia	195	80 (41.0)	5.6 [4.2, 12.2]	193	83 (43.0)	5.8 [4.4, 9.4]	0.982 [0.722, 1.335]	0.9169	
Number of Organs with Metastatic Sites									
0-2	219	104 (47.5)	5.6 [4.1, 8.5]	219	98 (44.7)	7.1 [4.8, 12.2]	1.099 [0.833, 1.448]	0.5039	0.4404
>=3	64	23 (35.9)	8.1 [3.3, NC]	63	28 (44.4)	6.6 [3.0, 11.1]	0.822 [0.468, 1.442]	0.4987	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.16.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	142 (50.2%)	140 (49.6%)	
Number of patients censored	141 (49.8%)	142 (50.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.2 [2.0, 4.4]	4.5 [2.3, 7.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.127 [0.890, 1.427]
Log-rank test			
Two-sided stratified log-rank p-value			0.3137

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; 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: 09SEP22

Table 301.1.3004.16.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	89 (49.2)	3.4 [1.6, 7.5]	181	87 (48.1)	4.0 [2.3, 10.6]	1.017 [0.755, 1.369]	0.9149	0.5407
>65 years	102	53 (52.0)	2.3 [1.5, 4.4]	101	53 (52.5)	4.6 [1.7, 7.8]	1.255 [0.857, 1.840]	0.2336	
Sex									
Male	176	93 (52.8)	2.8 [1.5, 3.7]	175	94 (53.7)	4.5 [2.3, 7.1]	1.162 [0.872, 1.549]	0.3001	0.6345
Female	107	49 (45.8)	5.4 [1.6, 10.9]	107	46 (43.0)	4.0 [1.8, 15.7]	1.011 [0.675, 1.513]	0.9523	
Region									
Asia	88	55 (62.5)	1.5 [1.0, 3.5]	89	52 (58.4)	3.9 [2.1, 8.1]	1.278 [0.874, 1.869]	0.2063	0.3028
Non-Asia	195	87 (44.6)	4.2 [2.3, 5.7]	193	88 (45.6)	4.9 [2.3, 7.8]	1.004 [0.746, 1.351]	0.9695	
Number of Organs with Metastatic Sites									
0-2	219	117 (53.4)	2.8 [1.5, 4.3]	219	108 (49.3)	4.5 [2.2, 7.4]	1.210 [0.931, 1.572]	0.1515	0.1002
>=3	64	25 (39.1)	4.8 [2.1, NC]	63	32 (50.8)	4.2 [1.5, 8.0]	0.748 [0.443, 1.262]	0.2760	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.17.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	136 (48.1%)	137 (48.6%)	
Number of patients censored	147 (51.9%)	145 (51.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.9 [2.9, 5.3]	4.2 [2.8, 6.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.013 [0.797, 1.287]
Log-rank test			
Two-sided stratified log-rank p-value			0.9207

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; 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: 09SEP22

Table 301.1.3004.17.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	90 (49.7)	3.9 [2.9, 5.3]	181	85 (47.0)	5.2 [2.5, 7.7]	1.083 [0.805, 1.457]	0.6056	0.5761
>65 years	102	46 (45.1)	3.4 [2.1, 13.8]	101	52 (51.5)	3.6 [2.1, 6.2]	0.947 [0.636, 1.408]	0.7944	
Sex									
Male	176	83 (47.2)	4.1 [2.8, 7.1]	175	88 (50.3)	4.9 [2.8, 7.7]	1.011 [0.749, 1.366]	0.9387	0.8709
Female	107	53 (49.5)	3.4 [2.1, 6.5]	107	49 (45.8)	3.6 [2.1, 6.5]	1.066 [0.722, 1.572]	0.7521	
Region									
Asia	88	51 (58.0)	4.4 [2.9, 7.1]	89	49 (55.1)	5.2 [2.3, 7.9]	1.057 [0.712, 1.568]	0.7897	0.8611
Non-Asia	195	85 (43.6)	3.4 [2.5, 6.0]	193	88 (45.6)	3.8 [2.4, 6.2]	1.014 [0.752, 1.366]	0.9276	
Number of Organs with Metastatic Sites									
0-2	219	109 (49.8)	3.9 [2.8, 5.3]	219	112 (51.1)	3.6 [2.4, 6.2]	0.995 [0.764, 1.296]	0.9629	0.5674
>=3	64	27 (42.2)	3.5 [1.6, NC]	63	25 (39.7)	6.2 [2.3, NC]	1.149 [0.666, 1.984]	0.6076	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.18.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	132 (46.6%)	134 (47.5%)	
Number of patients censored	151 (53.4%)	148 (52.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.9, 6.9]	5.6 [3.9, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.032 [0.810, 1.316]
Log-rank test			
Two-sided stratified log-rank p-value			0.7760

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; 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: 09SEP22

Table 301.1.3004.18.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	82 (45.3)	5.5 [3.9, 9.4]	181	93 (51.4)	4.7 [2.5, 6.1]	0.819 [0.609, 1.103]	0.1919	0.0192
>65 years	102	50 (49.0)	4.3 [2.2, 7.6]	101	41 (40.6)	10.4 [4.6, NC]	1.505 [0.995, 2.278]	0.0498	
Sex									
Male	176	80 (45.5)	5.2 [4.2, 9.4]	175	86 (49.1)	5.6 [3.7, 8.1]	0.922 [0.680, 1.251]	0.6160	0.2780
Female	107	52 (48.6)	3.9 [2.1, 6.5]	107	48 (44.9)	6.0 [3.6, 14.1]	1.205 [0.813, 1.785]	0.3529	
Region									
Asia	88	45 (51.1)	6.5 [4.4, 15.5]	89	43 (48.3)	7.2 [3.9, NC]	1.027 [0.676, 1.562]	0.8909	0.9767
Non-Asia	195	87 (44.6)	4.2 [3.1, 6.0]	193	91 (47.2)	4.9 [3.5, 7.5]	1.013 [0.755, 1.360]	0.9175	
Number of Organs with Metastatic Sites									
0-2	219	97 (44.3)	6.0 [4.1, 9.1]	219	108 (49.3)	5.2 [3.7, 7.5]	0.903 [0.686, 1.188]	0.4741	0.0669
>=3	64	35 (54.7)	3.9 [1.9, 5.3]	63	26 (41.3)	10.4 [2.4, NC]	1.562 [0.939, 2.598]	0.0804	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Table 301.1.3004.19.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	104 (36.7%)	97 (34.4%)	
Number of patients censored	179 (63.3%)	185 (65.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.2 [6.9, 16.4]	12.3 [9.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.087 [0.823, 1.436]
Log-rank test			
Two-sided stratified log-rank p-value			0.5540

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; 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: 09SEP22

Table 301.1.3004.19.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	70 (38.7)	8.6 [5.8, 16.4]	181	60 (33.1)	12.3 [7.6, NC]	1.183 [0.838, 1.670]	0.3374	0.4538
>65 years	102	34 (33.3)	13.8 [6.9, NC]	101	37 (36.6)	10.9 [7.3, 20.9]	0.931 [0.583, 1.485]	0.7621	
Sex									
Male	176	61 (34.7)	10.7 [6.7, NC]	175	62 (35.4)	12.3 [7.5, NC]	1.038 [0.729, 1.480]	0.8296	0.6902
Female	107	43 (40.2)	8.6 [5.8, 19.1]	107	35 (32.7)	11.1 [7.0, NC]	1.147 [0.733, 1.795]	0.5478	
Region									
Asia	88	45 (51.1)	7.5 [5.1, 13.7]	89	34 (38.2)	12.3 [7.0, NC]	1.250 [0.799, 1.955]	0.3272	0.4061
Non-Asia	195	59 (30.3)	13.5 [6.9, NC]	193	63 (32.6)	11.1 [9.4, NC]	0.981 [0.688, 1.401]	0.9241	
Number of Organs with Metastatic Sites									
0-2	219	83 (37.9)	10.4 [7.2, 16.4]	219	75 (34.2)	12.3 [7.9, NC]	1.117 [0.817, 1.527]	0.4882	0.7049
>=3	64	21 (32.8)	6.9 [5.1, NC]	63	22 (34.9)	10.9 [4.9, 20.9]	0.982 [0.538, 1.793]	0.9652	

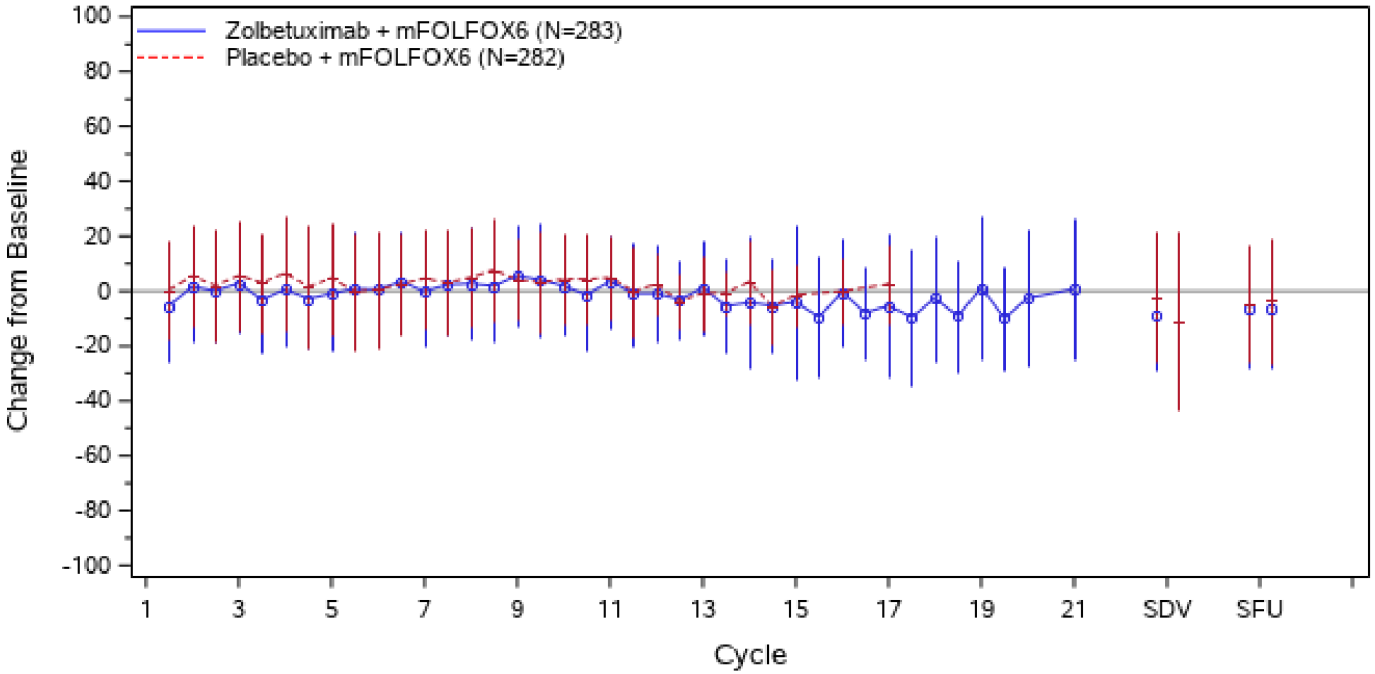
Abbreviations: CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; NC=not calculated.
Note: 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 [b] Calculated from unstratified Cox proportional hazards model [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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

The SAS System

Figure 301.1.3002.5: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Global Health Status - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

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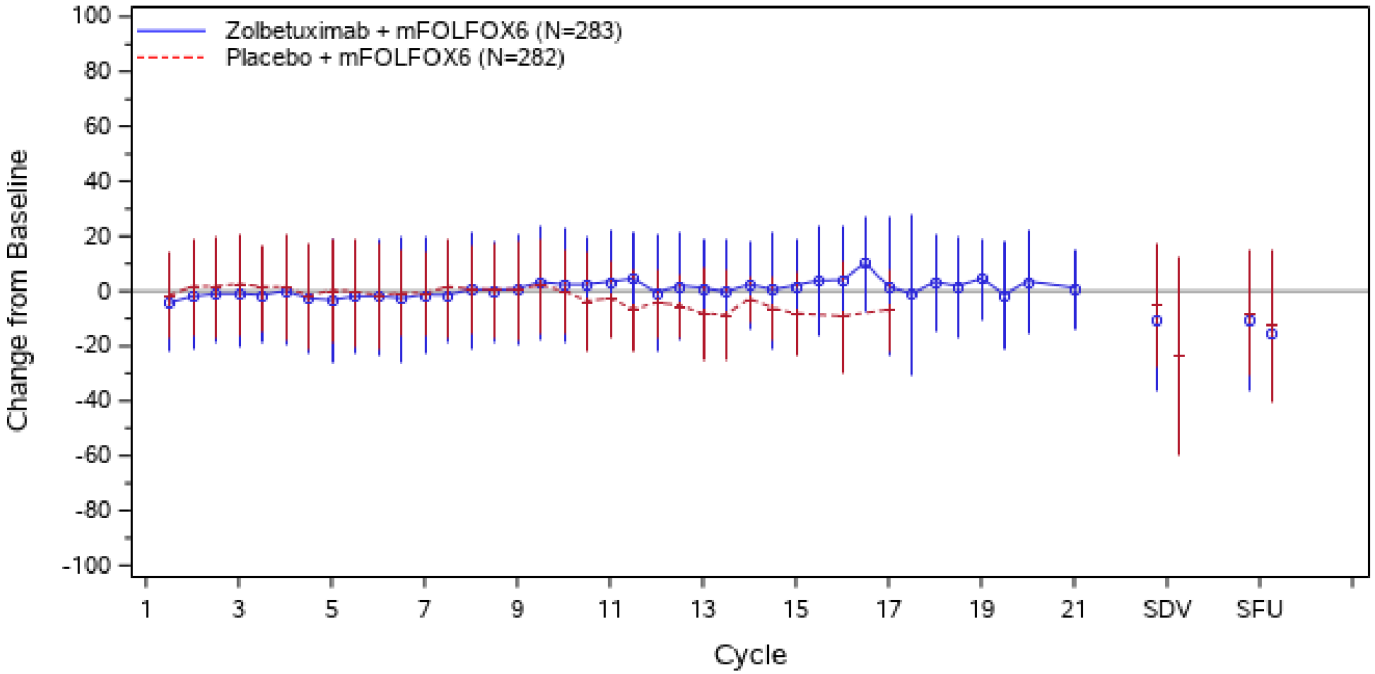
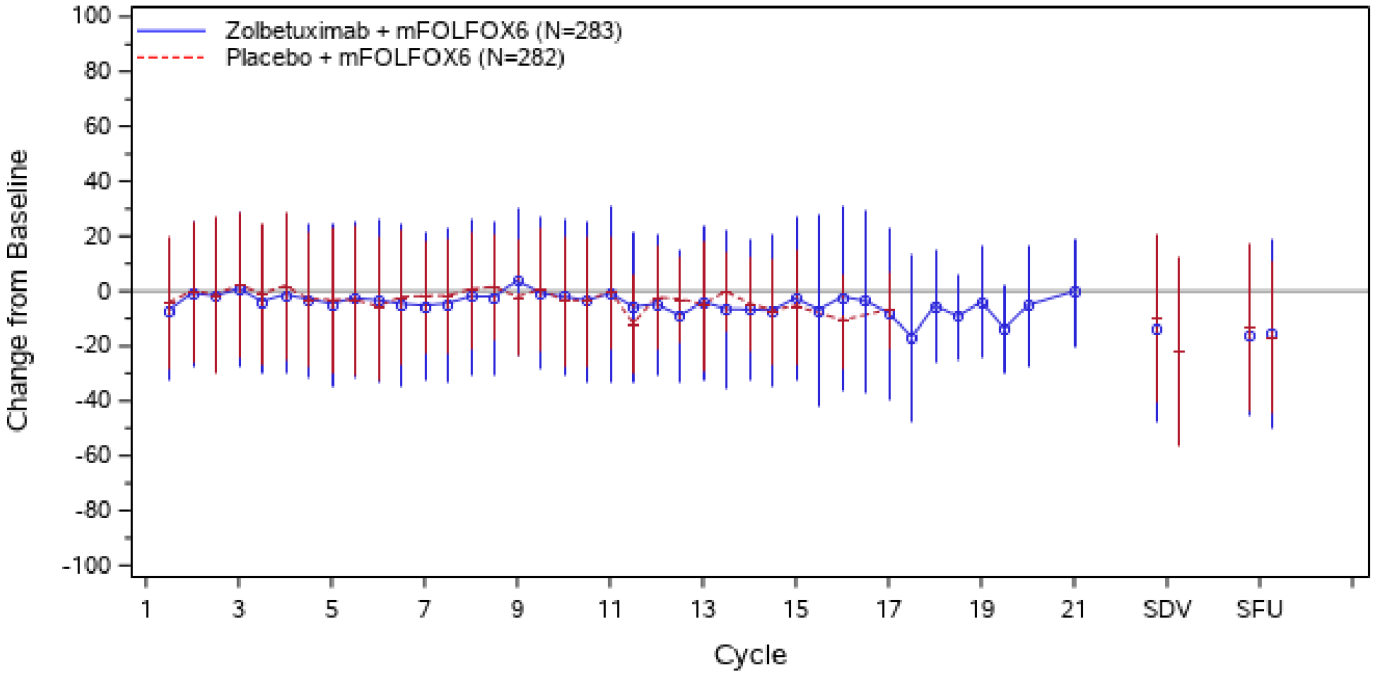
Figure 301.1.3002.6: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Physical Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

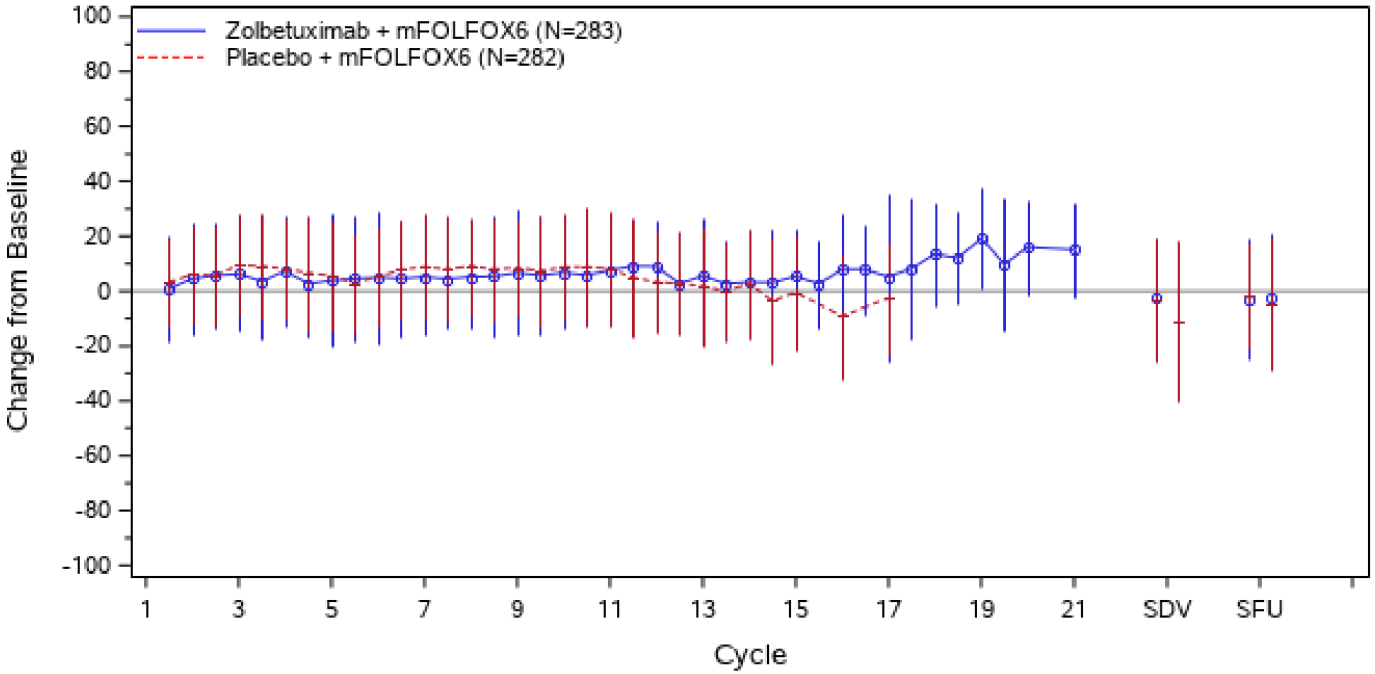
Figure 301.1.3002.7: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Role Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

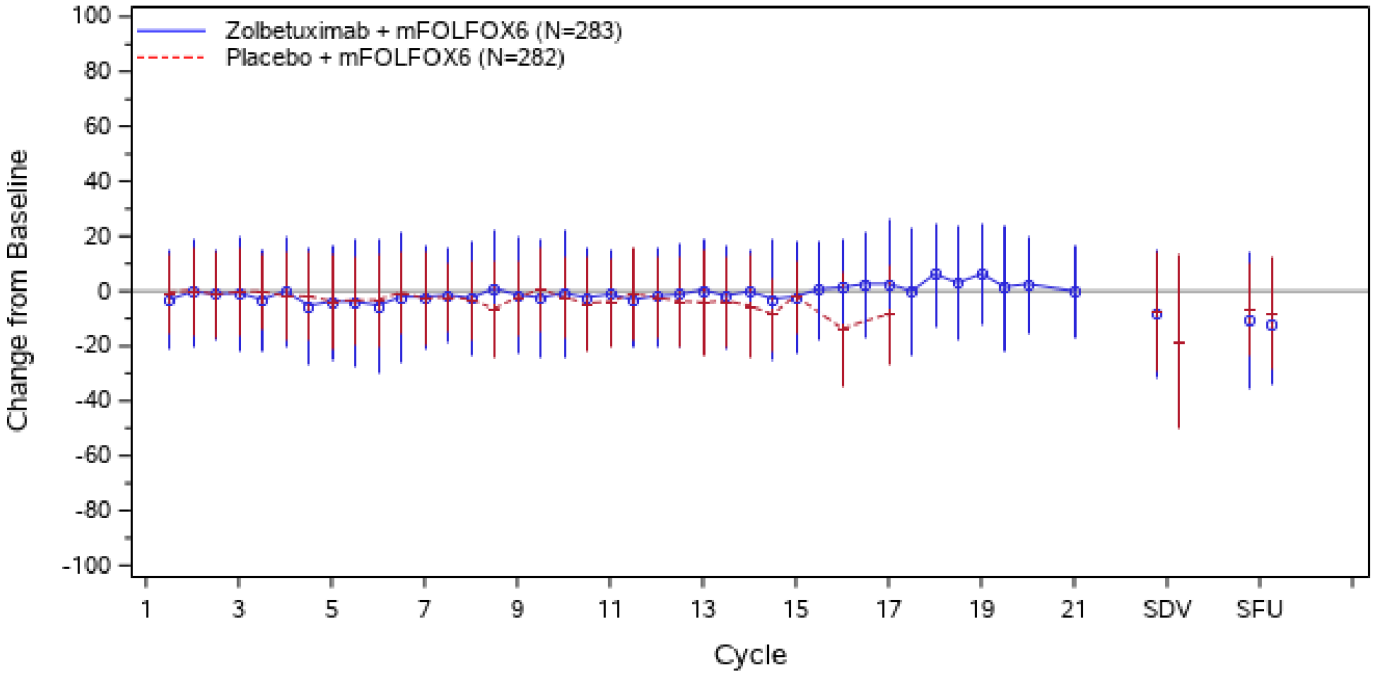
Figure 301.1.3002.8: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Emotional Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

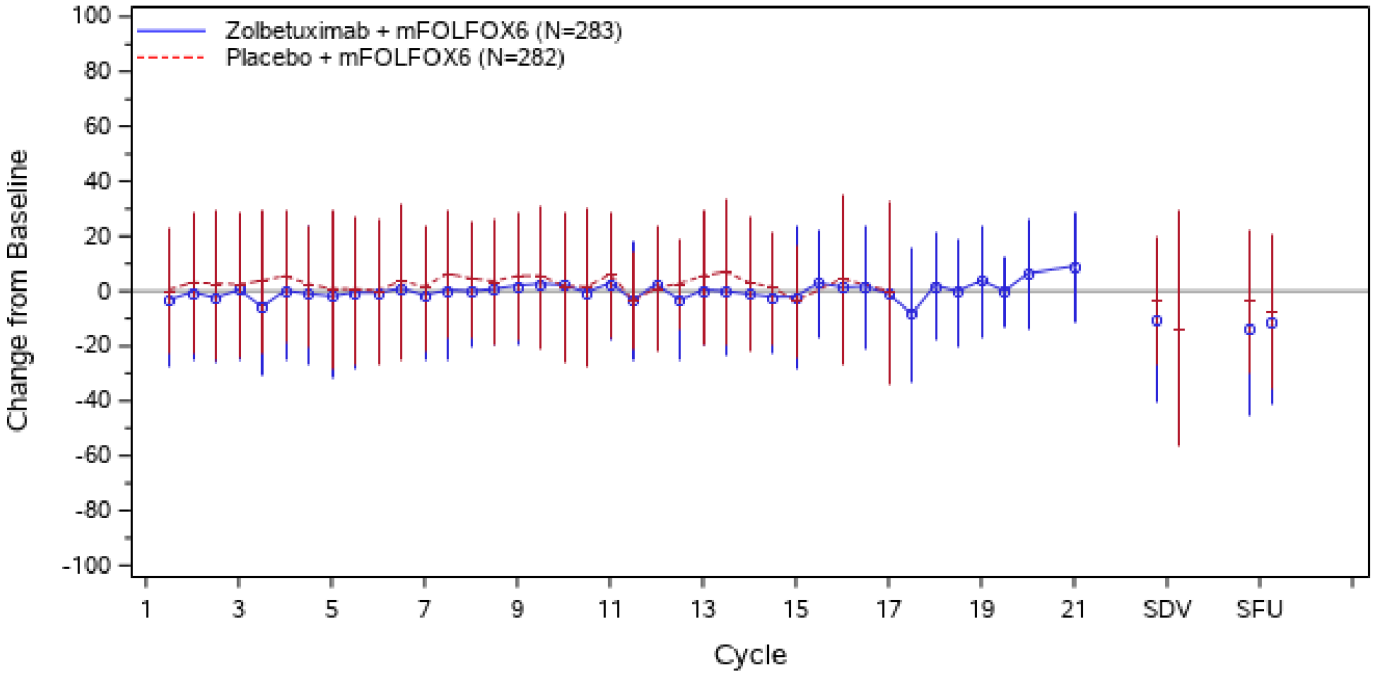
Figure 301.1.3002.9: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Cognitive Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.10: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Social Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

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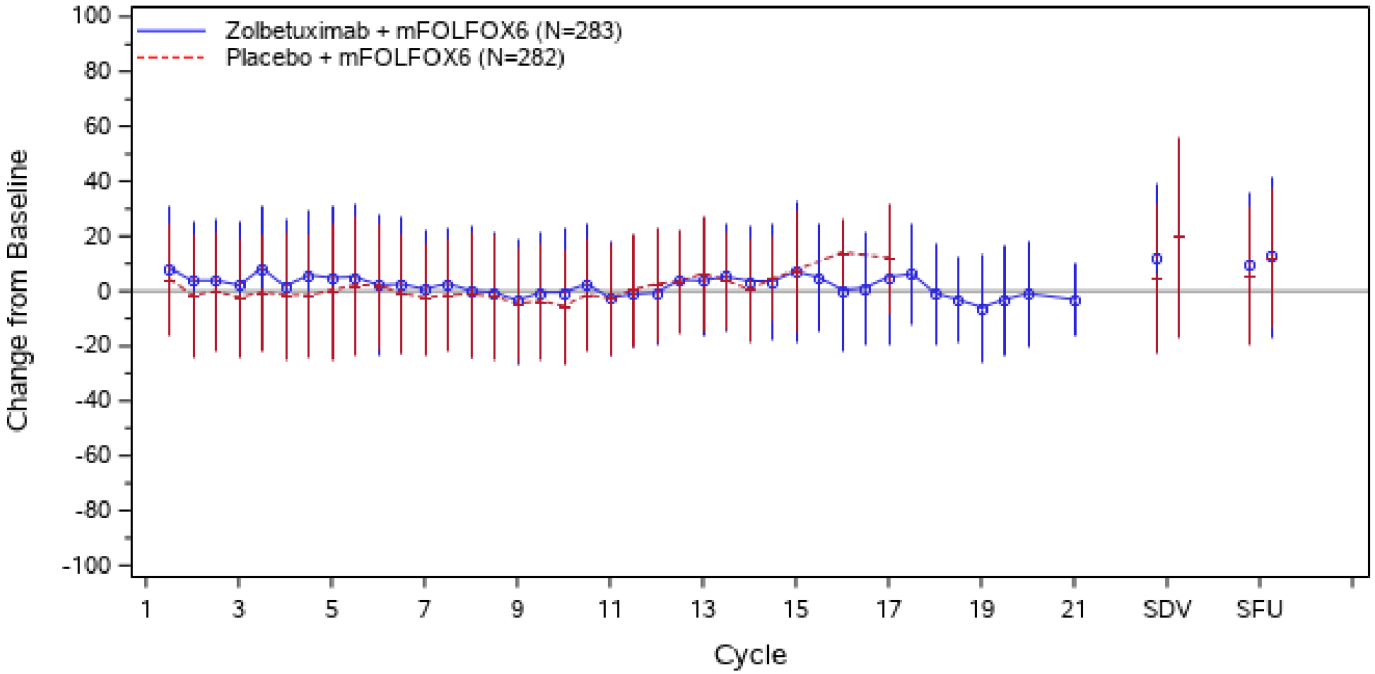
Figure 301.1.3002.11: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue - Full Analysis Set

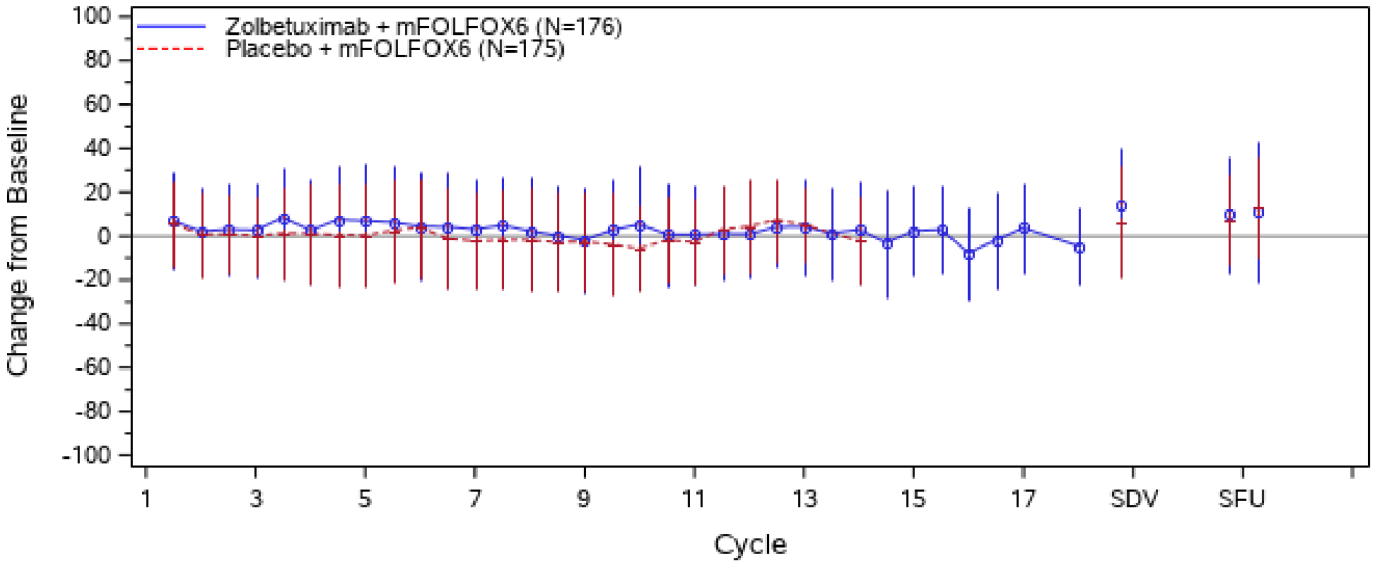


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.11.2: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue by Sex - Full Analysis Set

Sex: Male



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

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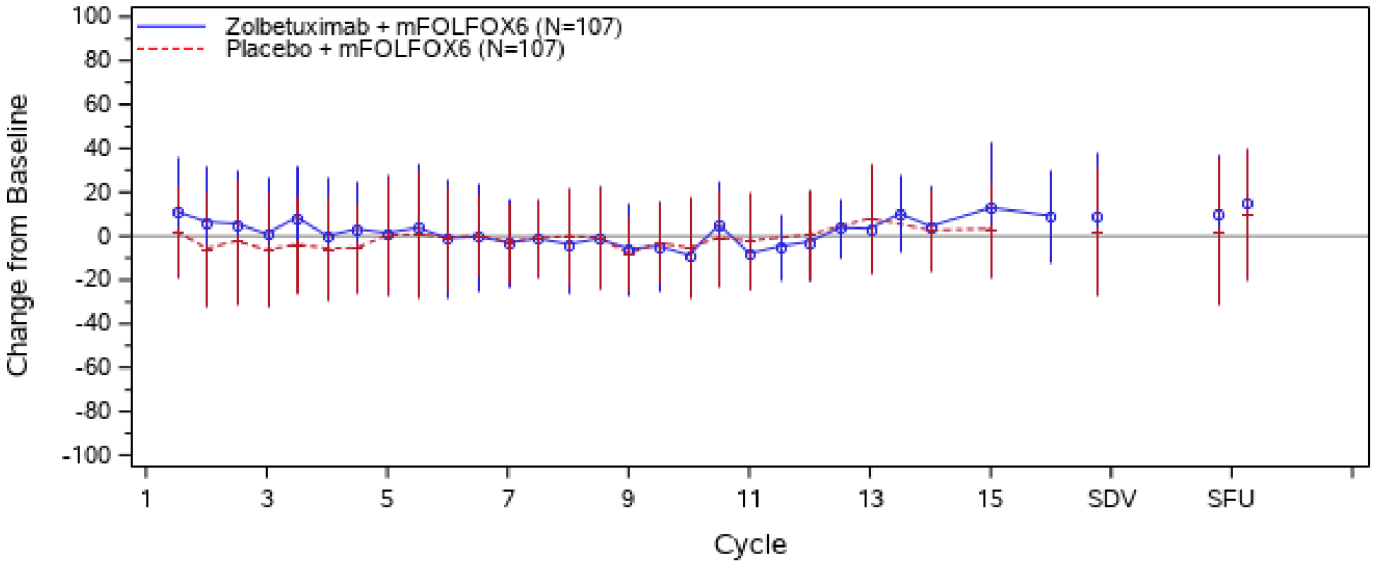
Figure 301.1.3002.11.2: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue by Sex - Full Analysis Set

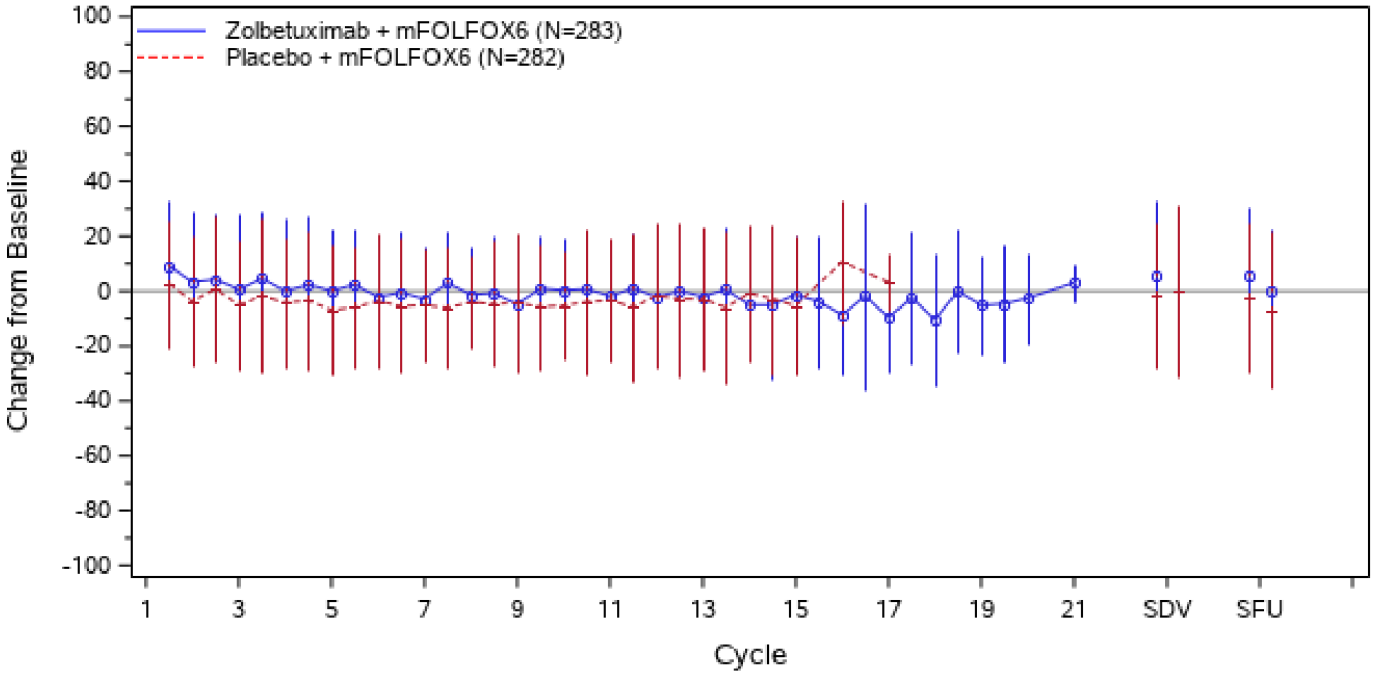
Sex: Female



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.12: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Nausea and Vomiting - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

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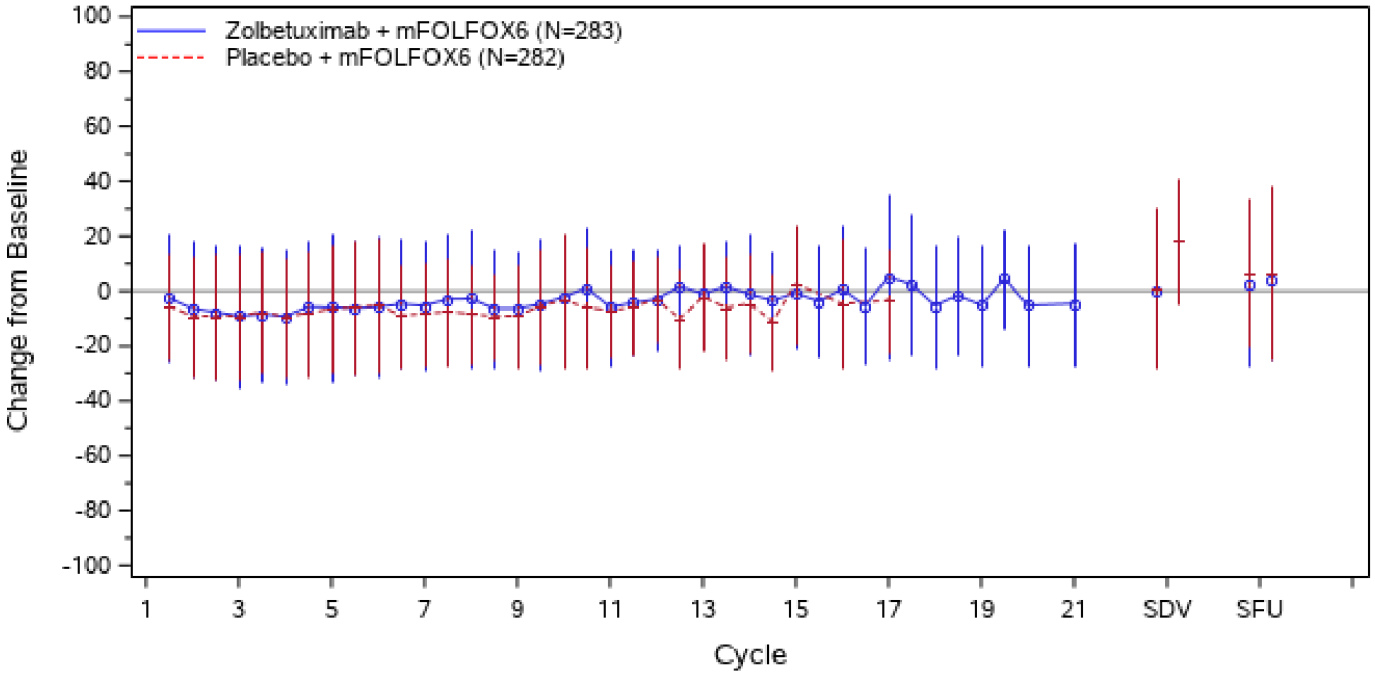
Figure 301.1.3002.13: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain - Full Analysis Set

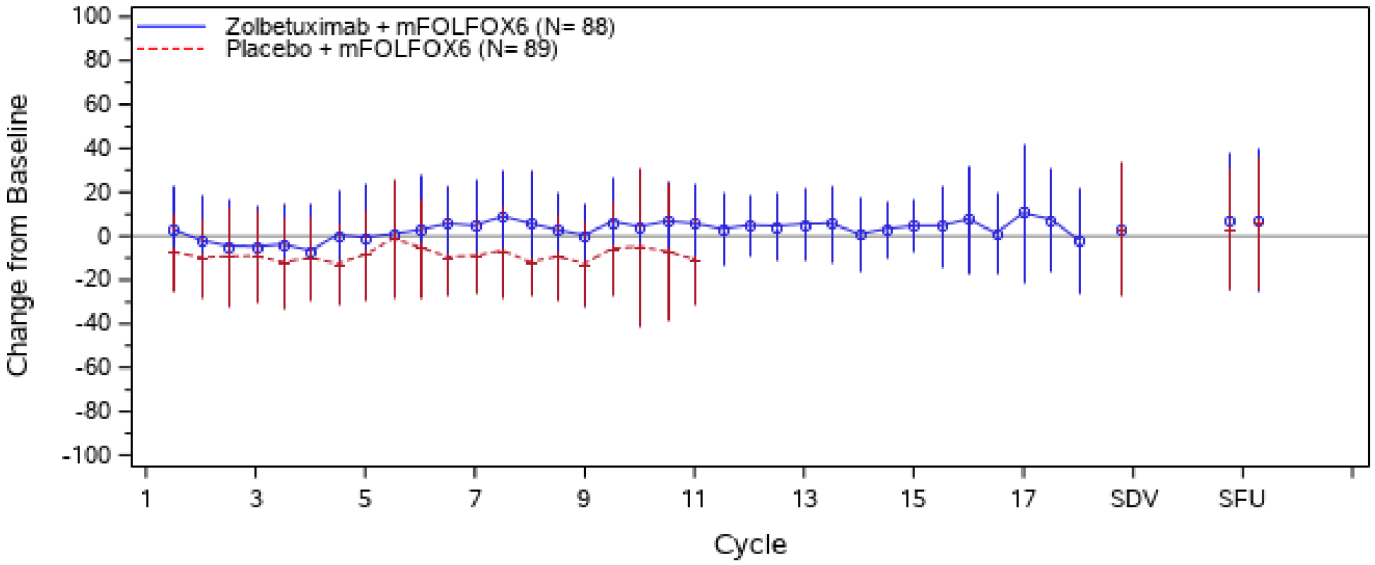


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.13.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain by Region - Full Analysis Set

Region: Asia

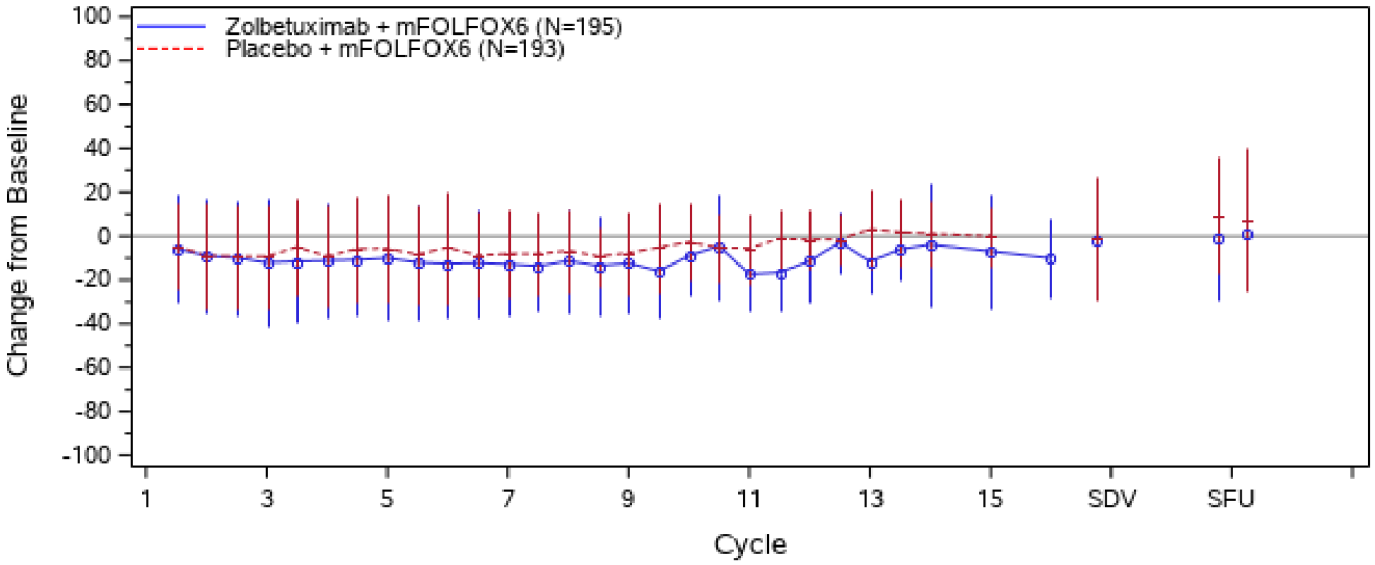


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.13.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain by Region - Full Analysis Set

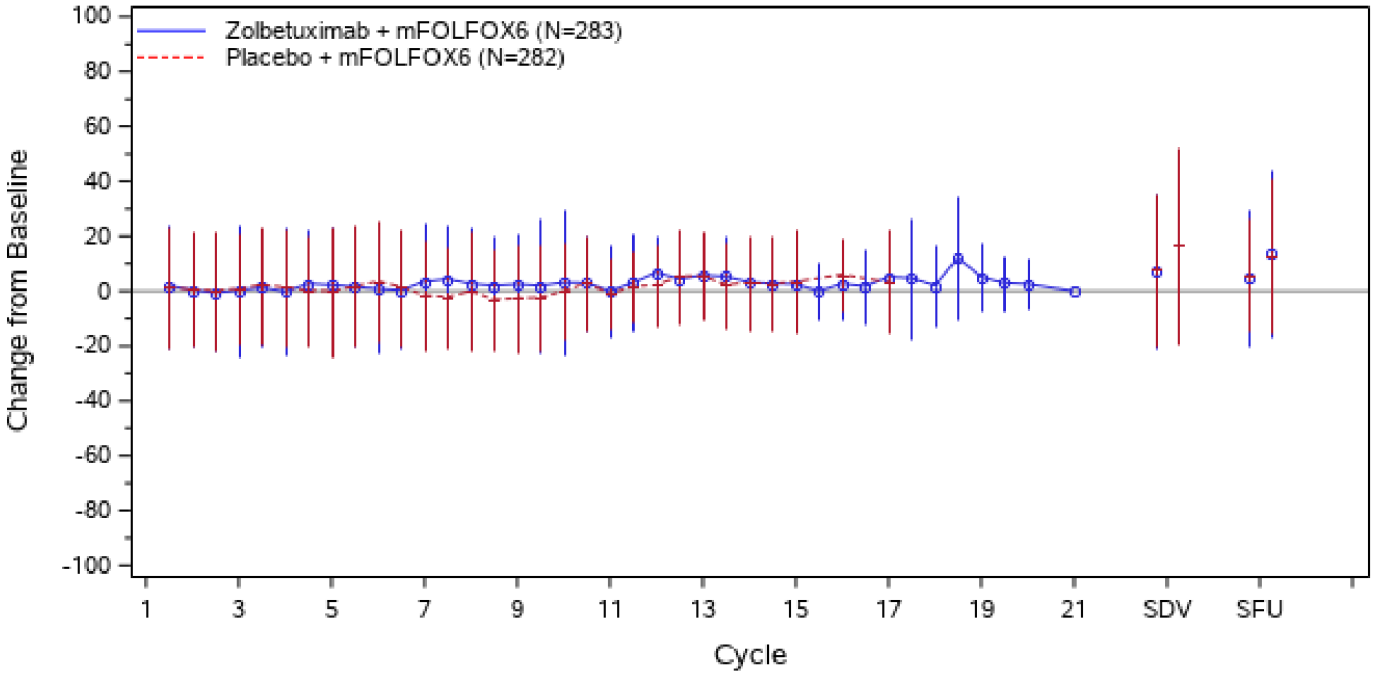
Region: Non-Asia



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

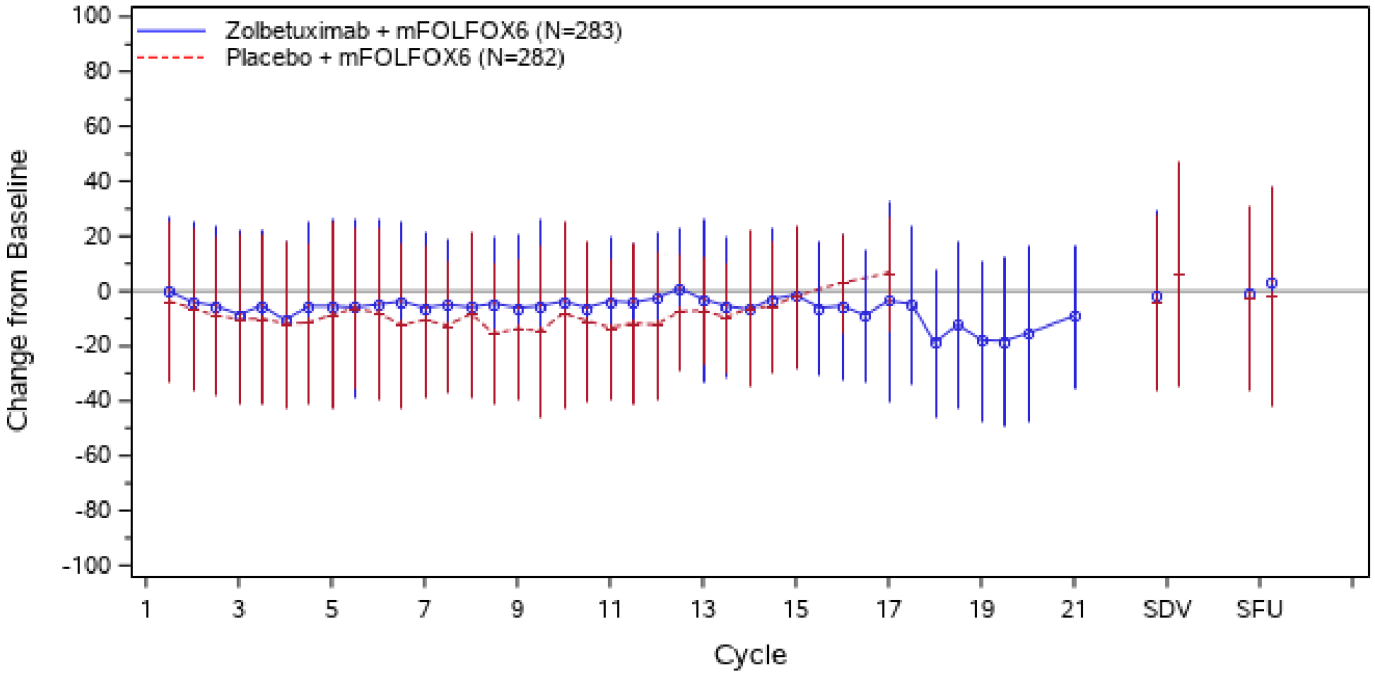
Figure 301.1.3002.14: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

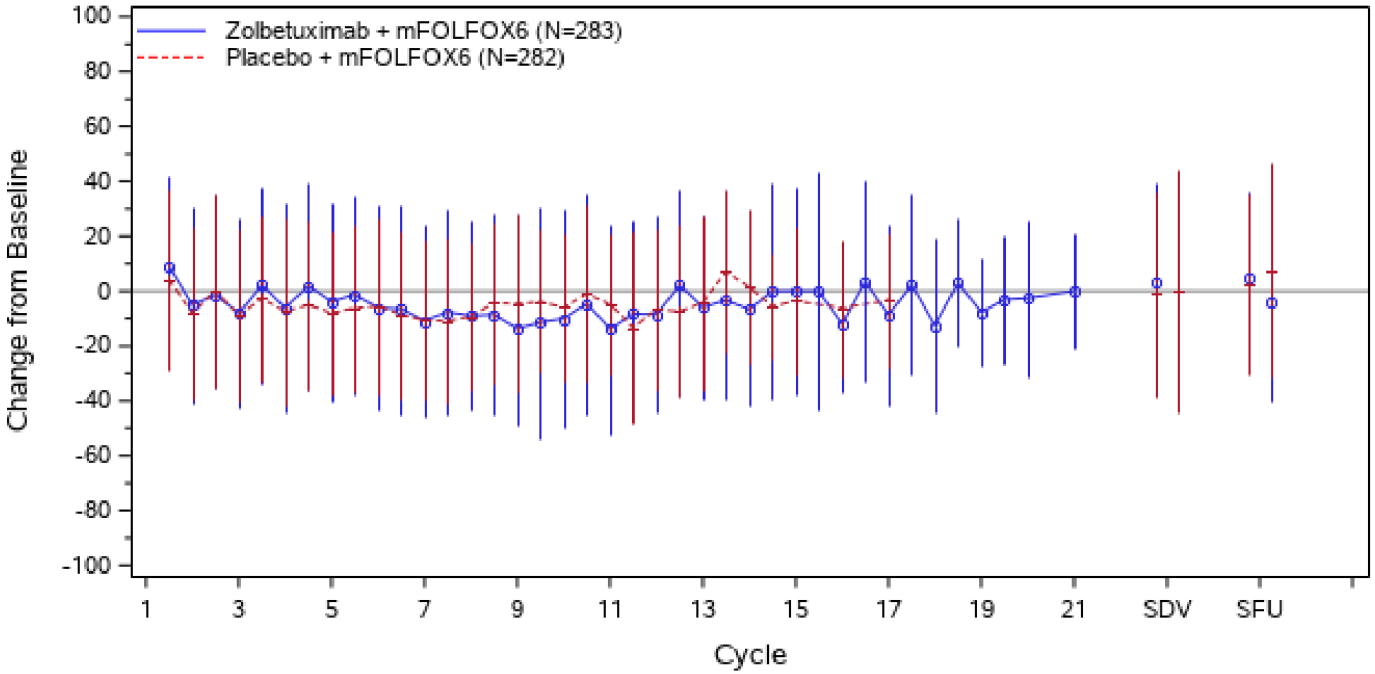
Figure 301.1.3002.15: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Insomnia - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

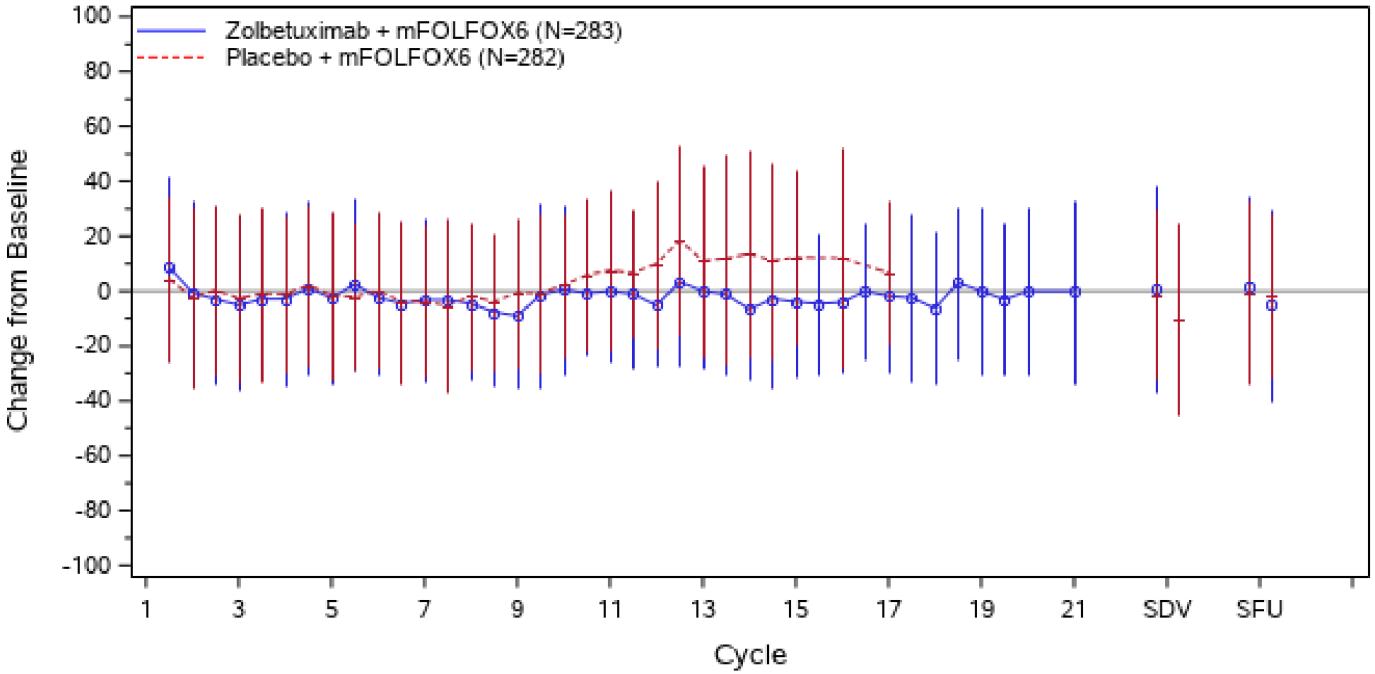
Figure 301.1.3002.16: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Appetite Loss - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

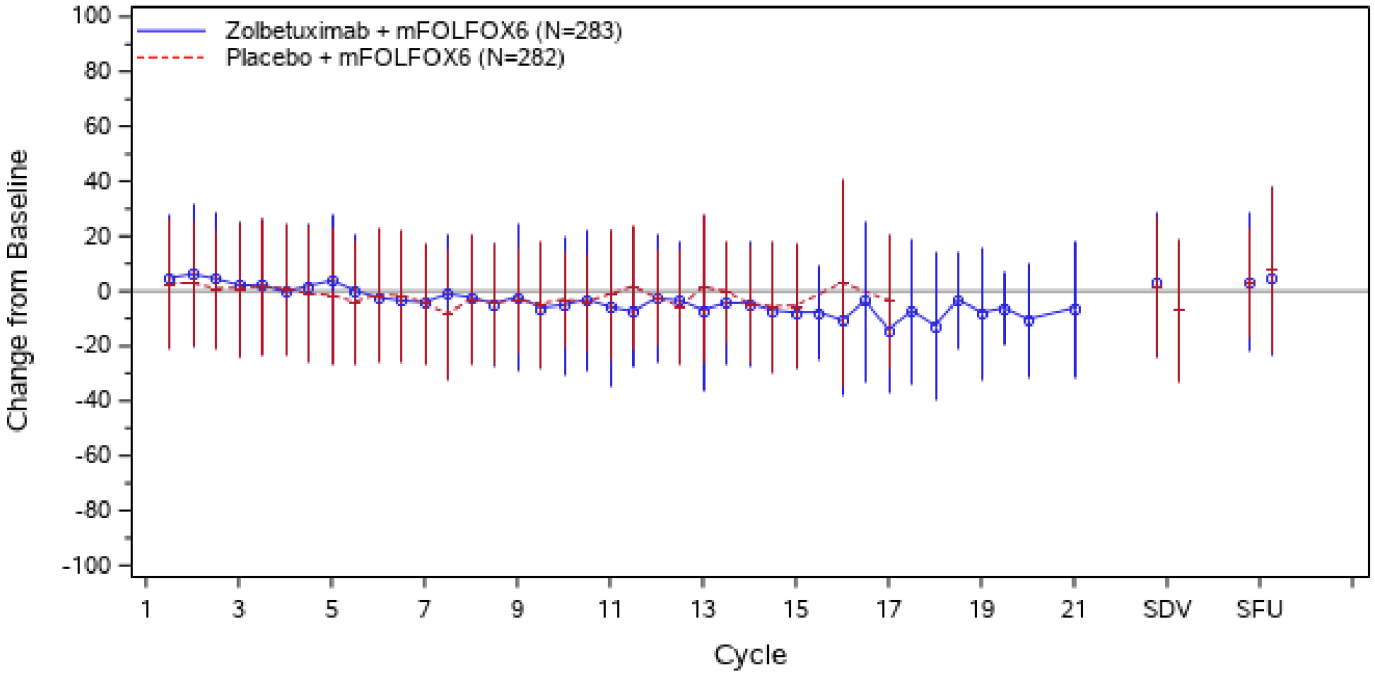
Figure 301.1.3002.17: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.18: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea - Full Analysis Set

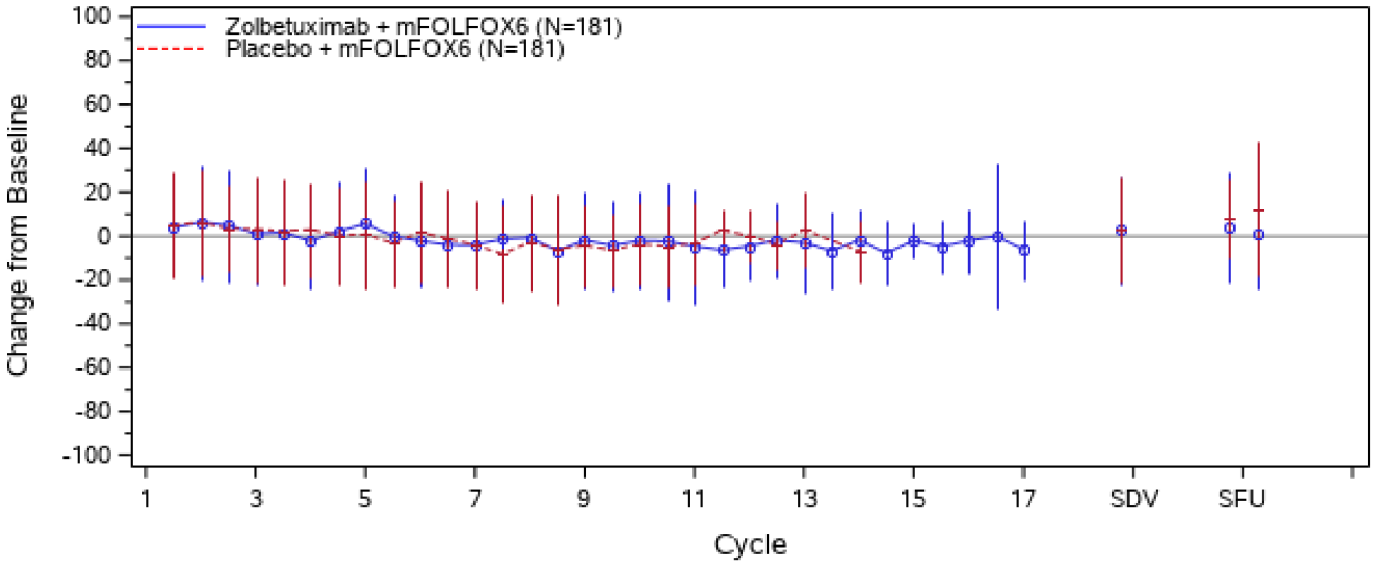


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.18.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

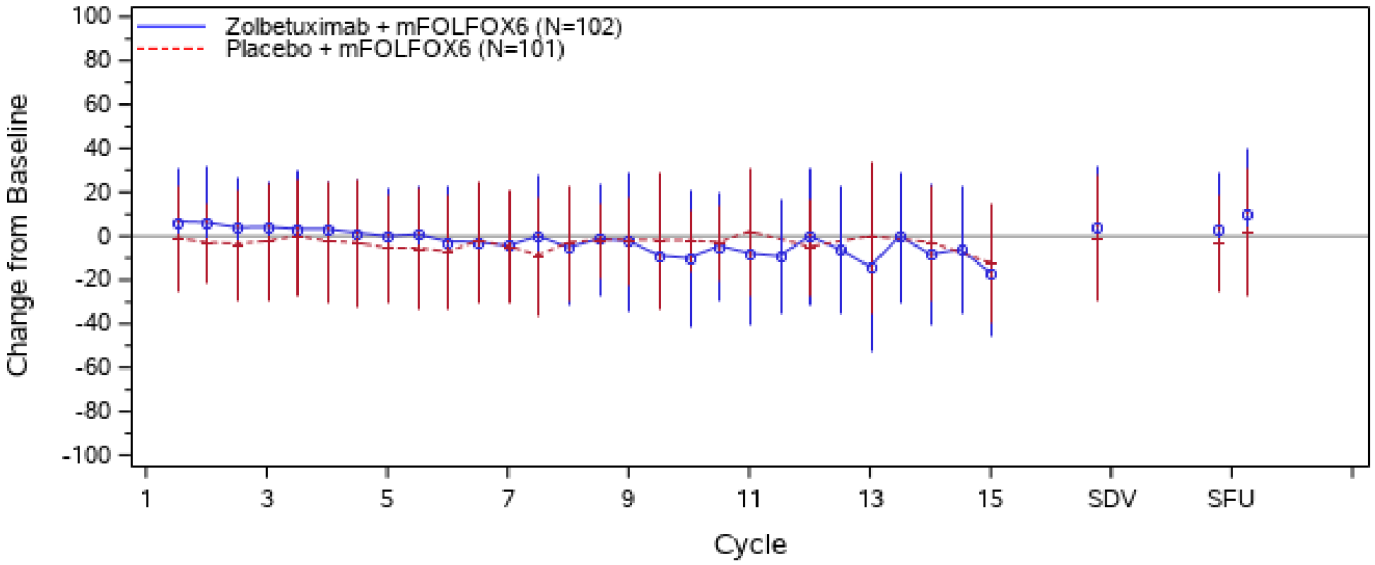


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.18.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

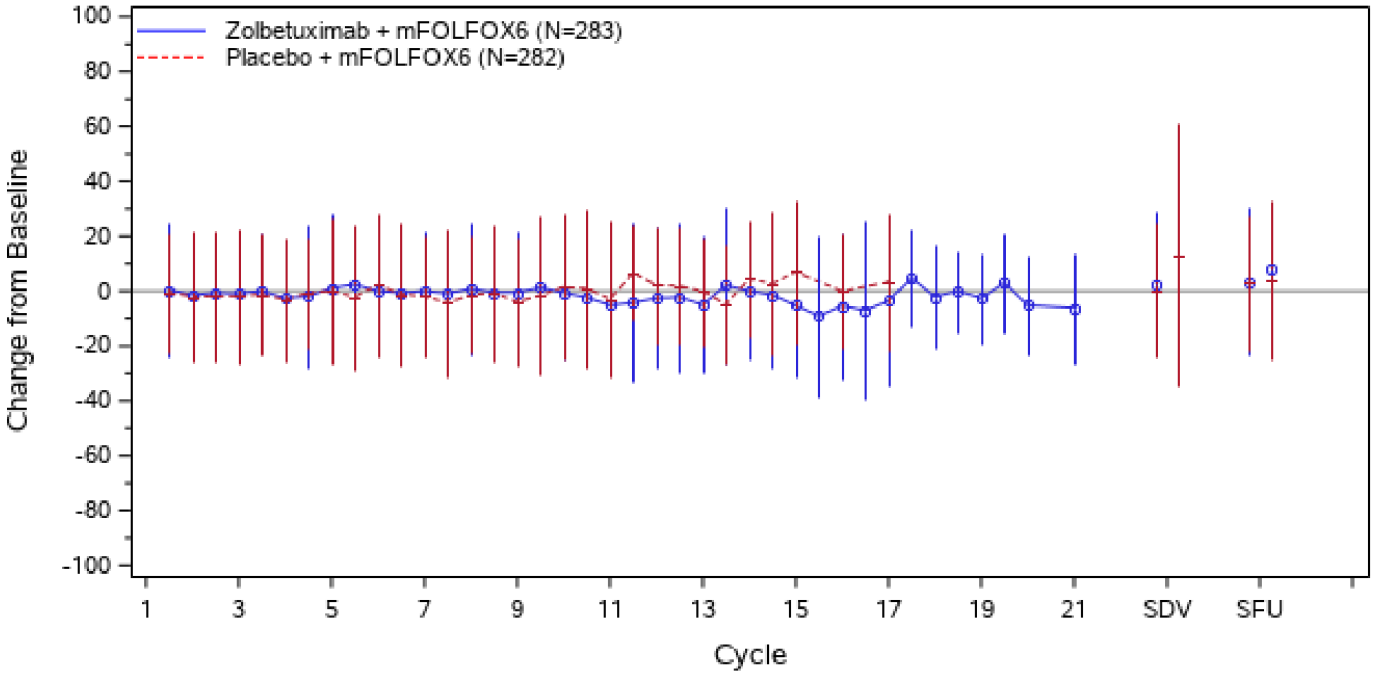
Age Group 1: >65 years



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.19: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Financial Difficulties - Full Analysis Set



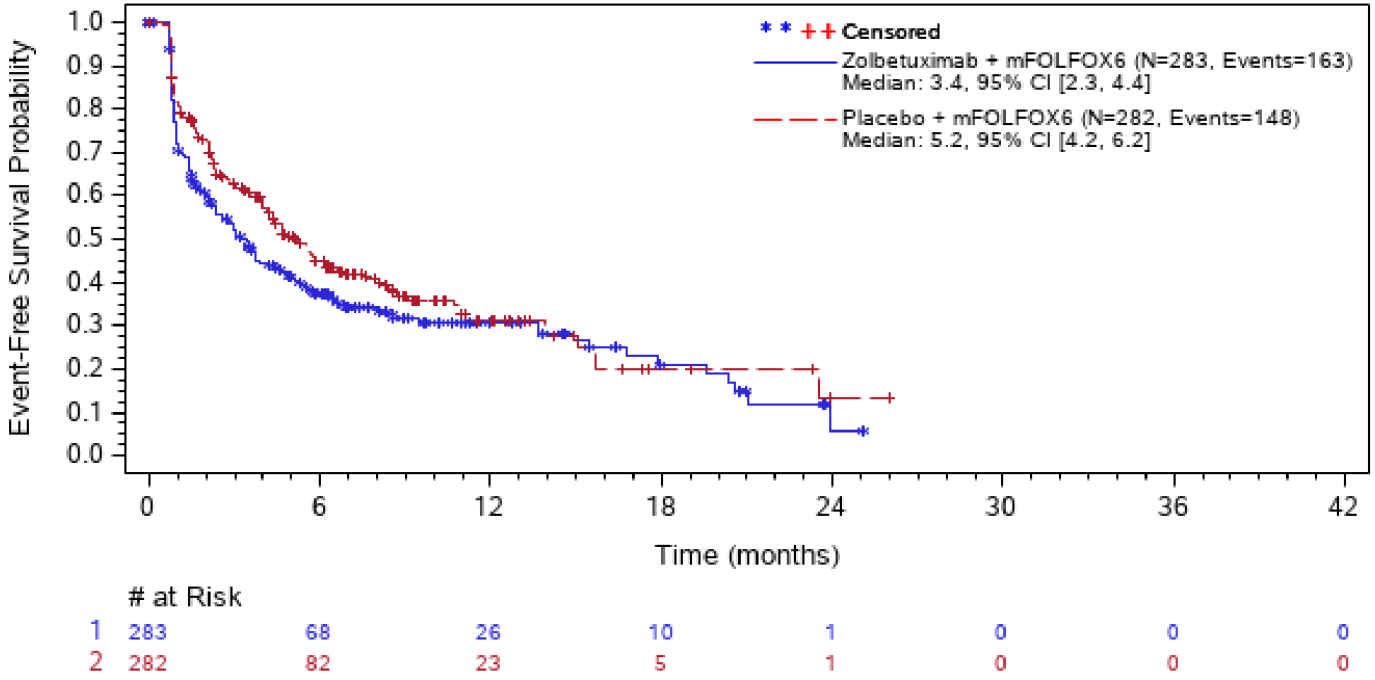
Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

5. Kaplan-Meier-Plots

The SAS System

Figure 301.1.3004.5: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Global Health Status (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

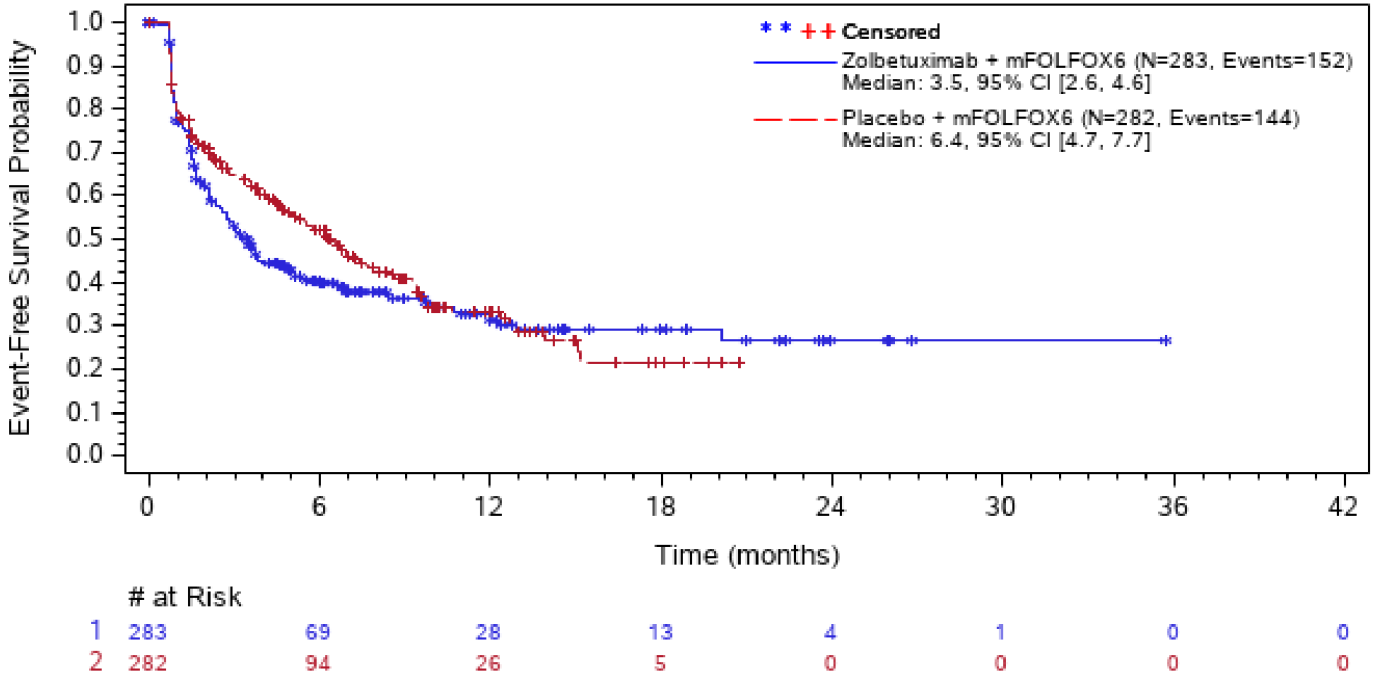
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.6: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Physical Functioning (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

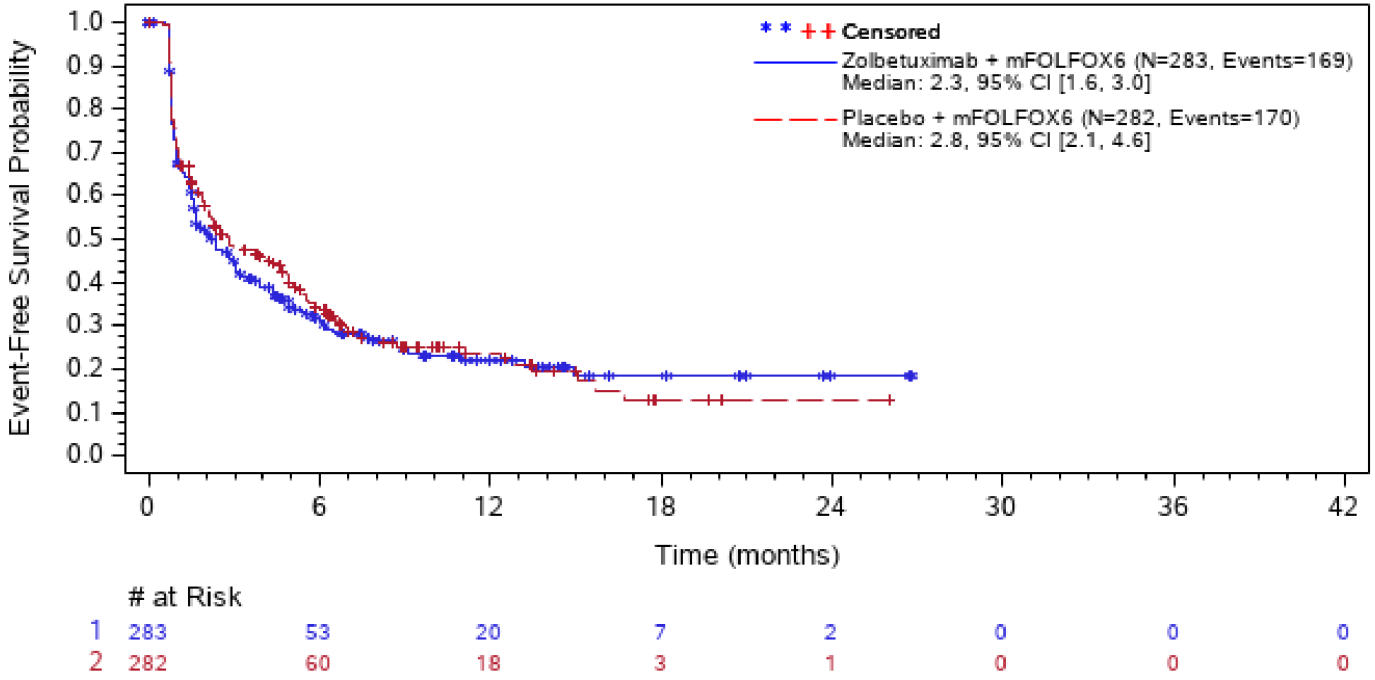
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.7: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

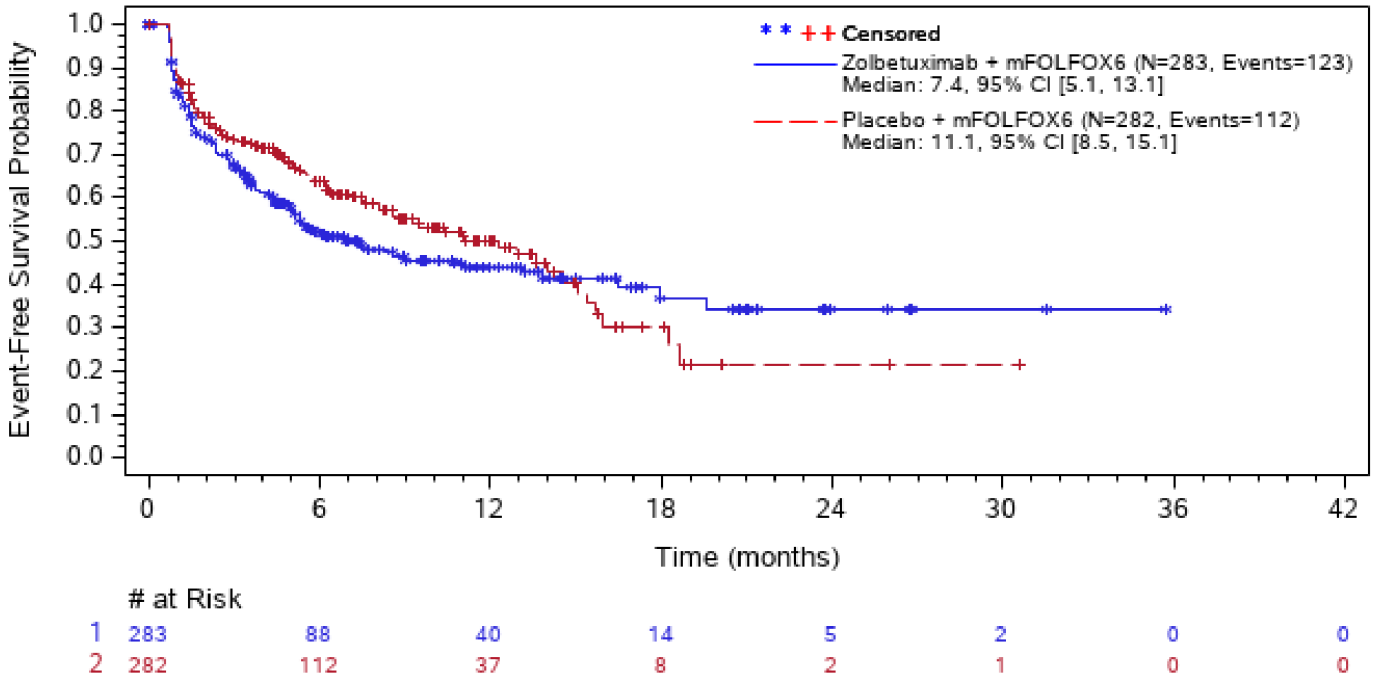
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.8: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Emotional Functioning (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

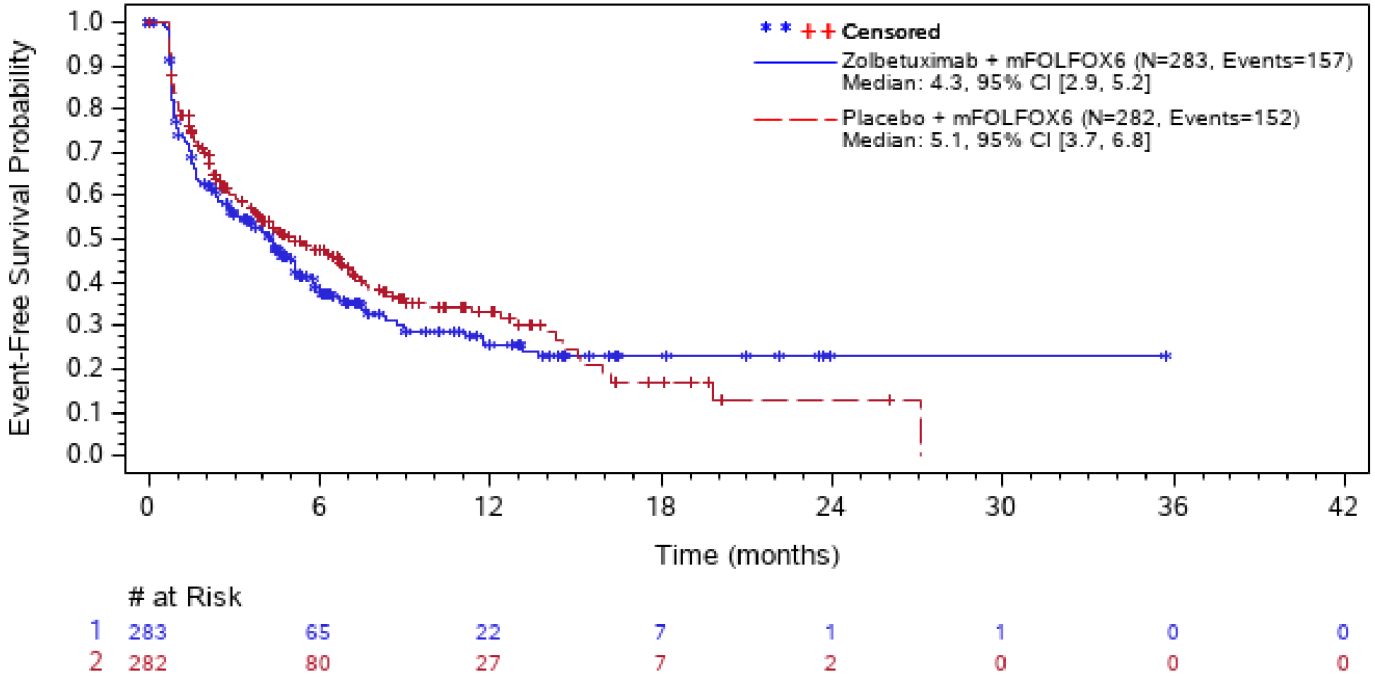
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.9: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Cognitive Functioning (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

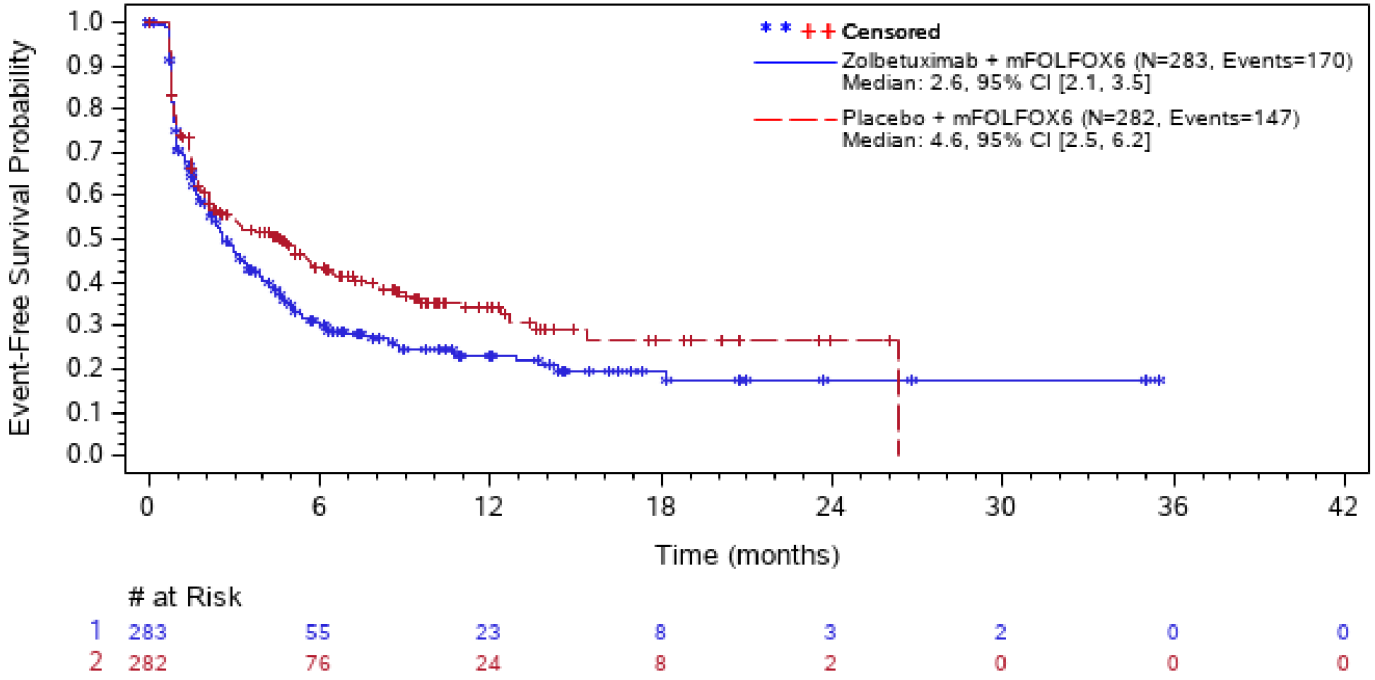
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.10: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Social Functioning (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

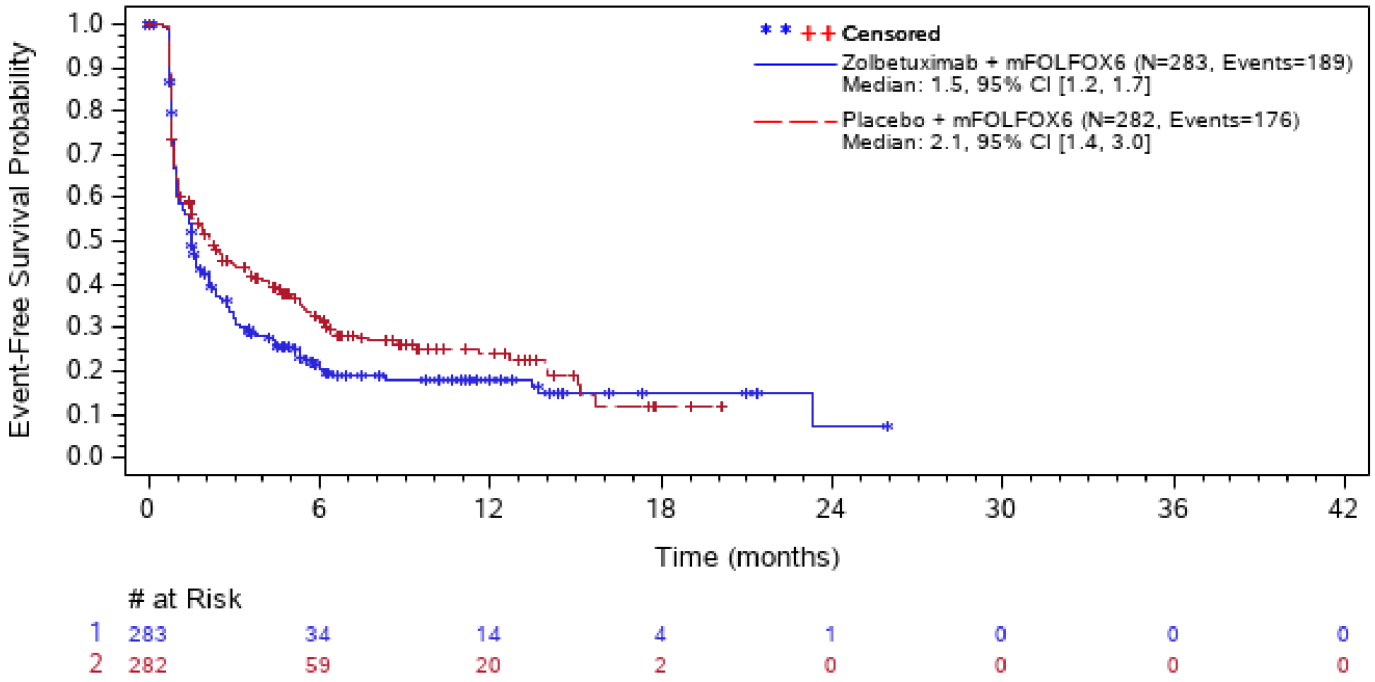
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point decrease. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.11: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue (MID=10) - Full 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; MID=minimally important difference; 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.

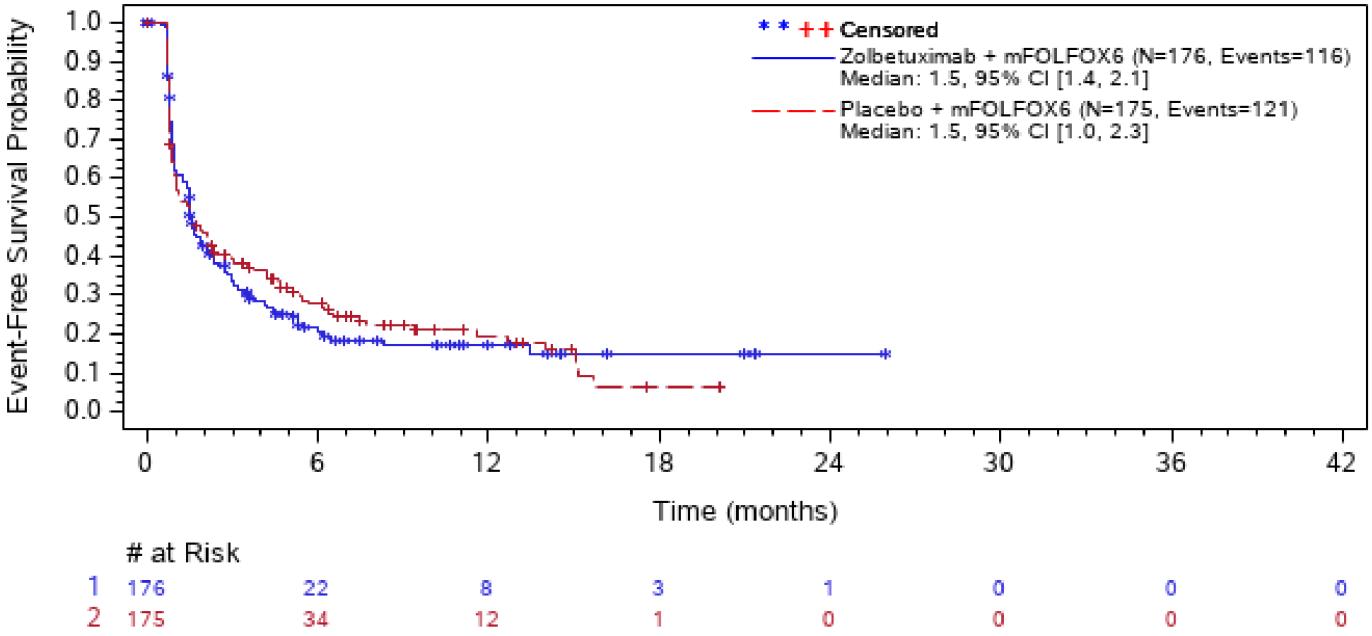
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.11.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue by Sex (MID=10) - Full 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; MID=minimally important difference; 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.

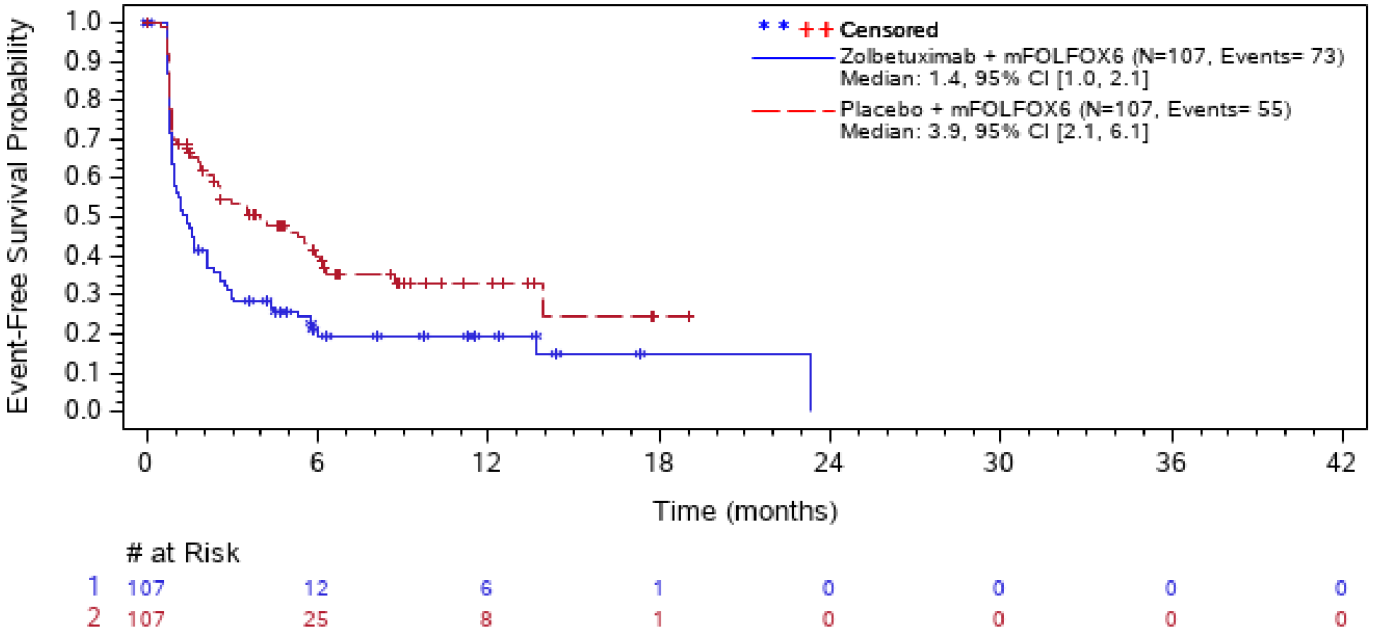
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.11.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue by Sex (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

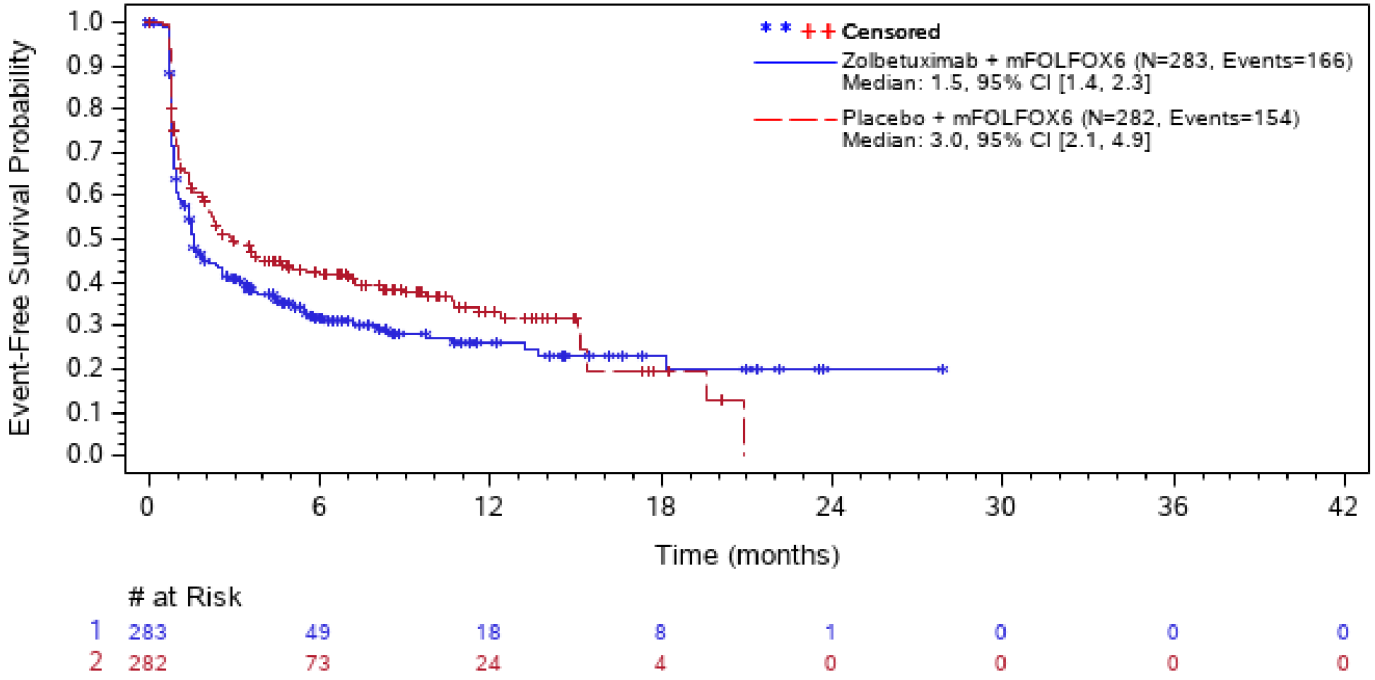
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.12: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

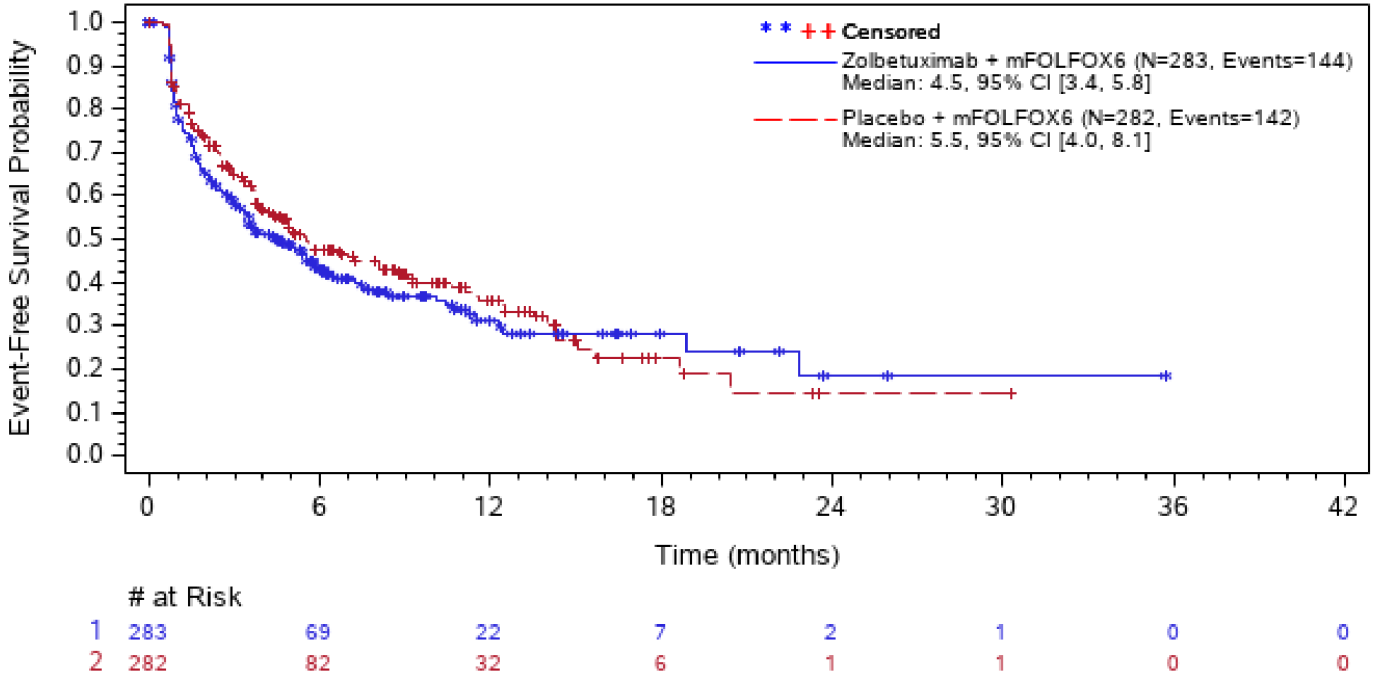
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.13: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain (MID=10) - Full 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; MID=minimally important difference; 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.

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: 09SEP22

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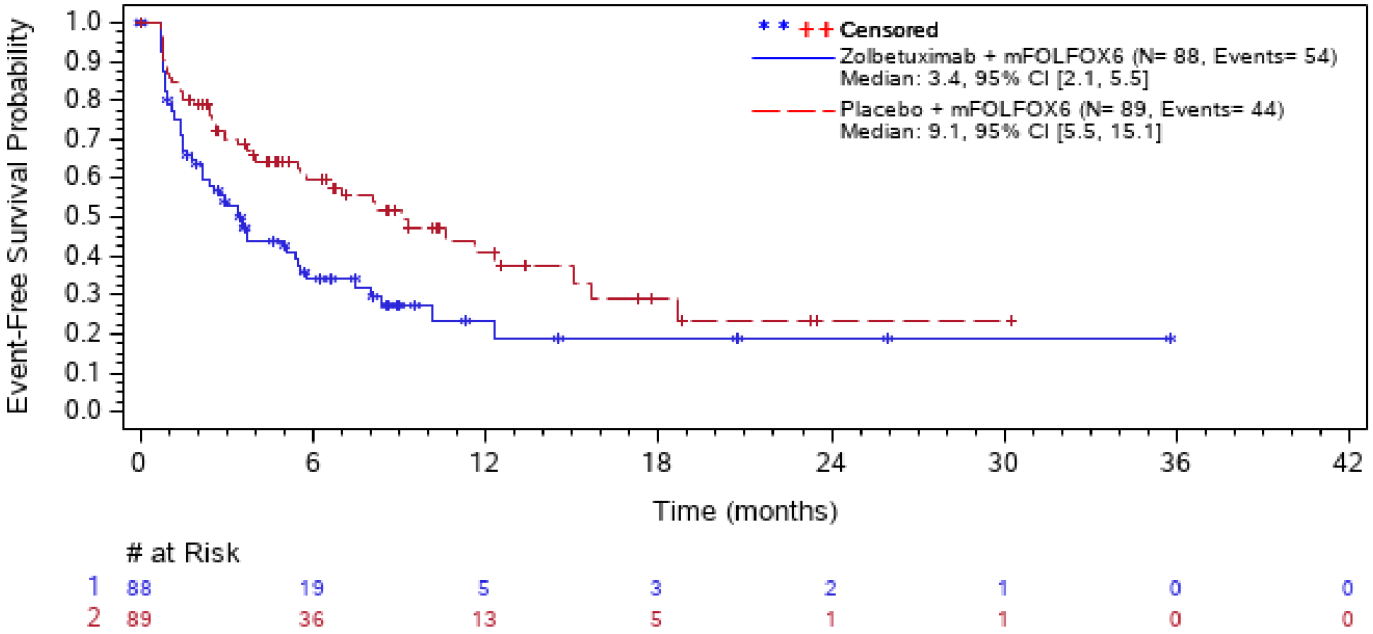
Figure 301.1.3004.13.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain by Region (MID=10) - Full Analysis Set

Region: Asia



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; MID=minimally important difference; 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.

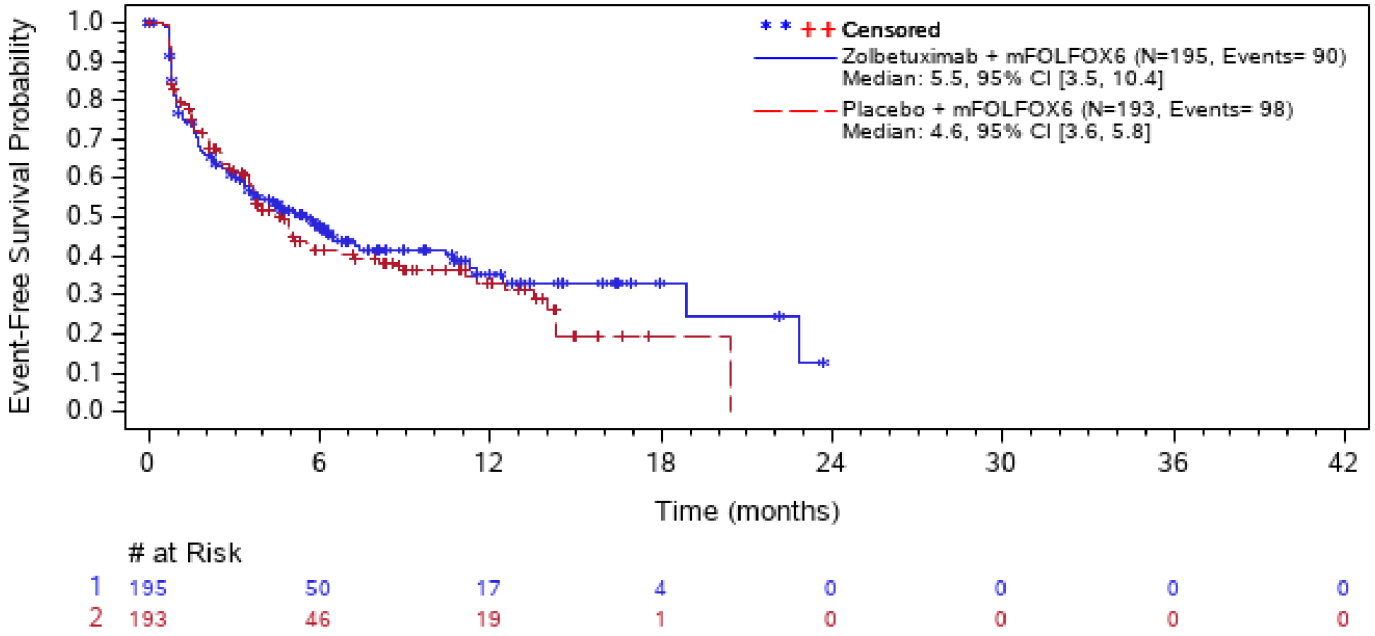
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.13.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain by Region (MID=10) - Full Analysis Set

Region: Non-Asia



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; MID=minimally important difference; N=number of patients; NC=not calculated.

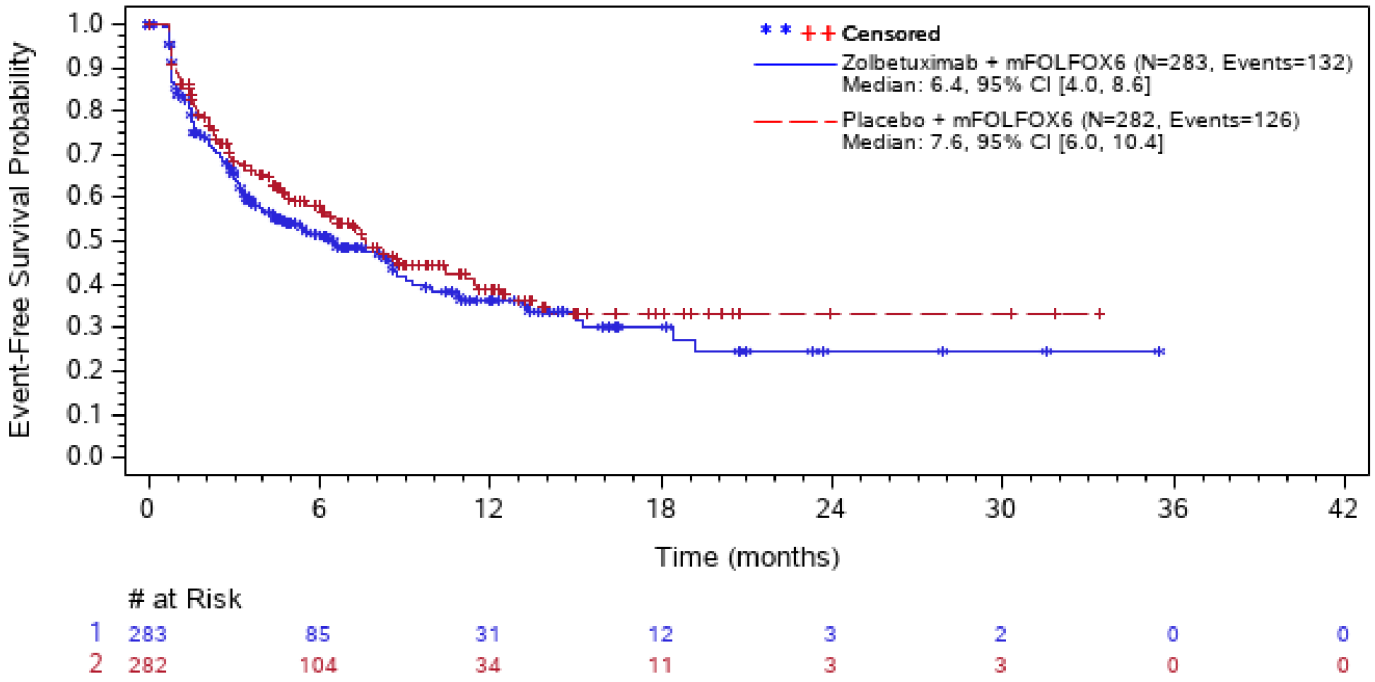
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.14: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

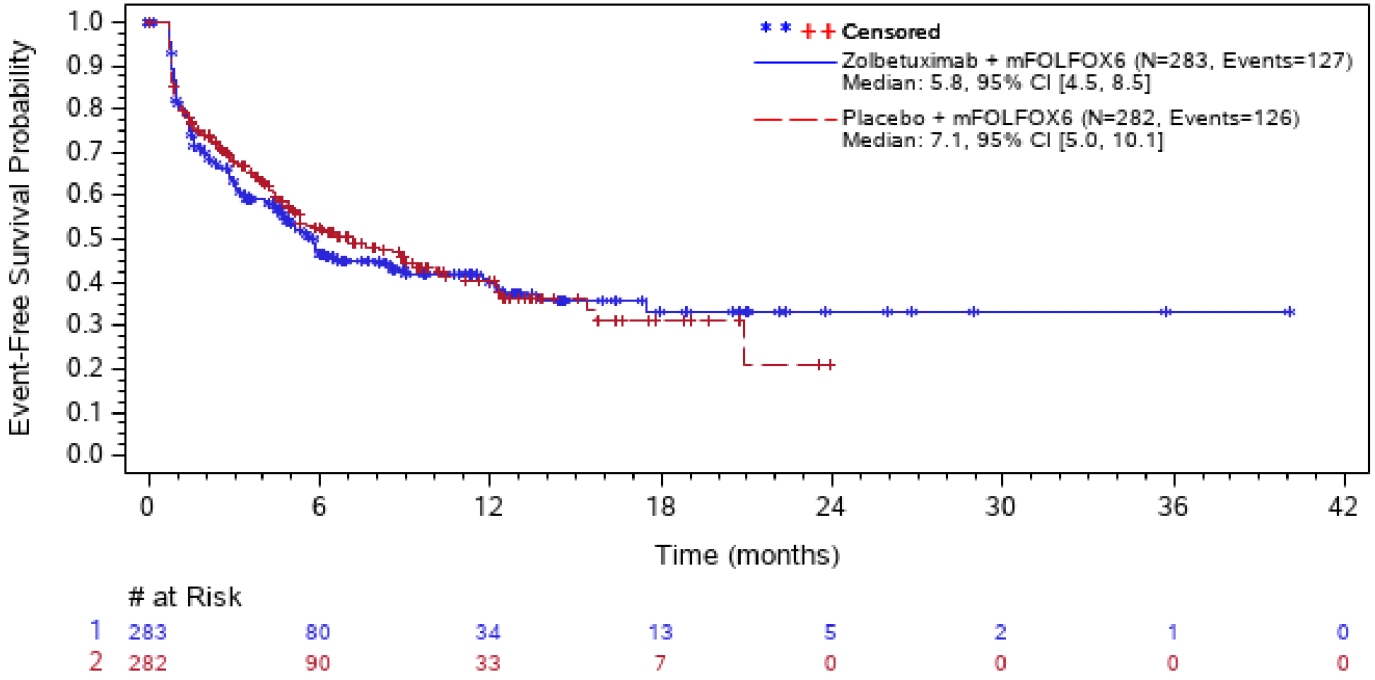
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.15: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Insomnia (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

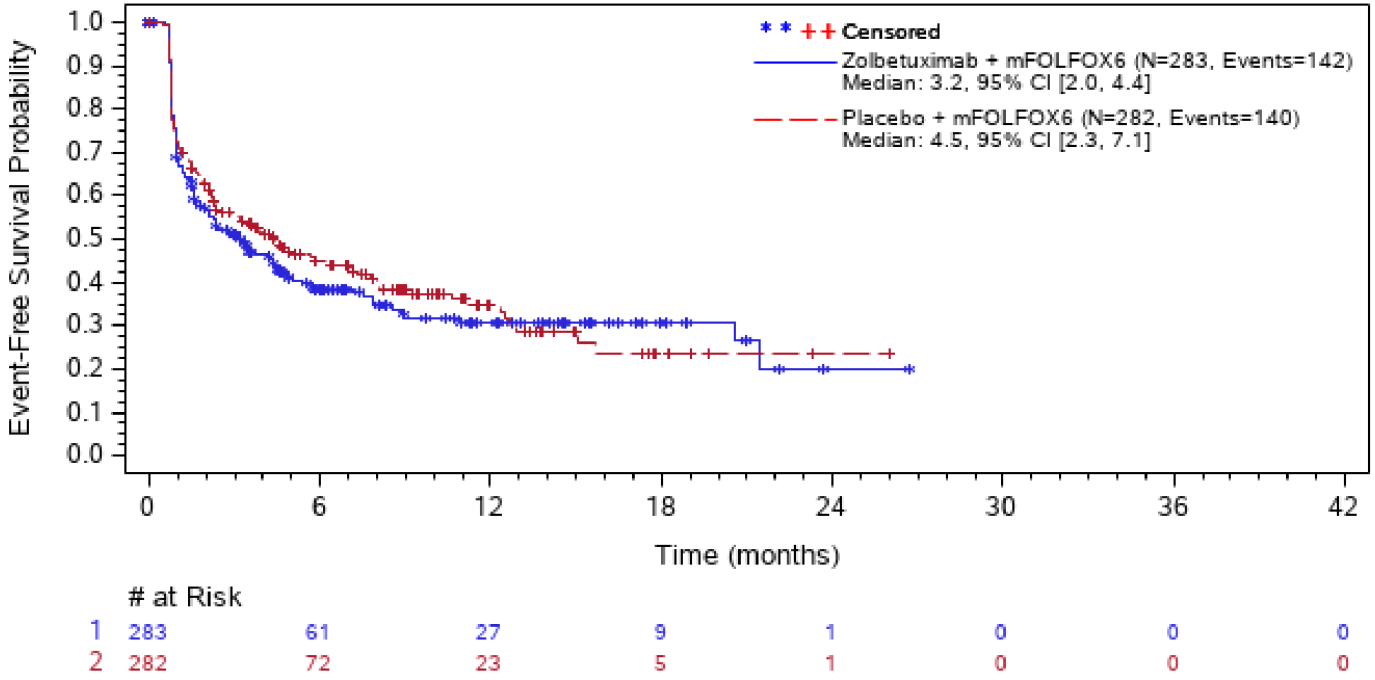
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.16: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Appetite Loss (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

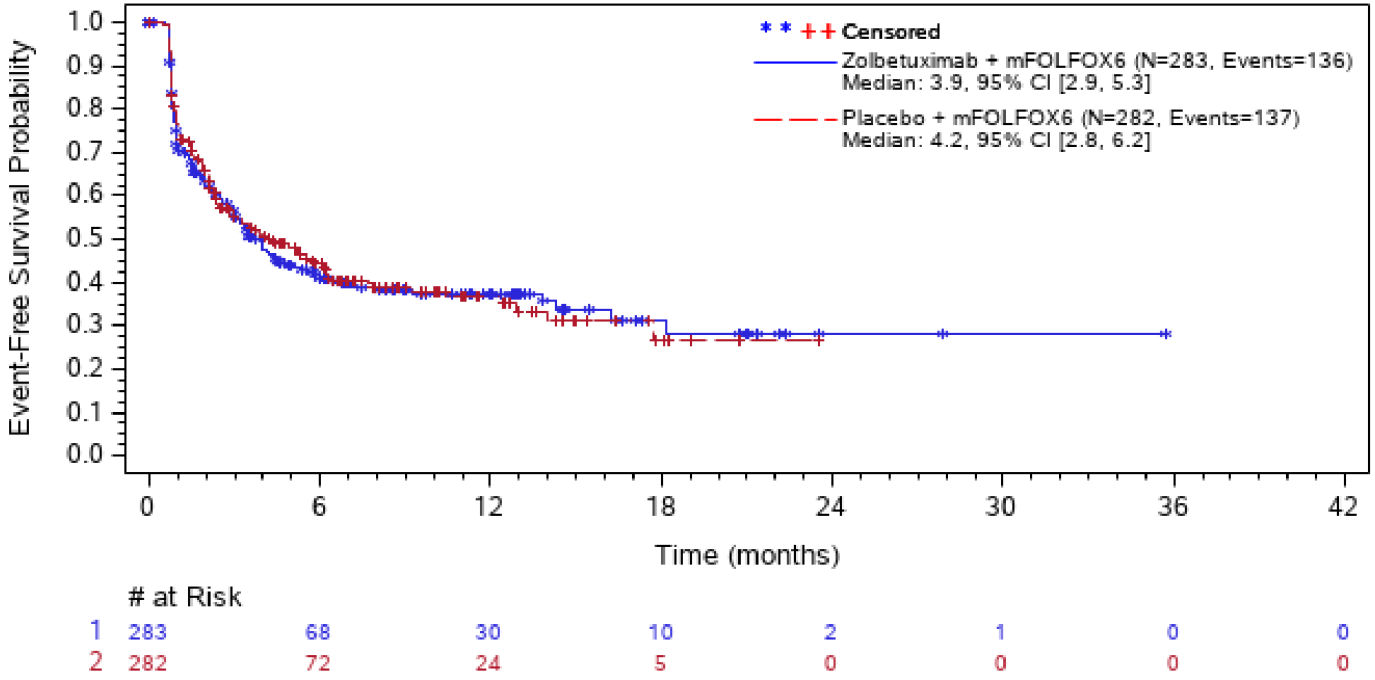
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.17: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

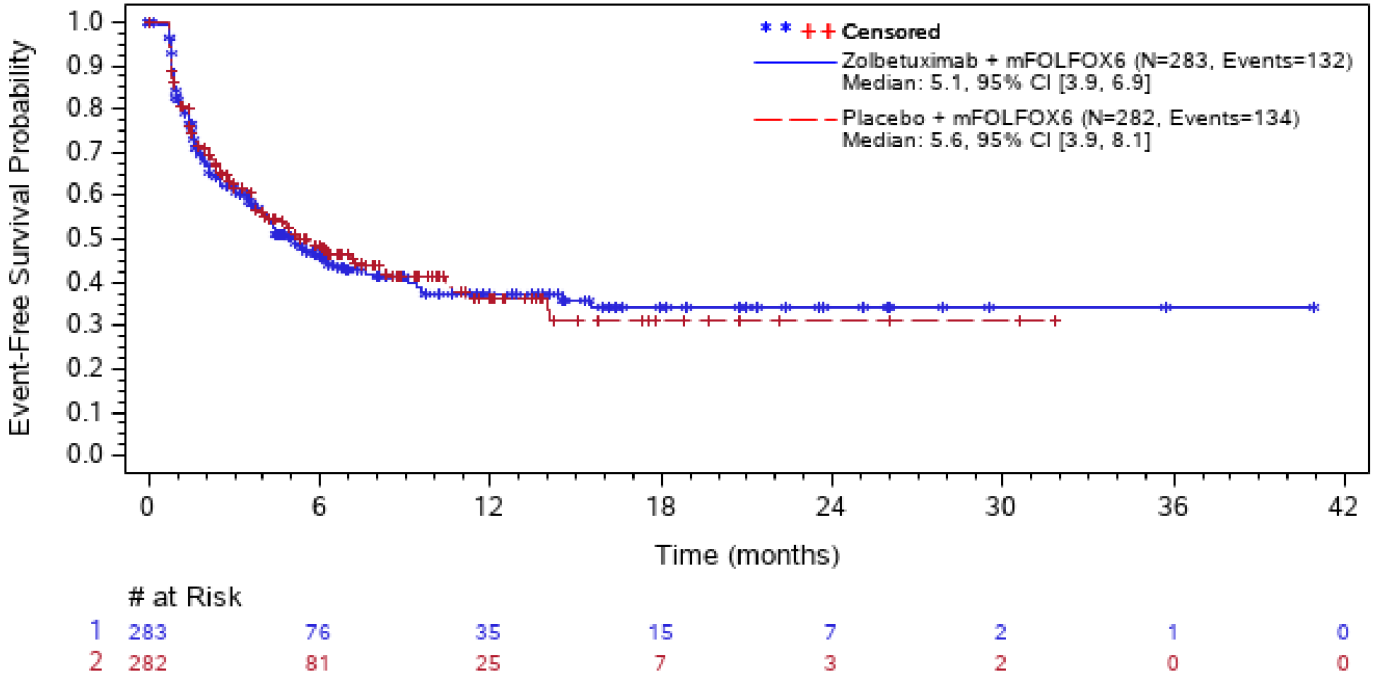
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.18: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea (MID=10) - Full 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; MID=minimally important difference; 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.

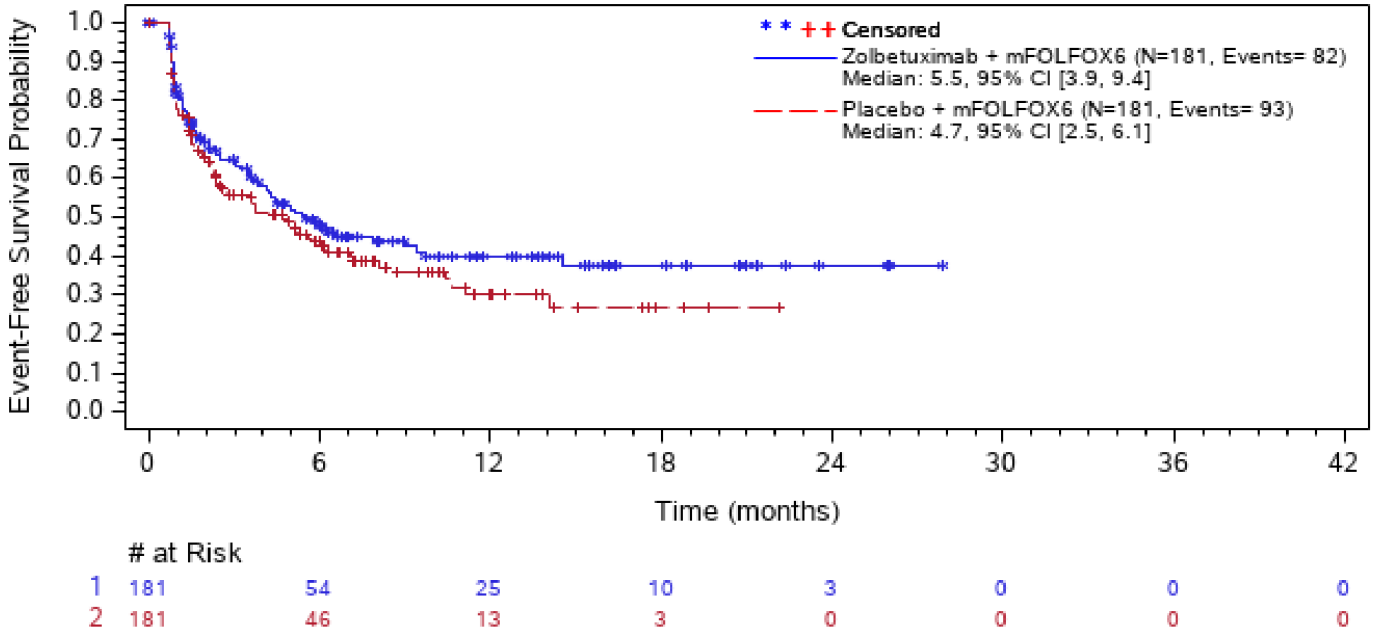
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.18.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea by Age Group 1 (MID=10) - Full 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; MID=minimally important difference; 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.

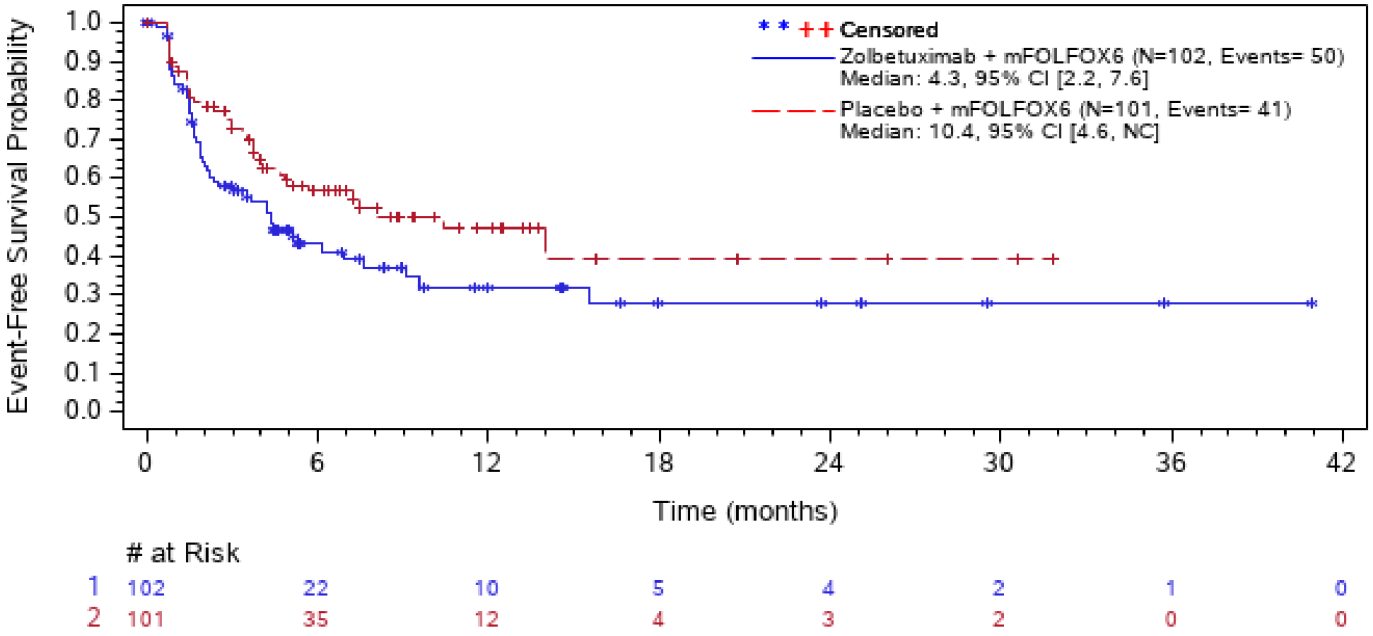
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.18.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea by Age Group 1 (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

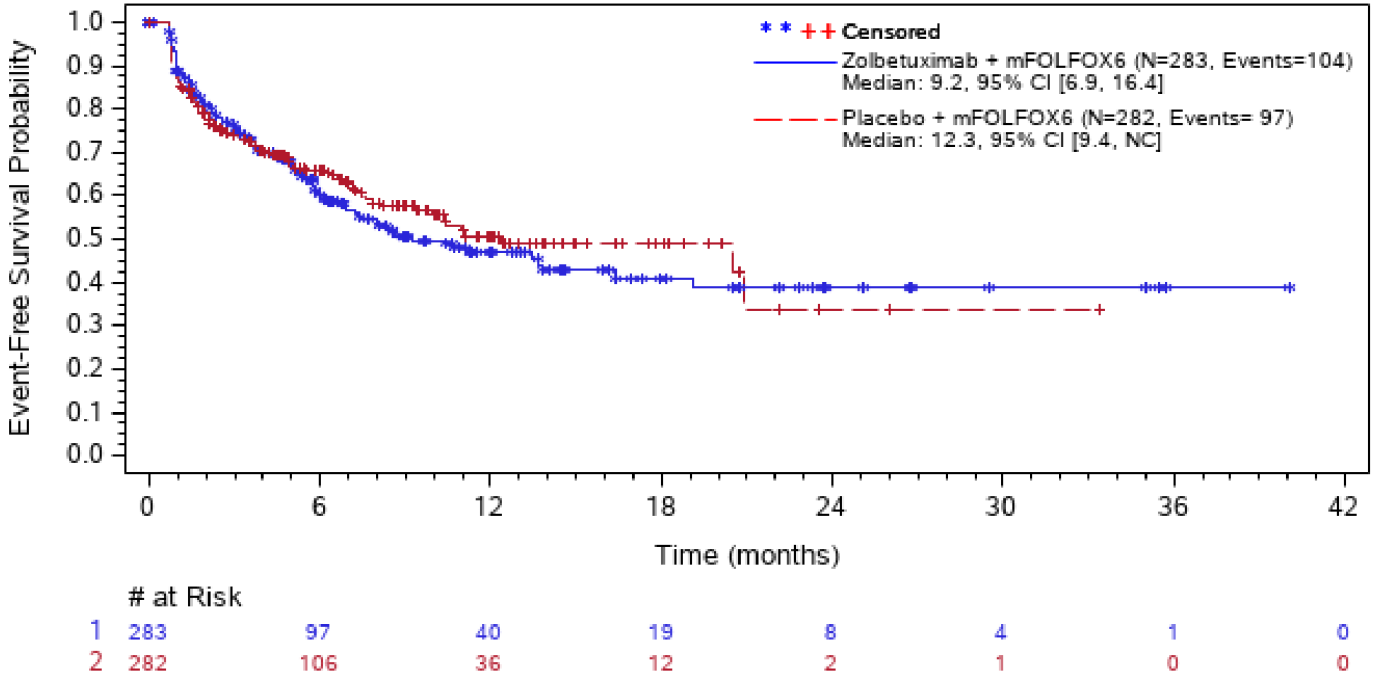
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.19: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Financial Difficulties (MID=10) - Full 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; MID=minimally important difference; 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.

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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

1. Rücklaufquoten

Table 301.1.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	256/278 (92.1%)	256/280 (91.4%)	256/282 (90.8%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/263 (81.0%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/250 (64.4%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/241 (52.7%)	127/283 (44.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	119/139 (85.6%)	121/244 (49.6%)	121/282 (42.9%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	31/ 45 (68.9%)	31/229 (13.5%)	31/283 (11.0%)	20/ 30 (66.7%)	20/235 (8.5%)	20/282 (7.1%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	10/ 16 (62.5%)	10/227 (4.4%)	10/283 (3.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	136/223 (61.0%)	137/270 (50.7%)	137/283 (48.4%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	70/160 (43.8%)	70/209 (33.5%)	71/282 (25.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	64/279 (22.9%)	64/282 (22.7%)	64/283 (22.6%)	66/278 (23.7%)	66/280 (23.6%)	66/282 (23.4%)
Cycle 1 Day 22	60/257 (23.3%)	61/273 (22.3%)	61/283 (21.6%)	85/266 (32.0%)	85/271 (31.4%)	85/282 (30.1%)
Cycle 2 Day 1	96/244 (39.3%)	96/263 (36.5%)	98/283 (34.6%)	106/263 (40.3%)	107/270 (39.6%)	107/282 (37.9%)
Cycle 2 Day 22	84/222 (37.8%)	84/257 (32.7%)	84/283 (29.7%)	89/243 (36.6%)	89/264 (33.7%)	89/282 (31.6%)
Cycle 3 Day 1	104/215 (48.4%)	104/254 (40.9%)	106/283 (37.5%)	99/228 (43.4%)	99/259 (38.2%)	99/282 (35.1%)
Cycle 3 Day 22	96/204 (47.1%)	96/250 (38.4%)	96/283 (33.9%)	80/219 (36.5%)	80/257 (31.1%)	80/282 (28.4%)
Cycle 4 Day 1	95/192 (49.5%)	97/244 (39.8%)	99/283 (35.0%)	87/202 (43.1%)	87/254 (34.3%)	87/282 (30.9%)
Cycle 4 Day 22	81/179 (45.3%)	81/241 (33.6%)	81/283 (28.6%)	67/184 (36.4%)	67/251 (26.7%)	67/282 (23.8%)
Cycle 5 Day 1	86/171 (50.3%)	88/239 (36.8%)	89/283 (31.4%)	80/170 (47.1%)	80/251 (31.9%)	80/282 (28.4%)
Cycle 5 Day 22	62/151 (41.1%)	62/236 (26.3%)	62/283 (21.9%)	57/150 (38.0%)	58/248 (23.4%)	58/282 (20.6%)
Cycle 6 Day 1	71/135 (52.6%)	73/236 (30.9%)	73/283 (25.8%)	57/139 (41.0%)	58/244 (23.8%)	58/282 (20.6%)
Cycle 6 Day 22	54/125 (43.2%)	54/234 (23.1%)	54/283 (19.1%)	43/120 (35.8%)	43/242 (17.8%)	43/282 (15.2%)
Cycle 7 Day 1	55/118 (46.6%)	56/234 (23.9%)	56/283 (19.8%)	43/103 (41.7%)	43/240 (17.9%)	43/282 (15.2%)
Cycle 7 Day 22	43/105 (41.0%)	43/232 (18.5%)	43/283 (15.2%)	28/ 93 (30.1%)	28/239 (11.7%)	28/282 (9.9%)
Cycle 8 Day 1	47/ 96 (49.0%)	47/231 (20.3%)	47/283 (16.6%)	32/ 85 (37.6%)	32/239 (13.4%)	32/282 (11.3%)
Cycle 8 Day 22	33/ 86 (38.4%)	34/231 (14.7%)	34/283 (12.0%)	24/ 75 (32.0%)	24/237 (10.1%)	24/282 (8.5%)
Cycle 9 Day 1	34/ 82 (41.5%)	34/229 (14.8%)	34/283 (12.0%)	22/ 63 (34.9%)	22/237 (9.3%)	22/282 (7.8%)
Cycle 9 Day 22	26/ 69 (37.7%)	26/229 (11.4%)	26/283 (9.2%)	21/ 58 (36.2%)	21/237 (8.9%)	21/282 (7.4%)
Cycle 10 Day 1	27/ 63 (42.9%)	28/229 (12.2%)	28/283 (9.9%)	17/ 49 (34.7%)	18/237 (7.6%)	18/282 (6.4%)
Cycle 10 Day 22	21/ 59 (35.6%)	21/229 (9.2%)	21/283 (7.4%)	12/ 43 (27.9%)	12/237 (5.1%)	12/282 (4.3%)
Cycle 11 Day 1	23/ 56 (41.1%)	23/229 (10.0%)	23/283 (8.1%)	13/ 40 (32.5%)	13/237 (5.5%)	13/282 (4.6%)
Cycle 11 Day 22	16/ 51 (31.4%)	17/229 (7.4%)	17/283 (6.0%)	7/ 35 (20.0%)	7/236 (3.0%)	7/282 (2.5%)
Cycle 12 Day 1	19/ 48 (39.6%)	19/229 (8.3%)	19/283 (6.7%)	10/ 34 (29.4%)	10/236 (4.2%)	10/282 (3.5%)
Cycle 12 Day 22	16/ 45 (35.6%)	16/229 (7.0%)	16/283 (5.7%)	9/ 30 (30.0%)	9/235 (3.8%)	9/282 (3.2%)
Cycle 13 Day 1	21/ 43 (48.8%)	21/229 (9.2%)	21/283 (7.4%)	6/ 27 (22.2%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 13 Day 22	17/ 37 (45.9%)	17/228 (7.5%)	18/283 (6.4%)	5/ 26 (19.2%)	5/235 (2.1%)	5/282 (1.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	17/ 32 (53.1%)	17/228 (7.5%)	17/283 (6.0%)	8/ 25 (32.0%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 14 Day 22	12/ 30 (40.0%)	12/228 (5.3%)	12/283 (4.2%)	5/ 22 (22.7%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 15 Day 1	13/ 29 (44.8%)	13/228 (5.7%)	13/283 (4.6%)	5/ 20 (25.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 15 Day 22	10/ 29 (34.5%)	10/228 (4.4%)	10/283 (3.5%)	4/ 15 (26.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 16 Day 1	12/ 26 (46.2%)	12/228 (5.3%)	12/283 (4.2%)	5/ 13 (38.5%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 16 Day 22	8/ 23 (34.8%)	8/228 (3.5%)	8/283 (2.8%)	3/ 11 (27.3%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 17 Day 1	8/ 20 (40.0%)	8/227 (3.5%)	8/283 (2.8%)	3/ 10 (30.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 17 Day 22	7/ 18 (38.9%)	7/227 (3.1%)	7/283 (2.5%)	1/ 8 (12.5%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 18 Day 1	7/ 17 (41.2%)	7/227 (3.1%)	7/283 (2.5%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 18 Day 22	4/ 16 (25.0%)	4/227 (1.8%)	4/283 (1.4%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	5/ 15 (33.3%)	5/227 (2.2%)	5/283 (1.8%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 22	6/ 15 (40.0%)	6/227 (2.6%)	6/283 (2.1%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	5/ 14 (35.7%)	5/227 (2.2%)	5/283 (1.8%)	3/ 7 (42.9%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 20 Day 22	4/ 13 (30.8%)	4/227 (1.8%)	4/283 (1.4%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	4/ 12 (33.3%)	4/227 (1.8%)	4/283 (1.4%)	3/ 6 (50.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 21 Day 22	2/ 11 (18.2%)	2/227 (0.9%)	2/283 (0.7%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	2/ 10 (20.0%)	2/227 (0.9%)	2/283 (0.7%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 22	0/ 9 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	1/ 9 (11.1%)	1/227 (0.4%)	1/283 (0.4%)	3/ 4 (75.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 22	0/ 7 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	1/ 7 (14.3%)	1/227 (0.4%)	1/283 (0.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 22	0/ 6 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	1/ 5 (20.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 22	0/ 5 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	0/ 5 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	0/ 4 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 27 Day 22	0/ 4 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	0/ 3 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 22	0/ 3 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	0/ 2 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 22	0/ 2 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	0/ 2 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 22	0/ 2 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	0/ 2 (0.0%)	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Study Disc	60/223 (26.9%)	60/270 (22.2%)	60/283 (21.2%)	61/222 (27.5%)	61/264 (23.1%)	61/282 (21.6%)
30 D SFU Z/P	29/203 (14.3%)	30/251 (12.0%)	30/283 (10.6%)	34/199 (17.1%)	34/241 (14.1%)	34/282 (12.1%)
90 D SFU Z/P	50/179 (27.9%)	50/230 (21.7%)	50/283 (17.7%)	40/160 (25.0%)	40/209 (19.1%)	40/282 (14.2%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.

[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.

ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

Table 301.1.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	18.50	24.39	0.0	11.11	100.0						
Cycle 1 Day 22	186	20.07	22.59	0.0	11.11	100.0	176	2.90	21.18	-66.7	0.00	66.7
Cycle 2 Day 1	216	13.12	18.06	0.0	11.11	100.0	206	-3.83	23.11	-77.8	0.00	88.9
Cycle 2 Day 22	157	13.52	19.50	0.0	11.11	100.0	150	-4.00	22.34	-88.9	0.00	66.7
Cycle 3 Day 1	200	8.89	15.07	0.0	0.00	100.0	190	-8.30	23.64	-100.0	0.00	88.9
Cycle 3 Day 22	161	13.32	16.89	0.0	11.11	77.8	152	-4.02	23.60	-88.9	0.00	55.6
Cycle 4 Day 1	177	10.55	15.36	0.0	0.00	77.8	169	-6.64	23.49	-88.9	0.00	55.6
Cycle 4 Day 22	127	12.42	16.89	0.0	0.00	77.8	122	-2.82	22.11	-88.9	0.00	66.7
Cycle 5 Day 1	155	10.47	16.86	0.0	0.00	100.0	147	-6.42	22.67	-88.9	0.00	66.7
Cycle 5 Day 22	113	10.62	17.34	0.0	0.00	100.0	106	-5.24	21.91	-100.0	0.00	55.6
Cycle 6 Day 1	124	9.59	16.78	0.0	0.00	88.9	115	-4.25	19.67	-88.9	0.00	44.4
Cycle 6 Day 22	102	11.00	17.72	0.0	0.00	100.0	97	-4.47	20.14	-88.9	0.00	33.3
Cycle 7 Day 1	110	8.08	17.22	0.0	0.00	100.0	104	-5.77	19.15	-66.7	0.00	66.7
Cycle 7 Day 22	80	8.33	14.63	0.0	0.00	55.6	74	-4.65	19.38	-66.7	0.00	44.4
Cycle 8 Day 1	81	8.23	17.19	0.0	0.00	77.8	74	-3.30	18.37	-55.6	0.00	55.6
Cycle 8 Day 22	70	7.46	13.60	0.0	0.00	55.6	65	-6.15	17.68	-55.6	0.00	44.4
Cycle 9 Day 1	72	7.87	15.09	0.0	0.00	77.8	66	-5.72	17.02	-55.6	0.00	33.3
Cycle 9 Day 22	54	6.58	12.50	0.0	0.00	66.7	50	-5.78	18.41	-55.6	0.00	33.3
Cycle 10 Day 1	58	7.09	14.07	0.0	0.00	66.7	53	-2.94	17.45	-55.6	0.00	33.3
Cycle 10 Day 22	47	3.31	6.92	0.0	0.00	33.3	44	-7.07	15.91	-55.6	0.00	11.1
Cycle 11 Day 1	50	5.56	12.55	0.0	0.00	66.7	46	-3.86	18.77	-55.6	0.00	55.6
Cycle 11 Day 22	35	7.62	14.70	0.0	0.00	66.7	32	-4.86	18.06	-55.6	0.00	33.3
Cycle 12 Day 1	43	5.94	10.67	0.0	0.00	33.3	39	-3.99	16.02	-44.4	0.00	33.3
Cycle 12 Day 22	31	6.09	11.77	0.0	0.00	55.6	29	-3.83	16.34	-55.6	0.00	44.4
Cycle 13 Day 1	37	4.50	8.05	0.0	0.00	33.3	34	-4.25	11.61	-44.4	0.00	11.1

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	5.39	10.80	0.0	0.00	33.3	30	-3.70	12.49	-44.4	0.00	22.2
Cycle 14 Day 1	31	5.02	10.67	0.0	0.00	33.3	30	-4.81	12.95	-44.4	0.00	22.2
Cycle 14 Day 22	24	5.56	10.87	0.0	0.00	33.3	24	-4.63	14.62	-44.4	0.00	22.2
Cycle 15 Day 1	26	7.26	12.55	0.0	0.00	33.3	26	-1.28	12.70	-33.3	0.00	33.3
Cycle 15 Day 22	21	4.23	10.23	0.0	0.00	33.3	21	-5.29	15.56	-55.6	0.00	33.3
Cycle 16 Day 1	25	6.22	11.60	0.0	0.00	33.3	25	-3.56	16.27	-44.4	0.00	33.3
Cycle 16 Day 22	19	8.77	14.14	0.0	0.00	33.3	19	-3.51	18.54	-44.4	0.00	33.3
Cycle 17 Day 1	19	7.02	11.24	0.0	0.00	33.3	19	-4.09	18.60	-55.6	0.00	33.3
Cycle 17 Day 22	14	9.52	16.22	0.0	0.00	44.4	14	-3.97	21.62	-44.4	0.00	33.3
Cycle 18 Day 1	16	4.86	9.91	0.0	0.00	33.3	16	-6.94	19.40	-55.6	0.00	33.3
Cycle 18 Day 22	10	1.11	3.51	0.0	0.00	11.1	10	-4.44	9.37	-22.2	0.00	11.1
Cycle 19 Day 1	13	2.56	6.66	0.0	0.00	22.2	13	-2.56	10.30	-22.2	0.00	22.2
Cycle 19 Day 22	11	5.05	9.11	0.0	0.00	22.2	11	-1.01	9.24	-11.1	0.00	22.2
Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-0.85	11.53	-11.1	0.00	33.3
Cycle 21 Day 1	11	2.02	4.49	0.0	0.00	11.1	11	-1.01	7.78	-11.1	0.00	11.1
Study Disc 1	132	22.22	29.80	0.0	11.11	100.0	125	3.56	26.08	-100.0	0.00	100.0
30 D SFU Z/P	69	18.52	25.33	0.0	11.11	100.0	64	1.22	21.24	-55.6	0.00	66.7
90 D SFU Z/P	83	15.66	21.04	0.0	0.00	88.9	80	-2.22	26.31	-66.7	0.00	88.9
Placebo + mFOLFOX6 (N=282)												
Baseline	257	20.02	26.71	0.0	11.11	100.0						
Cycle 1 Day 22	211	17.69	23.79	0.0	11.11	100.0	208	-1.66	22.31	-77.8	0.00	100.0
Cycle 2 Day 1	230	12.27	20.58	0.0	0.00	100.0	223	-7.92	25.87	-100.0	0.00	88.9
Cycle 2 Day 22	185	10.51	17.67	0.0	0.00	100.0	180	-8.46	23.70	-100.0	0.00	77.8
Cycle 3 Day 1	203	9.85	19.12	0.0	0.00	100.0	196	-8.45	24.83	-100.0	0.00	77.8
Cycle 3 Day 22	156	9.90	16.72	0.0	0.00	88.9	148	-9.16	26.55	-100.0	0.00	77.8
Cycle 4 Day 1	170	8.56	16.75	0.0	0.00	100.0	161	-8.70	23.49	-100.0	0.00	77.8

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	10.27	18.04	0.0	0.00	100.0	126	-7.32	24.83	-100.0	0.00	77.8
Cycle 5 Day 1	147	8.54	16.35	0.0	0.00	100.0	142	-8.14	24.75	-100.0	0.00	44.4
Cycle 5 Day 22	119	7.94	15.86	0.0	0.00	77.8	112	-7.74	23.00	-100.0	0.00	66.7
Cycle 6 Day 1	121	8.17	16.96	0.0	0.00	100.0	116	-6.23	20.21	-88.9	0.00	66.7
Cycle 6 Day 22	92	5.68	12.92	0.0	0.00	66.7	88	-8.21	21.47	-88.9	0.00	44.4
Cycle 7 Day 1	91	4.40	10.72	0.0	0.00	66.7	88	-7.20	20.22	-88.9	0.00	66.7
Cycle 7 Day 22	66	3.54	9.38	0.0	0.00	44.4	64	-8.68	21.09	-88.9	0.00	33.3
Cycle 8 Day 1	71	3.44	9.31	0.0	0.00	44.4	70	-6.83	15.97	-88.9	0.00	11.1
Cycle 8 Day 22	56	4.17	11.32	0.0	0.00	66.7	54	-7.20	20.83	-88.9	0.00	66.7
Cycle 9 Day 1	53	3.77	8.70	0.0	0.00	33.3	51	-8.06	19.64	-88.9	0.00	33.3
Cycle 9 Day 22	46	4.35	10.07	0.0	0.00	44.4	44	-5.81	19.98	-88.9	0.00	33.3
Cycle 10 Day 1	47	3.07	7.93	0.0	0.00	33.3	45	-6.91	19.58	-88.9	0.00	22.2
Cycle 10 Day 22	35	4.44	10.15	0.0	0.00	33.3	34	-5.56	20.70	-88.9	0.00	33.3
Cycle 11 Day 1	37	5.41	18.07	0.0	0.00	100.0	35	-3.49	22.67	-88.9	0.00	55.6
Cycle 11 Day 22	22	2.53	6.80	0.0	0.00	22.2	20	-2.22	12.28	-44.4	0.00	22.2
Cycle 12 Day 1	32	2.43	6.76	0.0	0.00	22.2	30	-6.67	19.49	-88.9	0.00	22.2
Cycle 12 Day 22	20	2.78	6.11	0.0	0.00	22.2	18	-7.41	13.74	-44.4	0.00	11.1
Cycle 13 Day 1	25	2.67	7.37	0.0	0.00	33.3	24	-8.33	19.45	-77.8	0.00	22.2
Cycle 13 Day 22	15	3.70	8.04	0.0	0.00	22.2	14	-12.70	26.46	-88.9	-5.56	22.2
Cycle 14 Day 1	23	4.35	11.48	0.0	0.00	44.4	22	-7.58	22.32	-88.9	0.00	33.3
Cycle 14 Day 22	13	5.98	13.31	0.0	0.00	44.4	12	-7.41	14.47	-44.4	0.00	11.1
Cycle 15 Day 1	19	4.68	10.02	0.0	0.00	33.3	19	-4.09	13.46	-44.4	0.00	22.2
Cycle 16 Day 1	11	3.03	7.19	0.0	0.00	22.2	11	-1.01	7.78	-11.1	0.00	11.1
Cycle 17 Day 1	10	5.56	10.80	0.0	0.00	33.3	10	1.11	11.05	-11.1	0.00	22.2
Study Disc 1	137	20.19	29.28	0.0	0.00	100.0	133	-2.76	30.44	-100.0	0.00	100.0
Study Disc 2	10	21.11	23.10	0.0	16.67	66.7	9	2.47	25.32	-55.6	0.00	22.2

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	16.74	24.03	0.0	11.11	100.0	78	-6.70	28.22	-100.0	0.00	66.7
90 D SFU Z/P	71	14.87	22.53	0.0	0.00	100.0	69	-6.12	34.96	-100.0	0.00	88.9

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	19.93	25.11	0.0	11.11	100.0						
	Cycle 1 Day 22	124	18.82	22.77	0.0	11.11	100.0	116	0.67	19.95	-66.7	0.00	55.6
	Cycle 2 Day 1	137	12.00	17.78	0.0	0.00	100.0	129	-7.24	21.18	-77.8	0.00	55.6
	Cycle 2 Day 22	103	13.81	21.47	0.0	0.00	100.0	97	-6.76	23.10	-88.9	0.00	44.4
	Cycle 3 Day 1	125	8.89	14.80	0.0	0.00	88.9	117	-9.50	21.85	-100.0	0.00	44.4
	Cycle 3 Day 22	97	14.20	18.48	0.0	11.11	77.8	90	-4.32	23.24	-88.9	0.00	44.4
	Cycle 4 Day 1	112	10.62	15.31	0.0	0.00	77.8	104	-8.01	23.76	-88.9	0.00	44.4
	Cycle 4 Day 22	83	13.92	18.19	0.0	0.00	77.8	78	-3.56	23.04	-88.9	0.00	44.4
	Cycle 5 Day 1	101	11.66	18.42	0.0	0.00	100.0	94	-6.03	22.62	-88.9	0.00	66.7
	Cycle 5 Day 22	70	12.22	19.49	0.0	0.00	100.0	64	-4.51	20.92	-55.6	0.00	55.6
	Cycle 6 Day 1	75	9.48	16.61	0.0	0.00	88.9	67	-6.47	21.11	-88.9	0.00	33.3
	Cycle 6 Day 22	64	11.81	18.87	0.0	0.00	100.0	60	-5.74	21.70	-88.9	0.00	33.3
	Cycle 7 Day 1	69	8.53	19.26	0.0	0.00	100.0	63	-7.05	20.58	-66.7	0.00	66.7
	Cycle 7 Day 22	53	8.60	14.56	0.0	0.00	55.6	47	-5.91	21.34	-66.7	0.00	44.4
	Cycle 8 Day 1	54	8.44	17.53	0.0	0.00	77.8	47	-4.96	20.30	-55.6	0.00	55.6
	Cycle 8 Day 22	44	7.58	14.73	0.0	0.00	55.6	39	-8.26	19.53	-55.6	0.00	44.4
	Cycle 9 Day 1	45	10.12	17.38	0.0	0.00	77.8	39	-5.98	19.55	-55.6	0.00	33.3
	Cycle 9 Day 22	32	6.94	13.75	0.0	0.00	66.7	28	-7.54	19.61	-55.6	0.00	33.3
	Cycle 10 Day 1	36	7.72	15.45	0.0	0.00	66.7	31	-3.94	18.71	-55.6	0.00	33.3
	Cycle 10 Day 22	30	4.44	8.04	0.0	0.00	33.3	27	-7.00	16.64	-55.6	0.00	11.1
	Cycle 11 Day 1	33	7.07	14.11	0.0	0.00	66.7	29	-3.45	20.81	-55.6	0.00	55.6
	Cycle 11 Day 22	23	9.18	16.63	0.0	0.00	66.7	20	-6.67	18.87	-55.6	0.00	33.3
	Cycle 12 Day 1	26	5.98	10.53	0.0	0.00	33.3	22	-7.58	15.86	-44.4	0.00	33.3
	Cycle 12 Day 22	18	7.41	14.76	0.0	0.00	55.6	16	-4.86	19.44	-55.6	0.00	44.4
	Cycle 13 Day 1	21	5.82	9.70	0.0	0.00	33.3	18	-5.56	12.78	-44.4	0.00	11.1

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	20	5.56	11.68	0.0	0.00	33.3	17	-5.23	13.10	-44.4	0.00	22.2
	Cycle 14 Day 1	16	6.94	12.75	0.0	0.00	33.3	15	-7.41	14.34	-44.4	-11.11	22.2
	Cycle 14 Day 22	15	5.93	12.51	0.0	0.00	33.3	15	-8.89	15.83	-44.4	-11.11	22.2
	Cycle 15 Day 1	14	5.56	12.13	0.0	0.00	33.3	14	-7.94	10.15	-33.3	-5.56	0.0
	Cycle 15 Day 22	14	3.97	9.35	0.0	0.00	33.3	14	-9.52	15.01	-55.6	-5.56	0.0
	Cycle 16 Day 1	13	3.42	8.35	0.0	0.00	22.2	13	-11.97	13.95	-44.4	-11.11	0.0
	Cycle 16 Day 22	13	4.27	10.68	0.0	0.00	33.3	13	-11.11	14.34	-44.4	-11.11	0.0
	Cycle 17 Day 1	12	2.78	5.03	0.0	0.00	11.1	12	-12.04	16.72	-55.6	-11.11	11.1
	Cycle 18 Day 1	10	1.11	3.51	0.0	0.00	11.1	10	-15.56	17.53	-55.6	-11.11	0.0
	Study Disc 1	86	24.42	32.60	0.0	11.11	100.0	79	5.77	27.27	-55.6	0.00	100.0
	30 D SFU Z/P	44	19.70	27.41	0.0	11.11	100.0	40	0.56	20.74	-55.6	0.00	33.3
	90 D SFU Z/P	49	13.15	20.87	0.0	0.00	88.9	47	-6.38	28.26	-66.7	0.00	88.9
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	21.10	28.24	0.0	11.11	100.0						
	Cycle 1 Day 22	138	19.48	24.93	0.0	11.11	100.0	135	-0.33	23.59	-66.7	0.00	100.0
	Cycle 2 Day 1	151	13.69	21.79	0.0	0.00	100.0	144	-7.18	26.82	-88.9	0.00	88.9
	Cycle 2 Day 22	128	11.98	19.15	0.0	0.00	100.0	123	-7.14	22.59	-100.0	0.00	33.3
	Cycle 3 Day 1	130	9.40	17.19	0.0	0.00	77.8	124	-8.60	25.61	-100.0	0.00	77.8
	Cycle 3 Day 22	105	11.85	19.14	0.0	0.00	88.9	99	-7.30	27.82	-100.0	0.00	77.8
	Cycle 4 Day 1	109	8.97	16.94	0.0	0.00	77.8	101	-8.36	25.01	-88.9	0.00	77.8
	Cycle 4 Day 22	87	12.01	18.58	0.0	0.00	88.9	82	-5.01	24.82	-100.0	0.00	77.8
	Cycle 5 Day 1	93	9.56	17.69	0.0	0.00	100.0	89	-8.24	25.92	-100.0	0.00	44.4
	Cycle 5 Day 22	83	9.37	17.91	0.0	0.00	77.8	77	-5.92	23.05	-88.9	0.00	66.7
	Cycle 6 Day 1	73	10.05	19.35	0.0	0.00	100.0	69	-5.48	23.69	-88.9	0.00	66.7
	Cycle 6 Day 22	60	8.33	15.26	0.0	0.00	66.7	57	-8.19	24.71	-88.9	0.00	44.4
	Cycle 7 Day 1	58	5.75	12.53	0.0	0.00	66.7	55	-7.47	23.82	-88.9	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	40	5.00	11.24	0.0	0.00	44.4	38	-8.48	25.10	-88.9	0.00	33.3
	Cycle 8 Day 1	44	4.55	11.06	0.0	0.00	44.4	43	-7.49	18.58	-88.9	0.00	11.1
	Cycle 8 Day 22	34	5.88	14.01	0.0	0.00	66.7	32	-8.33	24.93	-88.9	0.00	66.7
	Cycle 9 Day 1	33	5.39	10.44	0.0	0.00	33.3	31	-8.60	23.08	-88.9	0.00	33.3
	Cycle 9 Day 22	28	5.16	11.10	0.0	0.00	44.4	26	-5.98	23.36	-88.9	0.00	33.3
	Cycle 10 Day 1	26	2.99	7.41	0.0	0.00	33.3	24	-8.80	24.51	-88.9	0.00	22.2
	Cycle 10 Day 22	21	5.29	10.90	0.0	0.00	33.3	20	-7.78	25.26	-88.9	0.00	33.3
	Cycle 11 Day 1	22	8.08	22.79	0.0	0.00	100.0	20	-4.44	29.81	-88.9	0.00	55.6
	Cycle 11 Day 22	13	2.56	6.66	0.0	0.00	22.2	11	-4.04	14.29	-44.4	0.00	11.1
	Cycle 12 Day 1	17	2.61	7.38	0.0	0.00	22.2	15	-8.89	26.63	-88.9	0.00	22.2
	Cycle 12 Day 22	11	3.03	7.19	0.0	0.00	22.2	9	-8.64	15.49	-44.4	0.00	0.0
	Cycle 13 Day 1	14	3.97	9.35	0.0	0.00	33.3	13	-9.40	25.19	-77.8	0.00	22.2
	Cycle 14 Day 1	11	5.05	10.38	0.0	0.00	33.3	10	-11.11	33.13	-88.9	0.00	33.3
	Study Disc 1	83	23.29	31.74	0.0	11.11	100.0	81	0.69	31.93	-100.0	0.00	100.0
	30 D SFU Z/P	57	19.69	26.81	0.0	11.11	100.0	55	-4.65	30.74	-100.0	0.00	66.7
	90 D SFU Z/P	50	15.33	22.66	0.0	11.11	100.0	48	-7.18	36.78	-100.0	0.00	88.9

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	16.15	23.08	0.0	0.00	100.0						
	Cycle 1 Day 22	62	22.58	22.22	0.0	16.67	100.0	60	7.22	22.95	-55.6	5.56	66.7
	Cycle 2 Day 1	79	15.05	18.49	0.0	11.11	88.9	77	1.88	25.13	-55.6	0.00	88.9
	Cycle 2 Day 22	54	12.96	15.22	0.0	11.11	66.7	53	1.05	20.12	-55.6	0.00	66.7
	Cycle 3 Day 1	75	8.89	15.61	0.0	0.00	100.0	73	-6.39	26.31	-100.0	0.00	88.9
	Cycle 3 Day 22	64	11.98	14.18	0.0	11.11	55.6	62	-3.58	24.29	-77.8	0.00	55.6
	Cycle 4 Day 1	65	10.43	15.58	0.0	0.00	66.7	65	-4.44	23.06	-66.7	0.00	55.6
	Cycle 4 Day 22	44	9.60	13.89	0.0	5.56	66.7	44	-1.52	20.56	-66.7	0.00	66.7
	Cycle 5 Day 1	54	8.23	13.34	0.0	0.00	66.7	53	-7.13	22.97	-66.7	0.00	66.7
	Cycle 5 Day 22	43	8.01	12.90	0.0	0.00	44.4	42	-6.35	23.56	-100.0	0.00	33.3
	Cycle 6 Day 1	49	9.75	17.22	0.0	0.00	66.7	48	-1.16	17.19	-33.3	0.00	44.4
	Cycle 6 Day 22	38	9.65	15.75	0.0	0.00	55.6	37	-2.40	17.40	-33.3	0.00	33.3
	Cycle 7 Day 1	41	7.32	13.29	0.0	0.00	44.4	41	-3.79	16.78	-33.3	0.00	44.4
	Cycle 7 Day 22	27	7.82	15.04	0.0	0.00	44.4	27	-2.47	15.51	-33.3	0.00	44.4
	Cycle 8 Day 1	27	7.82	16.83	0.0	0.00	66.7	27	-0.41	14.28	-33.3	0.00	33.3
	Cycle 8 Day 22	26	7.26	11.73	0.0	0.00	33.3	26	-2.99	14.25	-33.3	0.00	33.3
	Cycle 9 Day 1	27	4.12	9.32	0.0	0.00	33.3	27	-5.35	12.84	-44.4	0.00	11.1
	Cycle 9 Day 22	22	6.06	10.69	0.0	0.00	33.3	22	-3.54	16.93	-44.4	0.00	33.3
	Cycle 10 Day 1	22	6.06	11.74	0.0	0.00	33.3	22	-1.52	15.82	-33.3	0.00	33.3
	Cycle 10 Day 22	17	1.31	3.69	0.0	0.00	11.1	17	-7.19	15.18	-44.4	0.00	11.1
	Cycle 11 Day 1	17	2.61	8.36	0.0	0.00	33.3	17	-4.58	15.24	-33.3	0.00	33.3
	Cycle 11 Day 22	12	4.63	10.00	0.0	0.00	33.3	12	-1.85	16.97	-33.3	0.00	33.3
	Cycle 12 Day 1	17	5.88	11.19	0.0	0.00	33.3	17	0.65	15.45	-33.3	0.00	33.3
	Cycle 12 Day 22	13	4.27	5.63	0.0	0.00	11.1	13	-2.56	12.13	-33.3	0.00	11.1
	Cycle 13 Day 1	16	2.78	4.97	0.0	0.00	11.1	16	-2.78	10.34	-33.3	0.00	11.1

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	13	5.13	9.75	0.0	0.00	33.3	13	-1.71	11.87	-33.3	0.00	11.1
	Cycle 14 Day 1	15	2.96	7.82	0.0	0.00	22.2	15	-2.22	11.27	-33.3	0.00	22.2
	Cycle 15 Day 1	12	9.26	13.26	0.0	0.00	33.3	12	6.48	11.07	0.0	0.00	33.3
	Cycle 16 Day 1	12	9.26	14.08	0.0	0.00	33.3	12	5.56	13.81	-11.1	0.00	33.3
	Study Disc 1	46	18.12	23.47	0.0	11.11	100.0	46	-0.24	23.71	-100.0	0.00	44.4
	30 D SFU Z/P	25	16.44	21.55	0.0	11.11	66.7	24	2.31	22.46	-33.3	0.00	66.7
	90 D SFU Z/P	34	19.28	21.07	0.0	11.11	77.8	33	3.70	22.34	-55.6	0.00	44.4
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	18.25	24.05	0.0	11.11	100.0						
	Cycle 1 Day 22	73	14.31	21.23	0.0	11.11	100.0	73	-4.11	19.64	-77.8	0.00	33.3
	Cycle 2 Day 1	79	9.56	17.86	0.0	0.00	100.0	79	-9.28	24.16	-100.0	0.00	55.6
	Cycle 2 Day 22	57	7.21	13.36	0.0	0.00	77.8	57	-11.31	25.93	-100.0	-11.11	77.8
	Cycle 3 Day 1	73	10.65	22.26	0.0	0.00	100.0	72	-8.18	23.59	-100.0	0.00	66.7
	Cycle 3 Day 22	51	5.88	8.99	0.0	0.00	33.3	49	-12.93	23.61	-100.0	0.00	11.1
	Cycle 4 Day 1	61	7.83	16.52	0.0	0.00	100.0	60	-9.26	20.88	-100.0	0.00	22.2
	Cycle 4 Day 22	45	6.91	16.63	0.0	0.00	100.0	44	-11.62	24.55	-100.0	0.00	22.2
	Cycle 5 Day 1	54	6.79	13.72	0.0	0.00	66.7	53	-7.97	22.89	-100.0	0.00	44.4
	Cycle 5 Day 22	36	4.63	8.96	0.0	0.00	44.4	35	-11.75	22.70	-100.0	0.00	11.1
	Cycle 6 Day 1	48	5.32	12.13	0.0	0.00	66.7	47	-7.33	13.76	-66.7	0.00	11.1
	Cycle 6 Day 22	32	0.69	2.73	0.0	0.00	11.1	31	-8.24	14.05	-44.4	0.00	11.1
	Cycle 7 Day 1	33	2.02	5.86	0.0	0.00	22.2	33	-6.73	12.40	-44.4	0.00	11.1
	Cycle 7 Day 22	26	1.28	4.79	0.0	0.00	22.2	26	-8.97	13.71	-44.4	0.00	0.0
	Cycle 8 Day 1	27	1.65	5.07	0.0	0.00	22.2	27	-5.76	10.84	-44.4	0.00	11.1
	Cycle 8 Day 22	22	1.52	3.90	0.0	0.00	11.1	22	-5.56	13.17	-44.4	0.00	11.1
	Cycle 9 Day 1	20	1.11	3.42	0.0	0.00	11.1	20	-7.22	13.13	-44.4	0.00	11.1
	Cycle 9 Day 22	18	3.09	8.35	0.0	0.00	33.3	18	-5.56	14.39	-44.4	0.00	22.2

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	21	3.17	8.71	0.0	0.00	33.3	21	-4.76	11.95	-44.4	0.00	11.1
	Cycle 10 Day 22	14	3.17	9.17	0.0	0.00	33.3	14	-2.38	11.68	-33.3	0.00	22.2
	Cycle 11 Day 1	15	1.48	5.74	0.0	0.00	22.2	15	-2.22	6.23	-11.1	0.00	11.1
	Cycle 12 Day 1	15	2.22	6.23	0.0	0.00	22.2	15	-4.44	8.19	-22.2	0.00	11.1
	Cycle 13 Day 1	11	1.01	3.35	0.0	0.00	11.1	11	-7.07	10.27	-33.3	0.00	0.0
	Cycle 14 Day 1	12	3.70	12.83	0.0	0.00	44.4	12	-4.63	5.72	-11.1	0.00	0.0
	Cycle 15 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	5.74	-11.1	-11.11	0.0
	Study Disc 1	54	15.43	24.55	0.0	0.00	100.0	52	-8.12	27.40	-100.0	0.00	55.6
	30 D SFU Z/P	24	9.72	13.63	0.0	0.00	33.3	23	-11.59	20.78	-77.8	-11.11	22.2
	90 D SFU Z/P	21	13.76	22.75	0.0	0.00	66.7	21	-3.70	31.10	-77.8	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	30.54	29.05	0.0	25.00	100.0						
Cycle 1 Day 22	186	32.08	25.79	0.0	33.33	100.0	176	4.40	22.82	-66.7	0.00	100.0
Cycle 2 Day 1	216	24.96	25.09	0.0	16.67	100.0	206	-3.32	27.60	-91.7	0.00	75.0
Cycle 2 Day 22	157	24.42	22.77	0.0	16.67	100.0	150	-5.00	26.41	-83.3	0.00	75.0
Cycle 3 Day 1	200	20.17	21.31	0.0	16.67	100.0	190	-8.77	27.65	-100.0	-4.17	66.7
Cycle 3 Day 22	161	29.04	25.26	0.0	25.00	100.0	152	-0.38	27.39	-83.3	0.00	100.0
Cycle 4 Day 1	177	23.12	22.55	0.0	16.67	100.0	169	-6.41	29.50	-91.7	0.00	75.0
Cycle 4 Day 22	127	25.00	23.22	0.0	25.00	91.7	122	-1.09	28.26	-83.3	0.00	66.7
Cycle 5 Day 1	155	23.44	22.73	0.0	16.67	100.0	147	-4.54	27.64	-91.7	0.00	66.7
Cycle 5 Day 22	113	21.76	22.42	0.0	16.67	100.0	106	-3.85	29.68	-100.0	0.00	75.0
Cycle 6 Day 1	124	18.68	21.34	0.0	16.67	100.0	115	-5.94	25.21	-100.0	0.00	50.0
Cycle 6 Day 22	102	18.38	19.60	0.0	16.67	100.0	97	-7.65	26.83	-83.3	0.00	66.7
Cycle 7 Day 1	110	16.44	21.37	0.0	8.33	100.0	104	-8.49	26.43	-83.3	-8.33	66.7
Cycle 7 Day 22	80	16.87	19.80	0.0	8.33	83.3	74	-7.66	26.49	-83.3	-4.17	66.7
Cycle 8 Day 1	81	15.84	23.00	0.0	8.33	100.0	74	-7.77	21.91	-75.0	-8.33	75.0
Cycle 8 Day 22	70	15.71	19.64	0.0	8.33	83.3	65	-9.62	22.93	-75.0	-8.33	50.0
Cycle 9 Day 1	72	15.28	20.46	0.0	8.33	91.7	66	-9.97	22.61	-75.0	-8.33	58.3
Cycle 9 Day 22	54	17.44	20.49	0.0	8.33	83.3	50	-6.33	26.38	-66.7	-8.33	75.0
Cycle 10 Day 1	58	15.66	20.24	0.0	8.33	83.3	53	-6.60	25.55	-66.7	-8.33	50.0
Cycle 10 Day 22	47	15.78	19.13	0.0	8.33	91.7	44	-6.63	25.01	-66.7	0.00	41.7
Cycle 11 Day 1	50	11.67	16.41	0.0	8.33	66.7	46	-9.60	24.15	-66.7	-8.33	58.3
Cycle 11 Day 22	35	15.00	21.08	0.0	8.33	83.3	32	-8.33	24.87	-66.7	-4.17	50.0
Cycle 12 Day 1	43	14.15	17.11	0.0	8.33	83.3	39	-8.97	19.90	-58.3	-8.33	41.7
Cycle 12 Day 22	31	16.40	18.69	0.0	8.33	58.3	29	-3.16	20.46	-50.0	0.00	50.0
Cycle 13 Day 1	37	12.84	18.07	0.0	0.00	83.3	34	-7.35	18.66	-58.3	-8.33	41.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	13.13	17.43	0.0	0.00	50.0	30	-5.56	19.12	-58.3	0.00	33.3
Cycle 14 Day 1	31	14.25	21.86	0.0	8.33	91.7	30	-7.50	22.14	-58.3	0.00	58.3
Cycle 14 Day 22	24	13.89	17.83	0.0	8.33	58.3	24	-6.25	24.11	-66.7	-4.17	50.0
Cycle 15 Day 1	26	15.71	18.31	0.0	8.33	58.3	26	-0.64	21.20	-33.3	0.00	50.0
Cycle 15 Day 22	21	14.68	18.43	0.0	8.33	58.3	21	-2.78	19.06	-41.7	0.00	41.7
Cycle 16 Day 1	25	11.00	14.38	0.0	0.00	33.3	25	-9.67	17.46	-66.7	0.00	16.7
Cycle 16 Day 22	19	20.61	30.35	0.0	0.00	100.0	19	-2.19	31.28	-66.7	0.00	83.3
Cycle 17 Day 1	19	12.28	17.65	0.0	0.00	66.7	19	-8.77	17.45	-41.7	-8.33	33.3
Cycle 17 Day 22	14	17.26	20.01	0.0	12.50	66.7	14	-4.76	18.98	-50.0	0.00	33.3
Cycle 18 Day 1	16	14.58	14.43	0.0	16.67	33.3	16	-7.29	17.97	-41.7	-4.17	33.3
Cycle 18 Day 22	10	10.00	13.49	0.0	0.00	33.3	10	-5.00	19.33	-41.7	0.00	33.3
Cycle 19 Day 1	13	9.62	15.90	0.0	0.00	50.0	13	-7.05	15.90	-41.7	0.00	16.7
Cycle 19 Day 22	11	13.64	16.36	0.0	0.00	41.7	11	-3.03	20.50	-41.7	0.00	41.7
Cycle 20 Day 1	13	16.03	26.23	0.0	0.00	75.0	13	1.28	26.97	-41.7	0.00	66.7
Cycle 21 Day 1	11	16.67	24.15	0.0	0.00	75.0	11	3.79	18.01	-25.0	0.00	41.7
Study Disc 1	132	35.04	31.45	0.0	25.00	100.0	125	3.07	31.01	-91.7	0.00	91.7
30 D SFU Z/P	69	34.06	26.73	0.0	33.33	100.0	64	4.04	24.84	-58.3	0.00	58.3
90 D SFU Z/P	83	24.00	23.48	0.0	16.67	100.0	80	-5.42	31.77	-83.3	0.00	91.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	33.01	30.26	0.0	25.00	100.0						
Cycle 1 Day 22	211	30.45	25.37	0.0	33.33	100.0	208	-1.32	23.11	-66.7	0.00	83.3
Cycle 2 Day 1	230	22.17	22.57	0.0	16.67	100.0	223	-9.94	29.44	-100.0	-8.33	91.7
Cycle 2 Day 22	185	22.61	23.89	0.0	16.67	100.0	180	-7.92	30.90	-100.0	0.00	91.7
Cycle 3 Day 1	203	17.69	19.46	0.0	16.67	100.0	196	-13.52	28.28	-100.0	-8.33	50.0
Cycle 3 Day 22	156	19.98	22.89	0.0	16.67	100.0	148	-10.98	29.80	-100.0	-8.33	66.7
Cycle 4 Day 1	170	17.75	20.34	0.0	8.33	100.0	161	-13.15	28.12	-100.0	-8.33	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	20.64	21.36	0.0	16.67	100.0	126	-11.04	28.88	-100.0	-4.17	58.3
Cycle 5 Day 1	147	17.18	19.68	0.0	8.33	100.0	142	-13.26	30.06	-100.0	-8.33	50.0
Cycle 5 Day 22	119	18.70	19.62	0.0	16.67	83.3	112	-11.24	28.64	-100.0	-8.33	58.3
Cycle 6 Day 1	121	17.84	21.95	0.0	8.33	100.0	116	-10.27	27.87	-100.0	0.00	50.0
Cycle 6 Day 22	92	14.04	16.10	0.0	8.33	66.7	88	-15.34	27.39	-100.0	-8.33	41.7
Cycle 7 Day 1	91	12.27	17.41	0.0	8.33	100.0	88	-12.69	24.66	-100.0	-8.33	50.0
Cycle 7 Day 22	66	10.48	16.30	0.0	4.17	100.0	64	-13.93	26.40	-100.0	-8.33	33.3
Cycle 8 Day 1	71	10.68	14.92	0.0	8.33	66.7	70	-11.07	24.27	-100.0	0.00	25.0
Cycle 8 Day 22	56	11.90	14.81	0.0	8.33	58.3	54	-11.57	27.54	-100.0	-4.17	58.3
Cycle 9 Day 1	53	11.64	15.70	0.0	8.33	58.3	51	-13.89	26.12	-100.0	-8.33	58.3
Cycle 9 Day 22	46	12.14	15.88	0.0	8.33	58.3	44	-10.61	26.37	-100.0	0.00	50.0
Cycle 10 Day 1	47	9.75	12.92	0.0	0.00	41.7	45	-11.85	26.38	-100.0	0.00	33.3
Cycle 10 Day 22	35	12.86	18.34	0.0	8.33	66.7	34	-8.09	30.25	-100.0	0.00	66.7
Cycle 11 Day 1	37	9.68	16.49	0.0	0.00	75.0	35	-11.19	27.19	-100.0	0.00	41.7
Cycle 11 Day 22	22	8.71	14.20	0.0	0.00	50.0	20	-8.33	23.57	-66.7	0.00	41.7
Cycle 12 Day 1	32	9.11	12.59	0.0	0.00	50.0	30	-11.39	25.47	-91.7	0.00	25.0
Cycle 12 Day 22	20	13.33	14.91	0.0	8.33	41.7	18	-11.11	23.40	-66.7	0.00	33.3
Cycle 13 Day 1	25	10.67	11.67	0.0	8.33	33.3	24	-12.15	28.02	-91.7	-4.17	33.3
Cycle 13 Day 22	15	15.00	16.73	0.0	8.33	50.0	14	-12.50	34.86	-100.0	-4.17	50.0
Cycle 14 Day 1	23	15.58	19.35	0.0	8.33	58.3	22	-9.47	31.42	-100.0	-8.33	33.3
Cycle 14 Day 22	13	20.51	20.02	0.0	16.67	58.3	12	-4.17	18.63	-33.3	0.00	25.0
Cycle 15 Day 1	19	16.23	17.89	0.0	8.33	66.7	19	-2.19	25.59	-58.3	0.00	41.7
Cycle 16 Day 1	11	15.15	14.82	0.0	16.67	41.7	11	0.76	23.11	-33.3	0.00	41.7
Cycle 17 Day 1	10	12.50	12.58	0.0	12.50	33.3	10	-4.17	20.88	-33.3	-8.33	25.0
Study Disc 1	137	31.45	31.38	0.0	25.00	100.0	133	-3.32	34.37	-100.0	0.00	100.0
Study Disc 2	10	28.33	31.23	0.0	20.83	100.0	9	4.63	29.79	-41.7	8.33	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	26.44	26.35	0.0	25.00	100.0	78	-7.16	33.03	-100.0	0.00	91.7
90 D SFU Z/P	71	26.29	27.30	0.0	16.67	100.0	69	-6.28	36.31	-100.0	0.00	91.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	17.64	24.43	0.0	0.00	100.0						
Cycle 1 Day 22	186	16.13	22.59	0.0	0.00	100.0	176	-1.70	21.61	-100.0	0.00	50.0
Cycle 2 Day 1	216	12.81	21.34	0.0	0.00	100.0	206	-2.99	24.32	-100.0	0.00	100.0
Cycle 2 Day 22	157	10.83	18.95	0.0	0.00	100.0	150	-4.56	23.00	-100.0	0.00	83.3
Cycle 3 Day 1	200	10.25	17.89	0.0	0.00	100.0	190	-5.61	23.71	-100.0	0.00	66.7
Cycle 3 Day 22	161	11.59	18.17	0.0	0.00	83.3	152	-4.39	21.16	-100.0	0.00	50.0
Cycle 4 Day 1	177	9.60	17.55	0.0	0.00	100.0	169	-5.52	22.18	-100.0	0.00	66.7
Cycle 4 Day 22	127	11.15	18.43	0.0	0.00	100.0	122	-2.46	21.18	-100.0	0.00	66.7
Cycle 5 Day 1	155	10.32	17.54	0.0	0.00	100.0	147	-4.54	21.94	-100.0	0.00	66.7
Cycle 5 Day 22	113	12.39	19.77	0.0	0.00	100.0	106	-2.83	20.89	-50.0	0.00	66.7
Cycle 6 Day 1	124	9.01	16.92	0.0	0.00	83.3	115	-4.64	22.79	-100.0	0.00	50.0
Cycle 6 Day 22	102	10.78	17.34	0.0	0.00	100.0	97	-3.26	19.34	-66.7	0.00	66.7
Cycle 7 Day 1	110	9.24	15.74	0.0	0.00	66.7	104	-3.69	19.42	-66.7	0.00	66.7
Cycle 7 Day 22	80	8.33	14.28	0.0	0.00	50.0	74	-4.50	21.06	-100.0	0.00	50.0
Cycle 8 Day 1	81	9.26	17.08	0.0	0.00	100.0	74	-4.73	20.92	-100.0	0.00	33.3
Cycle 8 Day 22	70	10.95	16.76	0.0	0.00	83.3	65	-5.90	22.13	-100.0	0.00	33.3
Cycle 9 Day 1	72	11.34	21.64	0.0	0.00	100.0	66	-5.05	21.28	-66.7	0.00	50.0
Cycle 9 Day 22	54	12.35	20.27	0.0	0.00	83.3	50	-2.00	15.30	-33.3	0.00	33.3
Cycle 10 Day 1	58	9.48	20.74	0.0	0.00	100.0	53	-5.03	23.02	-66.7	0.00	100.0
Cycle 10 Day 22	47	5.32	16.71	0.0	0.00	100.0	44	-6.44	15.34	-50.0	0.00	33.3
Cycle 11 Day 1	50	6.33	16.46	0.0	0.00	100.0	46	-6.16	19.99	-66.7	0.00	33.3
Cycle 11 Day 22	35	6.67	19.47	0.0	0.00	100.0	32	-5.73	16.18	-33.3	0.00	33.3
Cycle 12 Day 1	43	8.14	18.32	0.0	0.00	100.0	39	-3.42	19.19	-66.7	0.00	33.3
Cycle 12 Day 22	31	6.45	11.92	0.0	0.00	33.3	29	-4.60	21.77	-66.7	0.00	33.3
Cycle 13 Day 1	37	7.21	17.80	0.0	0.00	100.0	34	-4.41	20.64	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	6.06	14.32	0.0	0.00	50.0	30	-5.00	20.13	-66.7	0.00	33.3
Cycle 14 Day 1	31	11.83	22.02	0.0	0.00	100.0	30	-1.11	24.73	-66.7	0.00	33.3
Cycle 14 Day 22	24	5.56	12.69	0.0	0.00	50.0	24	-7.64	23.56	-66.7	0.00	33.3
Cycle 15 Day 1	26	7.05	12.63	0.0	0.00	33.3	26	-0.64	15.97	-33.3	0.00	33.3
Cycle 15 Day 22	21	7.14	11.27	0.0	0.00	33.3	21	-4.76	22.45	-66.7	0.00	16.7
Cycle 16 Day 1	25	6.00	11.67	0.0	0.00	33.3	25	-6.00	18.56	-50.0	0.00	33.3
Cycle 16 Day 22	19	4.39	10.89	0.0	0.00	33.3	19	-6.14	21.67	-50.0	0.00	33.3
Cycle 17 Day 1	19	7.89	12.87	0.0	0.00	33.3	19	-2.63	18.64	-50.0	0.00	33.3
Cycle 17 Day 22	14	9.52	14.19	0.0	0.00	33.3	14	0.00	17.30	-33.3	0.00	33.3
Cycle 18 Day 1	16	5.21	11.74	0.0	0.00	33.3	16	-4.17	19.72	-50.0	0.00	33.3
Cycle 18 Day 22	10	5.00	11.25	0.0	0.00	33.3	10	-1.67	18.34	-50.0	0.00	16.7
Cycle 19 Day 1	13	1.28	4.62	0.0	0.00	16.7	13	-3.85	13.87	-50.0	0.00	0.0
Cycle 19 Day 22	11	4.55	10.78	0.0	0.00	33.3	11	-1.52	17.41	-50.0	0.00	16.7
Cycle 20 Day 1	13	5.13	10.51	0.0	0.00	33.3	13	0.00	16.67	-50.0	0.00	16.7
Cycle 21 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	1.52	5.03	0.0	0.00	16.7
Study Disc 1	132	18.06	26.05	0.0	0.00	100.0	125	1.73	23.46	-50.0	0.00	100.0
30 D SFU Z/P	69	18.60	25.65	0.0	0.00	100.0	64	0.52	25.54	-83.3	0.00	66.7
90 D SFU Z/P	83	16.06	23.78	0.0	0.00	100.0	80	0.21	24.66	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	16.60	24.00	0.0	0.00	100.0						
Cycle 1 Day 22	211	14.69	21.33	0.0	0.00	100.0	208	-1.28	21.70	-100.0	0.00	66.7
Cycle 2 Day 1	230	10.87	19.02	0.0	0.00	100.0	223	-5.31	26.20	-100.0	0.00	100.0
Cycle 2 Day 22	185	11.35	19.59	0.0	0.00	100.0	180	-5.00	23.43	-100.0	0.00	66.7
Cycle 3 Day 1	203	9.52	16.74	0.0	0.00	66.7	196	-6.46	23.10	-100.0	0.00	66.7
Cycle 3 Day 22	156	8.97	15.07	0.0	0.00	83.3	148	-5.86	21.19	-100.0	0.00	50.0
Cycle 4 Day 1	170	9.51	16.70	0.0	0.00	100.0	161	-5.28	20.95	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	7.83	15.05	0.0	0.00	83.3	126	-5.69	20.57	-66.7	0.00	50.0
Cycle 5 Day 1	147	10.54	17.89	0.0	0.00	83.3	142	-3.40	23.02	-100.0	0.00	66.7
Cycle 5 Day 22	119	10.08	18.31	0.0	0.00	83.3	112	-3.42	22.50	-66.7	0.00	83.3
Cycle 6 Day 1	121	10.47	18.40	0.0	0.00	83.3	116	-1.72	21.13	-66.7	0.00	66.7
Cycle 6 Day 22	92	8.88	17.20	0.0	0.00	83.3	88	-2.08	20.50	-66.7	0.00	83.3
Cycle 7 Day 1	91	9.71	17.23	0.0	0.00	66.7	88	1.89	18.30	-50.0	0.00	66.7
Cycle 7 Day 22	66	6.82	13.39	0.0	0.00	66.7	64	-1.04	16.50	-50.0	0.00	33.3
Cycle 8 Day 1	71	7.28	15.87	0.0	0.00	83.3	70	0.71	14.03	-33.3	0.00	50.0
Cycle 8 Day 22	56	8.04	15.57	0.0	0.00	66.7	54	2.16	18.04	-33.3	0.00	66.7
Cycle 9 Day 1	53	4.72	10.53	0.0	0.00	50.0	51	-0.98	15.42	-50.0	0.00	50.0
Cycle 9 Day 22	46	6.16	10.16	0.0	0.00	33.3	44	1.14	15.42	-50.0	0.00	33.3
Cycle 10 Day 1	47	4.26	12.27	0.0	0.00	66.7	45	-0.74	17.75	-50.0	0.00	66.7
Cycle 10 Day 22	35	9.05	15.83	0.0	0.00	66.7	34	5.39	19.98	-50.0	0.00	66.7
Cycle 11 Day 1	37	11.26	18.03	0.0	0.00	66.7	35	7.14	21.50	-50.0	0.00	66.7
Cycle 11 Day 22	22	14.39	20.76	0.0	0.00	83.3	20	9.17	22.60	-33.3	0.00	66.7
Cycle 12 Day 1	32	11.46	18.66	0.0	0.00	66.7	30	7.22	22.18	-33.3	0.00	66.7
Cycle 12 Day 22	20	12.50	16.99	0.0	0.00	50.0	18	4.63	21.24	-50.0	0.00	33.3
Cycle 13 Day 1	25	10.00	12.73	0.0	0.00	33.3	24	4.17	17.89	-50.0	0.00	33.3
Cycle 13 Day 22	15	6.67	12.28	0.0	0.00	33.3	14	4.76	13.76	-16.7	0.00	33.3
Cycle 14 Day 1	23	3.62	8.64	0.0	0.00	33.3	22	-0.76	15.83	-50.0	0.00	33.3
Cycle 14 Day 22	13	12.82	20.59	0.0	0.00	66.7	12	6.94	15.01	-16.7	0.00	33.3
Cycle 15 Day 1	19	9.65	18.69	0.0	0.00	66.7	19	4.39	23.47	-50.0	0.00	66.7
Cycle 16 Day 1	11	13.64	20.84	0.0	0.00	66.7	11	10.61	23.89	-16.7	0.00	66.7
Cycle 17 Day 1	10	8.33	16.20	0.0	0.00	50.0	10	5.00	17.66	-16.7	0.00	50.0
Study Disc 1	137	13.50	22.55	0.0	0.00	100.0	133	-3.76	27.49	-100.0	0.00	100.0
Study Disc 2	10	21.67	32.44	0.0	8.33	100.0	9	0.00	22.05	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	13.79	21.86	0.0	0.00	100.0	78	-3.85	27.51	-83.3	0.00	66.7
90 D SFU Z/P	71	13.85	20.70	0.0	0.00	83.3	69	-0.24	26.43	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	16.87	23.94	0.0	0.00	100.0						
	Cycle 1 Day 22	124	14.65	22.75	0.0	0.00	100.0	116	-1.87	19.13	-100.0	0.00	33.3
	Cycle 2 Day 1	137	11.56	19.65	0.0	0.00	100.0	129	-2.97	19.92	-83.3	0.00	83.3
	Cycle 2 Day 22	103	10.52	19.10	0.0	0.00	100.0	97	-3.26	20.92	-100.0	0.00	66.7
	Cycle 3 Day 1	125	10.53	18.15	0.0	0.00	100.0	117	-3.42	19.64	-66.7	0.00	33.3
	Cycle 3 Day 22	97	12.20	19.17	0.0	0.00	83.3	90	-1.11	15.36	-50.0	0.00	33.3
	Cycle 4 Day 1	112	9.23	17.59	0.0	0.00	100.0	104	-3.53	18.09	-50.0	0.00	66.7
	Cycle 4 Day 22	83	13.05	20.50	0.0	0.00	100.0	78	1.07	16.41	-33.3	0.00	66.7
	Cycle 5 Day 1	101	10.40	18.23	0.0	0.00	100.0	94	-3.72	19.88	-100.0	0.00	66.7
	Cycle 5 Day 22	70	13.33	21.91	0.0	0.00	100.0	64	-2.08	20.25	-50.0	0.00	66.7
	Cycle 6 Day 1	75	8.00	16.29	0.0	0.00	83.3	67	-4.98	20.52	-100.0	0.00	33.3
	Cycle 6 Day 22	64	8.59	14.24	0.0	0.00	66.7	60	-3.06	18.28	-50.0	0.00	66.7
	Cycle 7 Day 1	69	9.18	16.30	0.0	0.00	66.7	63	-3.17	17.67	-66.7	0.00	50.0
	Cycle 7 Day 22	53	7.55	14.46	0.0	0.00	50.0	47	-6.03	22.10	-100.0	0.00	50.0
	Cycle 8 Day 1	54	9.26	18.22	0.0	0.00	100.0	47	-6.03	21.54	-100.0	0.00	33.3
	Cycle 8 Day 22	44	12.12	18.46	0.0	0.00	83.3	39	-4.27	18.22	-50.0	0.00	33.3
	Cycle 9 Day 1	45	12.59	24.14	0.0	0.00	100.0	39	-3.85	20.75	-50.0	0.00	50.0
	Cycle 9 Day 22	32	13.54	20.49	0.0	0.00	66.7	28	-1.79	16.57	-33.3	0.00	33.3
	Cycle 10 Day 1	36	10.19	22.98	0.0	0.00	100.0	31	-4.30	25.45	-50.0	0.00	100.0
	Cycle 10 Day 22	30	6.11	19.32	0.0	0.00	100.0	27	-7.41	16.88	-50.0	0.00	33.3
	Cycle 11 Day 1	33	7.58	19.14	0.0	0.00	100.0	29	-6.32	19.11	-50.0	0.00	16.7
	Cycle 11 Day 22	23	7.25	22.93	0.0	0.00	100.0	20	-9.17	15.74	-33.3	0.00	16.7
	Cycle 12 Day 1	26	9.62	21.17	0.0	0.00	100.0	22	-3.79	16.21	-33.3	0.00	16.7
	Cycle 12 Day 22	18	6.48	12.96	0.0	0.00	33.3	16	-5.21	19.92	-50.0	0.00	33.3
	Cycle 13 Day 1	21	6.35	22.03	0.0	0.00	100.0	18	-7.41	18.28	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	20	6.67	16.58	0.0	0.00	50.0	17	-3.92	17.21	-50.0	0.00	33.3
	Cycle 14 Day 1	16	12.50	27.55	0.0	0.00	100.0	15	-4.44	24.77	-50.0	0.00	33.3
	Cycle 14 Day 22	15	6.67	15.17	0.0	0.00	50.0	15	-6.67	23.40	-50.0	0.00	33.3
	Cycle 15 Day 1	14	5.95	12.42	0.0	0.00	33.3	14	-2.38	17.12	-33.3	0.00	33.3
	Cycle 15 Day 22	14	7.14	10.77	0.0	0.00	33.3	14	-4.76	20.07	-50.0	0.00	16.7
	Cycle 16 Day 1	13	1.28	4.62	0.0	0.00	16.7	13	-12.82	18.20	-50.0	0.00	0.0
	Cycle 16 Day 22	13	1.28	4.62	0.0	0.00	16.7	13	-12.82	21.68	-50.0	0.00	16.7
	Cycle 17 Day 1	12	4.17	10.36	0.0	0.00	33.3	12	-8.33	18.12	-50.0	0.00	16.7
	Cycle 18 Day 1	10	1.67	5.27	0.0	0.00	16.7	10	-11.67	19.33	-50.0	0.00	0.0
	Study Disc 1	86	18.22	27.85	0.0	0.00	100.0	79	1.69	24.40	-50.0	0.00	100.0
	30 D SFU Z/P	44	17.42	25.15	0.0	16.67	100.0	40	-2.08	23.02	-83.3	0.00	66.7
	90 D SFU Z/P	49	11.90	20.41	0.0	0.00	100.0	47	-1.77	25.83	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	15.62	22.32	0.0	0.00	100.0						
	Cycle 1 Day 22	138	13.65	20.76	0.0	0.00	100.0	135	-0.86	18.13	-50.0	0.00	50.0
	Cycle 2 Day 1	151	9.27	17.28	0.0	0.00	100.0	144	-5.32	23.04	-100.0	0.00	83.3
	Cycle 2 Day 22	128	8.85	17.62	0.0	0.00	100.0	123	-6.50	19.63	-100.0	0.00	33.3
	Cycle 3 Day 1	130	7.82	15.42	0.0	0.00	66.7	124	-6.05	21.71	-100.0	0.00	66.7
	Cycle 3 Day 22	105	8.57	14.27	0.0	0.00	50.0	99	-6.57	21.54	-100.0	0.00	33.3
	Cycle 4 Day 1	109	8.72	15.15	0.0	0.00	83.3	101	-4.46	19.56	-66.7	0.00	50.0
	Cycle 4 Day 22	87	6.70	13.07	0.0	0.00	50.0	82	-5.28	17.74	-50.0	0.00	50.0
	Cycle 5 Day 1	93	9.14	14.85	0.0	0.00	66.7	89	-4.31	21.10	-100.0	0.00	33.3
	Cycle 5 Day 22	83	9.04	15.68	0.0	0.00	66.7	77	-3.68	20.34	-50.0	0.00	66.7
	Cycle 6 Day 1	73	10.27	18.14	0.0	0.00	83.3	69	-0.97	21.56	-66.7	0.00	66.7
	Cycle 6 Day 22	60	9.44	17.99	0.0	0.00	83.3	57	-1.17	22.24	-66.7	0.00	83.3
	Cycle 7 Day 1	58	10.06	15.90	0.0	0.00	66.7	55	3.64	17.18	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	40	5.00	10.81	0.0	0.00	33.3	38	-0.44	13.13	-33.3	0.00	33.3
	Cycle 8 Day 1	44	6.82	14.07	0.0	0.00	50.0	43	1.16	11.73	-16.7	0.00	50.0
	Cycle 8 Day 22	34	7.35	13.73	0.0	0.00	50.0	32	1.56	13.63	-33.3	0.00	33.3
	Cycle 9 Day 1	33	5.56	11.54	0.0	0.00	50.0	31	1.08	12.86	-16.7	0.00	50.0
	Cycle 9 Day 22	28	5.36	10.20	0.0	0.00	33.3	26	2.56	10.21	-16.7	0.00	33.3
	Cycle 10 Day 1	26	2.56	6.13	0.0	0.00	16.7	24	-0.69	9.17	-16.7	0.00	16.7
	Cycle 10 Day 22	21	7.14	11.27	0.0	0.00	33.3	20	4.17	13.11	-16.7	0.00	33.3
	Cycle 11 Day 1	22	9.85	14.23	0.0	0.00	33.3	20	6.67	16.58	-16.7	0.00	33.3
	Cycle 11 Day 22	13	10.26	14.50	0.0	0.00	33.3	11	6.06	21.44	-33.3	0.00	33.3
	Cycle 12 Day 1	17	10.78	16.61	0.0	0.00	50.0	15	7.78	21.70	-33.3	0.00	50.0
	Cycle 12 Day 22	11	12.12	18.40	0.0	0.00	50.0	9	3.70	18.22	-16.7	0.00	33.3
	Cycle 13 Day 1	14	13.10	13.36	0.0	16.67	33.3	13	7.69	16.12	-16.7	0.00	33.3
	Cycle 14 Day 1	11	4.55	7.78	0.0	0.00	16.7	10	1.67	12.30	-16.7	0.00	16.7
	Study Disc 1	83	16.27	25.23	0.0	0.00	100.0	81	0.21	29.28	-100.0	0.00	100.0
	30 D SFU Z/P	57	10.53	18.27	0.0	0.00	100.0	55	-5.45	23.36	-66.7	0.00	50.0
	90 D SFU Z/P	50	11.33	18.58	0.0	0.00	66.7	48	-2.43	23.32	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	18.90	25.30	0.0	16.67	100.0						
	Cycle 1 Day 22	62	19.09	22.15	0.0	16.67	100.0	60	-1.39	25.91	-83.3	0.00	50.0
	Cycle 2 Day 1	79	14.98	23.96	0.0	0.00	100.0	77	-3.03	30.44	-100.0	0.00	100.0
	Cycle 2 Day 22	54	11.42	18.83	0.0	0.00	83.3	53	-6.92	26.44	-66.7	0.00	83.3
	Cycle 3 Day 1	75	9.78	17.56	0.0	0.00	100.0	73	-9.13	28.87	-100.0	0.00	66.7
	Cycle 3 Day 22	64	10.68	16.63	0.0	0.00	83.3	62	-9.14	26.94	-100.0	0.00	50.0
	Cycle 4 Day 1	65	10.26	17.60	0.0	0.00	66.7	65	-8.72	27.34	-100.0	0.00	66.7
	Cycle 4 Day 22	44	7.58	13.18	0.0	0.00	50.0	44	-8.71	26.78	-100.0	0.00	33.3
	Cycle 5 Day 1	54	10.19	16.32	0.0	0.00	66.7	53	-5.97	25.34	-83.3	0.00	66.7
	Cycle 5 Day 22	43	10.85	15.80	0.0	0.00	66.7	42	-3.97	22.03	-50.0	0.00	33.3
	Cycle 6 Day 1	49	10.54	17.90	0.0	0.00	66.7	48	-4.17	25.84	-100.0	0.00	50.0
	Cycle 6 Day 22	38	14.47	21.28	0.0	0.00	100.0	37	-3.60	21.20	-66.7	0.00	33.3
	Cycle 7 Day 1	41	9.35	14.93	0.0	0.00	66.7	41	-4.47	22.06	-66.7	0.00	66.7
	Cycle 7 Day 22	27	9.88	14.07	0.0	0.00	33.3	27	-1.85	19.25	-33.3	0.00	33.3
	Cycle 8 Day 1	27	9.26	14.86	0.0	0.00	33.3	27	-2.47	19.99	-50.0	0.00	33.3
	Cycle 8 Day 22	26	8.97	13.52	0.0	0.00	33.3	26	-8.33	27.18	-100.0	0.00	33.3
	Cycle 9 Day 1	27	9.26	16.88	0.0	0.00	66.7	27	-6.79	22.29	-66.7	0.00	33.3
	Cycle 9 Day 22	22	10.61	20.28	0.0	0.00	83.3	22	-2.27	13.89	-33.3	0.00	33.3
	Cycle 10 Day 1	22	8.33	16.86	0.0	0.00	66.7	22	-6.06	19.62	-66.7	0.00	16.7
	Cycle 10 Day 22	17	3.92	11.07	0.0	0.00	33.3	17	-4.90	12.86	-33.3	0.00	16.7
	Cycle 11 Day 1	17	3.92	9.37	0.0	0.00	33.3	17	-5.88	22.00	-66.7	0.00	33.3
	Cycle 11 Day 22	12	5.56	10.86	0.0	0.00	33.3	12	0.00	15.89	-33.3	0.00	33.3
	Cycle 12 Day 1	17	5.88	13.10	0.0	0.00	33.3	17	-2.94	23.00	-66.7	0.00	33.3
	Cycle 12 Day 22	13	6.41	10.84	0.0	0.00	33.3	13	-3.85	24.68	-66.7	0.00	33.3
	Cycle 13 Day 1	16	8.33	10.54	0.0	0.00	33.3	16	-1.04	23.15	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	13	5.13	10.51	0.0	0.00	33.3	13	-6.41	24.09	-66.7	0.00	33.3
	Cycle 14 Day 1	15	11.11	15.00	0.0	0.00	33.3	15	2.22	25.09	-66.7	0.00	33.3
	Cycle 15 Day 1	12	8.33	13.30	0.0	0.00	33.3	12	1.39	15.01	-33.3	0.00	33.3
	Cycle 16 Day 1	12	11.11	14.79	0.0	0.00	33.3	12	1.39	16.60	-33.3	0.00	33.3
	Study Disc 1	46	17.75	22.61	0.0	0.00	66.7	46	1.81	22.01	-50.0	0.00	66.7
	30 D SFU Z/P	25	20.67	26.91	0.0	0.00	66.7	24	4.86	29.27	-66.7	0.00	50.0
	90 D SFU Z/P	34	22.06	27.13	0.0	16.67	100.0	33	3.03	22.99	-50.0	0.00	66.7
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	18.20	26.55	0.0	0.00	100.0						
	Cycle 1 Day 22	73	16.67	22.40	0.0	0.00	83.3	73	-2.05	27.21	-100.0	0.00	66.7
	Cycle 2 Day 1	79	13.92	21.75	0.0	0.00	100.0	79	-5.27	31.30	-100.0	0.00	100.0
	Cycle 2 Day 22	57	16.96	22.60	0.0	0.00	66.7	57	-1.75	29.99	-100.0	0.00	66.7
	Cycle 3 Day 1	73	12.56	18.59	0.0	0.00	66.7	72	-7.18	25.46	-100.0	0.00	50.0
	Cycle 3 Day 22	51	9.80	16.73	0.0	0.00	83.3	49	-4.42	20.63	-83.3	0.00	50.0
	Cycle 4 Day 1	61	10.93	19.22	0.0	0.00	100.0	60	-6.67	23.21	-83.3	0.00	50.0
	Cycle 4 Day 22	45	10.00	18.26	0.0	0.00	83.3	44	-6.44	25.22	-66.7	0.00	50.0
	Cycle 5 Day 1	54	12.96	22.12	0.0	0.00	83.3	53	-1.89	26.08	-66.7	0.00	66.7
	Cycle 5 Day 22	36	12.50	23.36	0.0	0.00	83.3	35	-2.86	26.96	-66.7	0.00	83.3
	Cycle 6 Day 1	48	10.76	18.98	0.0	0.00	66.7	47	-2.84	20.65	-50.0	0.00	66.7
	Cycle 6 Day 22	32	7.81	15.83	0.0	0.00	66.7	31	-3.76	17.06	-50.0	0.00	33.3
	Cycle 7 Day 1	33	9.09	19.58	0.0	0.00	66.7	33	-1.01	19.96	-50.0	0.00	50.0
	Cycle 7 Day 22	26	9.62	16.45	0.0	0.00	66.7	26	-1.92	20.72	-50.0	0.00	33.3
	Cycle 8 Day 1	27	8.02	18.70	0.0	0.00	83.3	27	0.00	17.30	-33.3	0.00	33.3
	Cycle 8 Day 22	22	9.09	18.35	0.0	0.00	66.7	22	3.03	23.37	-33.3	0.00	66.7
	Cycle 9 Day 1	20	3.33	8.72	0.0	0.00	33.3	20	-4.17	18.63	-50.0	0.00	33.3
	Cycle 9 Day 22	18	7.41	10.26	0.0	0.00	33.3	18	-0.93	20.98	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	21	6.35	17.06	0.0	0.00	66.7	21	-0.79	24.42	-50.0	0.00	66.7
	Cycle 10 Day 22	14	11.90	21.11	0.0	0.00	66.7	14	7.14	27.51	-50.0	0.00	66.7
	Cycle 11 Day 1	15	13.33	22.89	0.0	0.00	66.7	15	7.78	27.36	-50.0	0.00	66.7
	Cycle 12 Day 1	15	12.22	21.33	0.0	0.00	66.7	15	6.67	23.40	-33.3	0.00	66.7
	Cycle 13 Day 1	11	6.06	11.24	0.0	0.00	33.3	11	0.00	19.72	-50.0	0.00	33.3
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	18.58	-50.0	0.00	33.3
	Cycle 15 Day 1	10	8.33	21.15	0.0	0.00	66.7	10	1.67	28.81	-50.0	0.00	66.7
	Study Disc 1	54	9.26	17.03	0.0	0.00	66.7	52	-9.94	23.40	-83.3	0.00	33.3
	30 D SFU Z/P	24	21.53	27.57	0.0	8.33	83.3	23	0.00	35.89	-83.3	0.00	66.7
	90 D SFU Z/P	21	19.84	24.51	0.0	16.67	83.3	21	4.76	32.55	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	22.18	25.96	0.0	16.67	100.0						
Cycle 1 Day 22	186	18.19	21.49	0.0	16.67	100.0	176	-2.37	24.22	-100.0	0.00	83.3
Cycle 2 Day 1	216	15.51	20.96	0.0	16.67	100.0	206	-4.77	24.64	-83.3	0.00	66.7
Cycle 2 Day 22	157	14.54	19.95	0.0	0.00	100.0	150	-6.22	24.62	-66.7	0.00	66.7
Cycle 3 Day 1	200	10.92	16.25	0.0	0.00	100.0	190	-9.39	24.63	-100.0	0.00	83.3
Cycle 3 Day 22	161	14.29	18.43	0.0	0.00	66.7	152	-6.36	22.77	-100.0	0.00	50.0
Cycle 4 Day 1	177	10.83	17.33	0.0	0.00	100.0	169	-9.66	24.84	-83.3	0.00	50.0
Cycle 4 Day 22	127	14.04	18.71	0.0	0.00	100.0	122	-3.69	25.67	-100.0	0.00	66.7
Cycle 5 Day 1	155	13.87	19.72	0.0	0.00	100.0	147	-4.65	23.55	-100.0	0.00	66.7
Cycle 5 Day 22	113	13.27	20.79	0.0	0.00	100.0	106	-5.82	25.62	-83.3	0.00	83.3
Cycle 6 Day 1	124	10.89	17.66	0.0	0.00	100.0	115	-7.68	20.39	-83.3	0.00	50.0
Cycle 6 Day 22	102	9.97	14.70	0.0	0.00	66.7	97	-8.42	22.96	-83.3	0.00	33.3
Cycle 7 Day 1	110	8.94	15.42	0.0	0.00	66.7	104	-9.94	22.22	-83.3	0.00	33.3
Cycle 7 Day 22	80	10.83	16.79	0.0	0.00	66.7	74	-8.33	22.79	-83.3	0.00	33.3
Cycle 8 Day 1	81	11.32	17.84	0.0	0.00	83.3	74	-5.63	21.42	-66.7	0.00	50.0
Cycle 8 Day 22	70	10.48	16.59	0.0	0.00	66.7	65	-9.23	23.02	-83.3	0.00	50.0
Cycle 9 Day 1	72	10.19	17.14	0.0	0.00	66.7	66	-9.34	20.90	-66.7	0.00	50.0
Cycle 9 Day 22	54	10.49	15.96	0.0	0.00	66.7	50	-7.00	21.58	-66.7	0.00	33.3
Cycle 10 Day 1	58	9.48	16.26	0.0	0.00	66.7	53	-8.18	19.78	-66.7	0.00	50.0
Cycle 10 Day 22	47	8.87	15.09	0.0	0.00	66.7	44	-6.06	19.72	-66.7	0.00	50.0
Cycle 11 Day 1	50	7.67	15.87	0.0	0.00	66.7	46	-7.25	19.13	-50.0	0.00	50.0
Cycle 11 Day 22	35	9.05	16.34	0.0	0.00	66.7	32	-6.25	13.88	-50.0	0.00	16.7
Cycle 12 Day 1	43	9.30	17.93	0.0	0.00	66.7	39	-8.12	21.59	-66.7	0.00	50.0
Cycle 12 Day 22	31	10.22	15.91	0.0	0.00	66.7	29	-3.45	19.61	-33.3	0.00	50.0
Cycle 13 Day 1	37	8.56	18.68	0.0	0.00	83.3	34	-6.37	18.36	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	6.57	16.64	0.0	0.00	83.3	30	-6.11	20.75	-50.0	0.00	66.7
Cycle 14 Day 1	31	12.90	24.99	0.0	0.00	100.0	30	-1.67	26.02	-50.0	0.00	83.3
Cycle 14 Day 22	24	5.56	15.28	0.0	0.00	66.7	24	-5.56	16.05	-33.3	0.00	50.0
Cycle 15 Day 1	26	8.33	16.50	0.0	0.00	66.7	26	-2.56	16.79	-33.3	0.00	50.0
Cycle 15 Day 22	21	9.52	16.31	0.0	0.00	66.7	21	-1.59	16.59	-33.3	0.00	50.0
Cycle 16 Day 1	25	7.33	12.80	0.0	0.00	33.3	25	-4.67	14.04	-33.3	0.00	16.7
Cycle 16 Day 22	19	9.65	15.03	0.0	0.00	33.3	19	-4.39	14.53	-33.3	0.00	16.7
Cycle 17 Day 1	19	6.14	9.95	0.0	0.00	33.3	19	-7.02	13.96	-33.3	0.00	16.7
Cycle 17 Day 22	14	11.90	13.76	0.0	8.33	33.3	14	-2.38	8.91	-16.7	0.00	16.7
Cycle 18 Day 1	16	6.25	11.98	0.0	0.00	33.3	16	-8.33	16.10	-33.3	0.00	16.7
Cycle 18 Day 22	10	10.00	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	16.7
Cycle 19 Day 1	13	3.85	7.31	0.0	0.00	16.7	13	-7.69	14.62	-33.3	0.00	0.0
Cycle 19 Day 22	11	7.58	13.67	0.0	0.00	33.3	11	-4.55	15.08	-33.3	0.00	16.7
Cycle 20 Day 1	13	3.85	9.99	0.0	0.00	33.3	13	-5.13	14.25	-33.3	0.00	16.7
Cycle 21 Day 1	11	6.06	11.24	0.0	0.00	33.3	11	-1.52	5.03	-16.7	0.00	0.0
Study Disc 1	132	22.22	28.58	0.0	16.67	100.0	125	-1.47	26.69	-83.3	0.00	100.0
30 D SFU Z/P	69	22.22	27.22	0.0	16.67	100.0	64	-2.86	25.98	-50.0	0.00	100.0
90 D SFU Z/P	83	19.68	24.30	0.0	16.67	100.0	80	-5.42	28.29	-83.3	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	22.44	26.60	0.0	16.67	100.0						
Cycle 1 Day 22	211	15.80	21.10	0.0	16.67	100.0	208	-5.69	22.72	-83.3	0.00	66.7
Cycle 2 Day 1	230	12.32	19.84	0.0	0.00	100.0	223	-9.19	24.94	-100.0	0.00	83.3
Cycle 2 Day 22	185	12.61	20.41	0.0	0.00	100.0	180	-9.35	25.05	-100.0	0.00	83.3
Cycle 3 Day 1	203	9.93	17.59	0.0	0.00	100.0	196	-11.39	24.00	-100.0	0.00	50.0
Cycle 3 Day 22	156	8.97	16.65	0.0	0.00	100.0	148	-12.50	23.56	-100.0	0.00	33.3
Cycle 4 Day 1	170	8.63	16.34	0.0	0.00	100.0	161	-11.18	23.26	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	11.36	18.11	0.0	0.00	100.0	126	-9.26	22.37	-83.3	0.00	50.0
Cycle 5 Day 1	147	8.96	15.02	0.0	0.00	100.0	142	-11.15	23.21	-100.0	0.00	33.3
Cycle 5 Day 22	119	9.66	16.45	0.0	0.00	100.0	112	-11.01	24.05	-100.0	0.00	50.0
Cycle 6 Day 1	121	10.19	19.05	0.0	0.00	100.0	116	-8.19	21.25	-83.3	0.00	66.7
Cycle 6 Day 22	92	7.07	11.39	0.0	0.00	33.3	88	-12.88	21.84	-100.0	0.00	33.3
Cycle 7 Day 1	91	7.14	13.87	0.0	0.00	66.7	88	-8.33	20.53	-83.3	0.00	33.3
Cycle 7 Day 22	66	7.07	13.09	0.0	0.00	50.0	64	-8.07	19.92	-66.7	0.00	33.3
Cycle 8 Day 1	71	6.34	13.02	0.0	0.00	66.7	70	-7.62	17.42	-66.7	0.00	33.3
Cycle 8 Day 22	56	6.85	12.22	0.0	0.00	50.0	54	-9.57	20.37	-83.3	0.00	33.3
Cycle 9 Day 1	53	6.29	11.43	0.0	0.00	33.3	51	-10.13	21.36	-83.3	0.00	33.3
Cycle 9 Day 22	46	9.42	14.34	0.0	0.00	50.0	44	-4.17	20.05	-83.3	0.00	50.0
Cycle 10 Day 1	47	7.80	12.93	0.0	0.00	50.0	45	-5.93	18.17	-66.7	0.00	33.3
Cycle 10 Day 22	35	6.67	12.91	0.0	0.00	50.0	34	-7.35	17.97	-66.7	0.00	16.7
Cycle 11 Day 1	37	5.86	18.09	0.0	0.00	100.0	35	-6.19	16.21	-50.0	0.00	33.3
Cycle 11 Day 22	22	8.33	19.07	0.0	0.00	83.3	20	0.00	12.09	-16.7	0.00	33.3
Cycle 12 Day 1	32	6.77	15.18	0.0	0.00	66.7	30	-3.89	14.31	-33.3	0.00	33.3
Cycle 12 Day 22	20	10.00	16.58	0.0	0.00	66.7	18	-6.48	12.96	-33.3	0.00	16.7
Cycle 13 Day 1	25	5.33	11.51	0.0	0.00	33.3	24	-6.25	14.59	-33.3	0.00	16.7
Cycle 13 Day 22	15	8.89	18.76	0.0	0.00	66.7	14	-1.19	15.28	-33.3	0.00	33.3
Cycle 14 Day 1	23	9.42	16.53	0.0	0.00	66.7	22	-3.03	12.21	-33.3	0.00	16.7
Cycle 14 Day 22	13	11.54	24.89	0.0	0.00	66.7	12	-5.56	14.79	-33.3	0.00	16.7
Cycle 15 Day 1	19	9.65	20.27	0.0	0.00	66.7	19	0.00	15.71	-33.3	0.00	33.3
Cycle 16 Day 1	11	7.58	13.67	0.0	0.00	33.3	11	1.52	13.85	-16.7	0.00	33.3
Cycle 17 Day 1	10	5.00	11.25	0.0	0.00	33.3	10	-1.67	9.46	-16.7	0.00	16.7
Study Disc 1	137	21.41	29.36	0.0	0.00	100.0	133	-2.76	27.84	-83.3	0.00	100.0
Study Disc 2	10	18.33	32.82	0.0	0.00	100.0	9	3.70	29.79	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	19.14	24.88	0.0	16.67	100.0	78	-4.91	25.21	-66.7	0.00	50.0
90 D SFU Z/P	71	15.49	21.33	0.0	0.00	83.3	69	-4.83	29.72	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	27.04	26.61	0.0	33.33	100.0						
Cycle 1 Day 22	186	22.49	20.81	0.0	33.33	100.0	176	-4.55	21.78	-83.3	0.00	50.0
Cycle 2 Day 1	216	21.14	23.42	0.0	16.67	100.0	206	-4.94	26.72	-100.0	0.00	100.0
Cycle 2 Day 22	157	18.58	20.76	0.0	16.67	100.0	150	-8.00	25.01	-66.7	0.00	100.0
Cycle 3 Day 1	200	16.33	19.19	0.0	8.33	100.0	190	-9.56	24.26	-83.3	0.00	66.7
Cycle 3 Day 22	161	19.77	21.26	0.0	16.67	100.0	152	-6.14	23.93	-66.7	0.00	66.7
Cycle 4 Day 1	177	15.73	18.78	0.0	0.00	66.7	169	-9.76	24.30	-83.3	0.00	66.7
Cycle 4 Day 22	127	16.67	18.78	0.0	16.67	100.0	122	-6.56	21.70	-83.3	0.00	33.3
Cycle 5 Day 1	155	17.53	21.22	0.0	16.67	100.0	147	-5.33	22.91	-83.3	0.00	66.7
Cycle 5 Day 22	113	15.63	20.33	0.0	0.00	100.0	106	-8.18	26.45	-83.3	0.00	50.0
Cycle 6 Day 1	124	15.32	19.55	0.0	0.00	100.0	115	-7.97	24.42	-83.3	0.00	50.0
Cycle 6 Day 22	102	13.73	19.26	0.0	0.00	66.7	97	-9.79	26.87	-83.3	0.00	66.7
Cycle 7 Day 1	110	13.03	18.11	0.0	0.00	66.7	104	-9.13	23.56	-83.3	0.00	50.0
Cycle 7 Day 22	80	13.96	16.86	0.0	0.00	66.7	74	-9.91	22.06	-66.7	0.00	33.3
Cycle 8 Day 1	81	15.02	20.85	0.0	0.00	83.3	74	-6.08	24.92	-66.7	0.00	83.3
Cycle 8 Day 22	70	13.10	18.15	0.0	0.00	66.7	65	-11.54	23.92	-66.7	0.00	33.3
Cycle 9 Day 1	72	13.19	18.96	0.0	0.00	66.7	66	-11.87	22.03	-83.3	-8.33	33.3
Cycle 9 Day 22	54	14.20	18.14	0.0	0.00	66.7	50	-9.00	23.14	-83.3	0.00	33.3
Cycle 10 Day 1	58	11.49	16.58	0.0	0.00	66.7	53	-11.01	22.87	-83.3	0.00	33.3
Cycle 10 Day 22	47	10.64	16.82	0.0	0.00	66.7	44	-9.47	24.48	-83.3	0.00	66.7
Cycle 11 Day 1	50	8.67	15.15	0.0	0.00	66.7	46	-11.59	19.84	-66.7	-8.33	33.3
Cycle 11 Day 22	35	8.10	17.33	0.0	0.00	66.7	32	-11.46	20.05	-66.7	-16.67	33.3
Cycle 12 Day 1	43	11.24	18.08	0.0	0.00	66.7	39	-7.69	20.89	-66.7	0.00	33.3
Cycle 12 Day 22	31	12.37	15.50	0.0	0.00	33.3	29	-6.32	20.61	-66.7	0.00	33.3
Cycle 13 Day 1	37	11.26	16.22	0.0	0.00	66.7	34	-7.35	21.40	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	11.11	17.51	0.0	0.00	66.7	30	-6.67	23.41	-66.7	0.00	33.3
Cycle 14 Day 1	31	17.20	21.72	0.0	0.00	66.7	30	-1.67	24.51	-50.0	0.00	66.7
Cycle 14 Day 22	24	6.94	12.93	0.0	0.00	33.3	24	-11.11	19.45	-66.7	0.00	16.7
Cycle 15 Day 1	26	12.82	20.17	0.0	0.00	66.7	26	-1.92	26.80	-50.0	0.00	66.7
Cycle 15 Day 22	21	11.90	15.04	0.0	0.00	33.3	21	-6.35	25.54	-66.7	0.00	16.7
Cycle 16 Day 1	25	8.67	13.71	0.0	0.00	33.3	25	-9.33	26.39	-66.7	0.00	33.3
Cycle 16 Day 22	19	9.65	16.02	0.0	0.00	50.0	19	-11.40	23.60	-66.7	0.00	33.3
Cycle 17 Day 1	19	9.65	13.96	0.0	0.00	33.3	19	-8.77	24.45	-66.7	0.00	33.3
Cycle 17 Day 22	14	9.52	12.60	0.0	0.00	33.3	14	-8.33	24.24	-66.7	0.00	33.3
Cycle 18 Day 1	16	8.33	12.17	0.0	0.00	33.3	16	-12.50	24.72	-66.7	-8.33	33.3
Cycle 18 Day 22	10	6.67	11.65	0.0	0.00	33.3	10	-10.00	23.83	-66.7	0.00	16.7
Cycle 19 Day 1	13	2.56	6.26	0.0	0.00	16.7	13	-15.38	18.59	-66.7	-16.67	0.0
Cycle 19 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	16.7
Cycle 20 Day 1	13	5.13	10.51	0.0	0.00	33.3	13	-11.54	18.49	-50.0	0.00	16.7
Cycle 21 Day 1	11	7.58	20.23	0.0	0.00	66.7	11	-6.06	17.12	-33.3	0.00	33.3
Study Disc 1	132	26.26	27.79	0.0	33.33	100.0	125	-3.87	25.41	-83.3	0.00	66.7
30 D SFU Z/P	69	26.57	26.86	0.0	33.33	100.0	64	-5.73	29.13	-66.7	0.00	100.0
90 D SFU Z/P	83	24.70	25.02	0.0	16.67	100.0	80	-6.04	30.61	-66.7	0.00	83.3
Placebo + mFOLFOX6 (N=282)												
Baseline	257	26.39	27.45	0.0	16.67	100.0						
Cycle 1 Day 22	211	22.43	23.68	0.0	16.67	100.0	208	-3.45	23.17	-100.0	0.00	66.7
Cycle 2 Day 1	230	17.83	22.54	0.0	16.67	100.0	223	-8.37	28.25	-100.0	0.00	100.0
Cycle 2 Day 22	185	18.29	21.29	0.0	16.67	100.0	180	-8.89	26.04	-100.0	0.00	100.0
Cycle 3 Day 1	203	16.17	19.83	0.0	16.67	100.0	196	-8.50	23.48	-83.3	0.00	83.3
Cycle 3 Day 22	156	16.56	20.26	0.0	0.00	83.3	148	-8.67	24.86	-100.0	0.00	33.3
Cycle 4 Day 1	170	14.80	19.14	0.0	0.00	100.0	161	-8.70	23.13	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	14.39	19.29	0.0	0.00	83.3	126	-8.86	24.01	-100.0	0.00	66.7
Cycle 5 Day 1	147	13.83	19.74	0.0	0.00	83.3	142	-8.33	23.80	-100.0	0.00	50.0
Cycle 5 Day 22	119	14.85	21.68	0.0	0.00	100.0	112	-9.37	22.57	-100.0	0.00	33.3
Cycle 6 Day 1	121	15.84	24.04	0.0	0.00	100.0	116	-6.03	23.71	-83.3	0.00	66.7
Cycle 6 Day 22	92	10.33	16.55	0.0	0.00	66.7	88	-13.64	24.44	-100.0	0.00	33.3
Cycle 7 Day 1	91	9.89	16.10	0.0	0.00	66.7	88	-9.47	21.11	-100.0	0.00	33.3
Cycle 7 Day 22	66	8.59	17.84	0.0	0.00	100.0	64	-10.16	20.71	-100.0	0.00	33.3
Cycle 8 Day 1	71	9.86	19.64	0.0	0.00	100.0	70	-9.05	24.36	-100.0	0.00	33.3
Cycle 8 Day 22	56	8.63	13.85	0.0	0.00	33.3	54	-11.11	24.66	-100.0	0.00	33.3
Cycle 9 Day 1	53	10.69	17.63	0.0	0.00	66.7	51	-9.15	22.93	-100.0	0.00	33.3
Cycle 9 Day 22	46	11.23	20.50	0.0	0.00	100.0	44	-9.47	23.40	-83.3	0.00	33.3
Cycle 10 Day 1	47	8.51	15.10	0.0	0.00	66.7	45	-10.00	19.91	-66.7	0.00	33.3
Cycle 10 Day 22	35	11.43	17.97	0.0	0.00	66.7	34	-5.88	19.19	-66.7	0.00	16.7
Cycle 11 Day 1	37	12.61	23.04	0.0	0.00	100.0	35	-2.86	20.00	-50.0	0.00	33.3
Cycle 11 Day 22	22	11.36	25.40	0.0	0.00	100.0	20	-5.83	16.47	-33.3	0.00	33.3
Cycle 12 Day 1	32	14.58	21.48	0.0	0.00	66.7	30	-1.67	20.22	-33.3	0.00	33.3
Cycle 12 Day 22	20	20.00	26.27	0.0	8.33	66.7	18	-3.70	21.05	-33.3	0.00	33.3
Cycle 13 Day 1	25	14.00	16.44	0.0	0.00	50.0	24	-0.69	16.65	-33.3	0.00	33.3
Cycle 13 Day 22	15	16.67	20.89	0.0	0.00	66.7	14	5.95	22.27	-50.0	0.00	33.3
Cycle 14 Day 1	23	13.04	20.69	0.0	0.00	66.7	22	-1.52	21.15	-50.0	0.00	33.3
Cycle 14 Day 22	13	16.67	24.53	0.0	0.00	66.7	12	-2.78	22.29	-50.0	0.00	33.3
Cycle 15 Day 1	19	16.67	25.46	0.0	0.00	66.7	19	2.63	27.37	-66.7	0.00	66.7
Cycle 16 Day 1	11	12.12	23.68	0.0	0.00	66.7	11	0.00	26.87	-33.3	0.00	66.7
Cycle 17 Day 1	10	18.33	22.84	0.0	8.33	66.7	10	5.00	20.86	-33.3	0.00	33.3
Study Disc 1	137	25.79	28.58	0.0	16.67	100.0	133	-0.75	29.93	-83.3	0.00	100.0
Study Disc 2	10	36.67	34.07	0.0	33.33	100.0	9	16.67	18.63	0.0	16.67	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	24.28	26.23	0.0	16.67	100.0	78	-3.21	27.27	-83.3	0.00	66.7
90 D SFU Z/P	71	24.18	24.20	0.0	16.67	100.0	69	-1.45	31.92	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	51.30	28.99	0.0	50.00	100.0						
Cycle 1 Day 22	186	42.92	26.89	0.0	33.33	100.0	176	-8.33	24.69	-66.7	0.00	66.7
Cycle 2 Day 1	216	40.74	26.83	0.0	33.33	100.0	206	-10.19	26.31	-100.0	0.00	66.7
Cycle 2 Day 22	157	39.17	25.17	0.0	33.33	100.0	150	-11.67	24.33	-100.0	0.00	66.7
Cycle 3 Day 1	200	37.08	25.85	0.0	33.33	100.0	190	-12.63	26.19	-100.0	0.00	66.7
Cycle 3 Day 22	161	42.55	27.32	0.0	33.33	100.0	152	-9.65	26.48	-100.0	0.00	66.7
Cycle 4 Day 1	177	36.63	26.89	0.0	33.33	100.0	169	-14.60	24.61	-100.0	-16.67	50.0
Cycle 4 Day 22	127	38.32	24.70	0.0	33.33	100.0	122	-11.34	26.87	-83.3	0.00	50.0
Cycle 5 Day 1	155	38.71	26.65	0.0	33.33	100.0	147	-11.79	28.35	-83.3	-16.67	66.7
Cycle 5 Day 22	113	40.86	25.20	0.0	33.33	100.0	106	-11.16	28.61	-66.7	0.00	66.7
Cycle 6 Day 1	124	38.31	27.79	0.0	33.33	100.0	115	-11.01	29.94	-100.0	0.00	66.7
Cycle 6 Day 22	102	37.91	26.13	0.0	33.33	100.0	97	-10.31	25.05	-66.7	0.00	50.0
Cycle 7 Day 1	110	35.61	23.73	0.0	33.33	100.0	104	-12.02	27.72	-100.0	0.00	66.7
Cycle 7 Day 22	80	37.29	25.88	0.0	33.33	100.0	74	-13.51	26.41	-100.0	-16.67	50.0
Cycle 8 Day 1	81	37.65	26.59	0.0	33.33	100.0	74	-10.36	25.54	-66.7	0.00	66.7
Cycle 8 Day 22	70	35.24	24.83	0.0	33.33	100.0	65	-12.82	24.79	-66.7	-16.67	33.3
Cycle 9 Day 1	72	33.33	25.48	0.0	33.33	100.0	66	-17.42	22.91	-66.7	-16.67	33.3
Cycle 9 Day 22	54	32.72	23.78	0.0	33.33	100.0	50	-18.33	22.90	-83.3	-16.67	33.3
Cycle 10 Day 1	58	34.48	26.28	0.0	33.33	100.0	53	-16.98	22.76	-66.7	-16.67	33.3
Cycle 10 Day 22	47	32.98	26.58	0.0	33.33	100.0	44	-18.94	26.07	-100.0	-16.67	33.3
Cycle 11 Day 1	50	31.33	23.72	0.0	33.33	100.0	46	-19.57	28.83	-100.0	-16.67	33.3
Cycle 11 Day 22	35	30.00	18.44	0.0	33.33	66.7	32	-20.83	27.76	-66.7	-16.67	33.3
Cycle 12 Day 1	43	31.01	25.87	0.0	33.33	100.0	39	-20.51	23.71	-66.7	-16.67	33.3
Cycle 12 Day 22	31	34.41	23.93	0.0	33.33	100.0	29	-14.94	29.66	-100.0	0.00	33.3
Cycle 13 Day 1	37	31.98	22.35	0.0	33.33	100.0	34	-17.16	27.06	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	34.85	25.47	0.0	33.33	100.0	30	-11.67	22.81	-66.7	0.00	33.3
Cycle 14 Day 1	31	36.56	23.73	0.0	33.33	100.0	30	-13.33	24.13	-83.3	0.00	33.3
Cycle 14 Day 22	24	25.69	27.79	0.0	33.33	100.0	24	-20.14	31.08	-100.0	-16.67	33.3
Cycle 15 Day 1	26	35.26	26.38	0.0	33.33	100.0	26	-14.10	29.32	-66.7	-16.67	33.3
Cycle 15 Day 22	21	28.57	26.43	0.0	33.33	100.0	21	-18.25	28.82	-66.7	-16.67	33.3
Cycle 16 Day 1	25	31.33	24.21	0.0	33.33	83.3	25	-18.67	33.44	-83.3	-16.67	33.3
Cycle 16 Day 22	19	34.21	29.64	0.0	33.33	100.0	19	-14.91	28.27	-66.7	-16.67	50.0
Cycle 17 Day 1	19	30.70	25.62	0.0	33.33	100.0	19	-20.18	34.95	-83.3	-16.67	66.7
Cycle 17 Day 22	14	34.52	21.15	0.0	33.33	83.3	14	-8.33	25.94	-66.7	0.00	33.3
Cycle 18 Day 1	16	32.29	21.49	0.0	33.33	66.7	16	-18.75	29.74	-66.7	-25.00	33.3
Cycle 18 Day 22	10	25.00	18.00	0.0	33.33	50.0	10	-21.67	28.38	-66.7	-16.67	16.7
Cycle 19 Day 1	13	21.79	15.79	0.0	33.33	33.3	13	-32.05	25.88	-66.7	-33.33	0.0
Cycle 19 Day 22	11	31.82	11.68	0.0	33.33	50.0	11	-15.15	22.92	-66.7	-16.67	16.7
Cycle 20 Day 1	13	24.36	22.17	0.0	33.33	66.7	13	-24.36	19.97	-66.7	-16.67	0.0
Cycle 21 Day 1	11	24.24	15.57	0.0	33.33	33.3	11	-25.76	23.99	-66.7	-33.33	0.0
Study Disc 1	132	54.17	29.51	0.0	50.00	100.0	125	-1.87	30.17	-83.3	0.00	66.7
30 D SFU Z/P	69	53.14	30.69	0.0	50.00	100.0	64	-2.60	28.67	-66.7	0.00	66.7
90 D SFU Z/P	83	48.80	28.72	0.0	50.00	100.0	80	-2.50	32.49	-83.3	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	52.92	30.74	0.0	50.00	100.0						
Cycle 1 Day 22	211	45.34	29.02	0.0	33.33	100.0	208	-6.09	25.60	-100.0	0.00	66.7
Cycle 2 Day 1	230	41.52	29.00	0.0	33.33	100.0	223	-11.29	29.40	-100.0	0.00	66.7
Cycle 2 Day 22	185	41.53	27.48	0.0	33.33	100.0	180	-11.85	30.33	-100.0	-16.67	66.7
Cycle 3 Day 1	203	38.67	26.90	0.0	33.33	100.0	196	-13.44	28.71	-100.0	0.00	66.7
Cycle 3 Day 22	156	39.00	27.21	0.0	33.33	100.0	148	-14.30	27.90	-100.0	-8.33	66.7
Cycle 4 Day 1	170	39.61	26.83	0.0	33.33	100.0	161	-12.63	26.21	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	40.53	26.47	0.0	33.33	100.0	126	-12.83	27.01	-83.3	-16.67	66.7
Cycle 5 Day 1	147	45.46	27.69	0.0	33.33	100.0	142	-7.98	28.54	-83.3	0.00	100.0
Cycle 5 Day 22	119	41.32	27.43	0.0	33.33	100.0	112	-8.48	25.80	-66.7	0.00	100.0
Cycle 6 Day 1	121	42.98	26.24	0.0	33.33	100.0	116	-9.91	28.40	-66.7	0.00	100.0
Cycle 6 Day 22	92	40.40	25.47	0.0	33.33	100.0	88	-14.20	25.59	-66.7	-8.33	50.0
Cycle 7 Day 1	91	35.71	25.04	0.0	33.33	100.0	88	-18.56	25.45	-100.0	-16.67	33.3
Cycle 7 Day 22	66	36.62	24.84	0.0	33.33	100.0	64	-17.45	28.55	-83.3	-8.33	66.7
Cycle 8 Day 1	71	38.73	28.84	0.0	33.33	100.0	70	-14.29	27.11	-66.7	-16.67	83.3
Cycle 8 Day 22	56	35.12	25.36	0.0	33.33	100.0	54	-18.83	26.51	-66.7	-16.67	50.0
Cycle 9 Day 1	53	39.31	23.13	0.0	33.33	100.0	51	-17.32	28.28	-100.0	-16.67	66.7
Cycle 9 Day 22	46	31.52	26.81	0.0	33.33	100.0	44	-26.52	25.75	-83.3	-33.33	16.7
Cycle 10 Day 1	47	34.04	28.01	0.0	33.33	100.0	45	-20.37	33.31	-100.0	-16.67	66.7
Cycle 10 Day 22	35	34.76	27.23	0.0	33.33	100.0	34	-17.16	30.84	-83.3	-16.67	66.7
Cycle 11 Day 1	37	38.29	26.60	0.0	33.33	100.0	35	-12.38	25.67	-66.7	0.00	33.3
Cycle 11 Day 22	22	36.36	31.97	0.0	33.33	100.0	20	-18.33	31.02	-83.3	0.00	16.7
Cycle 12 Day 1	32	41.67	26.77	0.0	33.33	100.0	30	-8.89	23.05	-66.7	0.00	16.7
Cycle 12 Day 22	20	37.50	29.56	0.0	33.33	100.0	18	-21.30	29.60	-100.0	-16.67	16.7
Cycle 13 Day 1	25	34.67	30.78	0.0	33.33	100.0	24	-15.97	26.68	-100.0	-8.33	16.7
Cycle 13 Day 22	15	43.33	36.08	0.0	33.33	100.0	14	-5.95	21.29	-33.3	0.00	16.7
Cycle 14 Day 1	23	34.78	30.53	0.0	33.33	100.0	22	-15.15	24.62	-83.3	-8.33	16.7
Cycle 14 Day 22	13	48.72	31.52	0.0	50.00	100.0	12	-1.39	18.06	-33.3	0.00	16.7
Cycle 15 Day 1	19	36.84	33.60	0.0	33.33	100.0	19	-14.04	31.56	-100.0	0.00	33.3
Cycle 16 Day 1	11	36.36	40.01	0.0	33.33	100.0	11	-9.09	23.99	-50.0	0.00	33.3
Cycle 17 Day 1	10	35.00	30.88	0.0	33.33	100.0	10	-8.33	22.57	-50.0	0.00	16.7
Study Disc 1	137	48.54	31.86	0.0	33.33	100.0	133	-5.14	32.96	-100.0	0.00	66.7
Study Disc 2	10	51.67	35.53	0.0	33.33	100.0	9	11.11	14.43	0.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	45.06	27.19	0.0	33.33	100.0	78	-7.48	33.30	-100.0	0.00	66.7
90 D SFU Z/P	71	47.89	30.59	0.0	33.33	100.0	69	-2.17	35.69	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	49.90	28.19	0.0	41.67	100.0						
	Cycle 1 Day 22	124	39.78	26.18	0.0	33.33	100.0	116	-7.90	21.70	-66.7	0.00	66.7
	Cycle 2 Day 1	137	38.20	26.21	0.0	33.33	100.0	129	-11.11	24.94	-100.0	0.00	66.7
	Cycle 2 Day 22	103	36.89	24.55	0.0	33.33	100.0	97	-11.34	24.60	-100.0	0.00	50.0
	Cycle 3 Day 1	125	34.40	25.73	0.0	33.33	100.0	117	-13.25	25.29	-83.3	-16.67	33.3
	Cycle 3 Day 22	97	41.58	27.23	0.0	33.33	100.0	90	-7.41	26.22	-66.7	0.00	66.7
	Cycle 4 Day 1	112	35.57	26.71	0.0	33.33	100.0	104	-13.78	24.52	-66.7	-16.67	50.0
	Cycle 4 Day 22	83	39.16	26.21	0.0	33.33	100.0	78	-7.91	27.09	-83.3	0.00	50.0
	Cycle 5 Day 1	101	38.28	27.54	0.0	33.33	100.0	94	-11.35	26.80	-83.3	0.00	33.3
	Cycle 5 Day 22	70	40.24	25.77	0.0	33.33	100.0	64	-9.11	26.55	-66.7	0.00	66.7
	Cycle 6 Day 1	75	36.00	27.41	0.0	33.33	100.0	67	-10.45	25.27	-83.3	0.00	33.3
	Cycle 6 Day 22	64	37.50	28.79	0.0	33.33	100.0	60	-8.61	26.66	-66.7	-8.33	50.0
	Cycle 7 Day 1	69	35.27	24.18	0.0	33.33	100.0	63	-10.05	25.84	-83.3	0.00	50.0
	Cycle 7 Day 22	53	36.48	27.16	0.0	33.33	100.0	47	-12.41	28.12	-100.0	-16.67	50.0
	Cycle 8 Day 1	54	36.42	27.86	0.0	33.33	100.0	47	-9.57	25.71	-66.7	0.00	33.3
	Cycle 8 Day 22	44	33.71	27.96	0.0	33.33	100.0	39	-14.10	26.36	-66.7	-16.67	33.3
	Cycle 9 Day 1	45	32.59	28.42	0.0	33.33	100.0	39	-17.09	25.21	-66.7	-16.67	33.3
	Cycle 9 Day 22	32	32.81	27.92	0.0	33.33	100.0	28	-20.24	26.20	-83.3	-25.00	33.3
	Cycle 10 Day 1	36	34.72	29.38	0.0	33.33	100.0	31	-17.20	25.63	-66.7	-16.67	33.3
	Cycle 10 Day 22	30	33.33	28.70	0.0	33.33	100.0	27	-21.60	28.80	-100.0	-16.67	33.3
	Cycle 11 Day 1	33	33.33	27.64	0.0	33.33	100.0	29	-17.82	30.84	-100.0	-16.67	33.3
	Cycle 11 Day 22	23	33.33	20.10	0.0	33.33	66.7	20	-22.50	30.72	-66.7	-33.33	33.3
	Cycle 12 Day 1	26	32.69	28.08	0.0	33.33	100.0	22	-21.21	26.82	-66.7	-25.00	33.3
	Cycle 12 Day 22	18	35.19	27.94	0.0	33.33	100.0	16	-18.75	34.36	-100.0	-16.67	33.3
	Cycle 13 Day 1	21	33.33	25.82	0.0	33.33	100.0	18	-15.74	26.49	-66.7	-8.33	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	20	36.67	29.91	0.0	33.33	100.0	17	-11.76	25.53	-66.7	0.00	33.3
	Cycle 14 Day 1	16	41.67	26.53	0.0	33.33	100.0	15	-10.00	26.58	-83.3	0.00	33.3
	Cycle 14 Day 22	15	27.78	30.65	0.0	33.33	100.0	15	-23.33	37.69	-100.0	-16.67	33.3
	Cycle 15 Day 1	14	34.52	28.09	0.0	33.33	100.0	14	-15.48	29.57	-66.7	-8.33	33.3
	Cycle 15 Day 22	14	33.33	29.24	0.0	33.33	100.0	14	-17.86	31.67	-66.7	-8.33	33.3
	Cycle 16 Day 1	13	29.49	24.68	0.0	33.33	83.3	13	-21.79	35.61	-83.3	-16.67	33.3
	Cycle 16 Day 22	13	34.62	27.61	0.0	33.33	100.0	13	-17.95	32.96	-66.7	-16.67	50.0
	Cycle 17 Day 1	12	30.56	21.12	0.0	33.33	83.3	12	-22.22	27.83	-66.7	-16.67	33.3
	Cycle 18 Day 1	10	31.67	22.84	0.0	33.33	66.7	10	-20.00	26.99	-66.7	-33.33	16.7
	Study Disc 1	86	54.07	30.57	0.0	50.00	100.0	79	0.00	26.01	-66.7	0.00	66.7
	30 D SFU Z/P	44	53.03	32.80	0.0	66.67	100.0	40	0.00	27.48	-33.3	0.00	66.7
	90 D SFU Z/P	49	43.54	30.77	0.0	33.33	100.0	47	-6.03	32.68	-83.3	0.00	66.7
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	50.84	30.80	0.0	50.00	100.0						
	Cycle 1 Day 22	138	45.05	28.79	0.0	33.33	100.0	135	-5.68	25.93	-100.0	0.00	50.0
	Cycle 2 Day 1	151	40.95	28.07	0.0	33.33	100.0	144	-10.76	29.00	-100.0	0.00	66.7
	Cycle 2 Day 22	128	39.71	27.91	0.0	33.33	100.0	123	-11.92	29.76	-100.0	-16.67	66.7
	Cycle 3 Day 1	130	36.92	27.69	0.0	33.33	100.0	124	-13.31	27.30	-100.0	0.00	66.7
	Cycle 3 Day 22	105	38.25	27.82	0.0	33.33	100.0	99	-13.13	30.05	-100.0	0.00	66.7
	Cycle 4 Day 1	109	38.53	27.56	0.0	33.33	100.0	101	-11.55	27.56	-100.0	0.00	66.7
	Cycle 4 Day 22	87	39.46	27.74	0.0	33.33	100.0	82	-11.59	26.92	-83.3	-16.67	66.7
	Cycle 5 Day 1	93	43.91	28.53	0.0	33.33	100.0	89	-8.05	28.55	-66.7	0.00	100.0
	Cycle 5 Day 22	83	40.76	26.83	0.0	33.33	100.0	77	-8.01	26.71	-66.7	0.00	100.0
	Cycle 6 Day 1	73	41.55	26.52	0.0	33.33	100.0	69	-8.21	28.67	-66.7	0.00	100.0
	Cycle 6 Day 22	60	37.50	25.60	0.0	33.33	100.0	57	-14.33	24.28	-66.7	-16.67	33.3
	Cycle 7 Day 1	58	31.90	26.54	0.0	33.33	100.0	55	-18.48	25.19	-100.0	-16.67	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	40	33.75	27.08	0.0	33.33	100.0	38	-16.67	25.41	-66.7	-16.67	33.3
	Cycle 8 Day 1	44	34.47	28.84	0.0	33.33	100.0	43	-14.73	22.48	-66.7	-16.67	33.3
	Cycle 8 Day 22	34	30.39	25.78	0.0	33.33	100.0	32	-21.87	21.77	-66.7	-16.67	16.7
	Cycle 9 Day 1	33	37.37	24.66	0.0	33.33	100.0	31	-16.67	22.36	-66.7	-16.67	16.7
	Cycle 9 Day 22	28	30.36	28.71	0.0	33.33	100.0	26	-24.36	25.05	-66.7	-33.33	16.7
	Cycle 10 Day 1	26	26.28	27.96	0.0	33.33	100.0	24	-23.61	29.04	-100.0	-25.00	16.7
	Cycle 10 Day 22	21	30.16	27.70	0.0	33.33	100.0	20	-20.83	25.86	-83.3	-33.33	16.7
	Cycle 11 Day 1	22	31.82	27.65	0.0	33.33	100.0	20	-15.00	22.88	-66.7	-8.33	16.7
	Cycle 11 Day 22	13	29.49	28.18	0.0	33.33	100.0	11	-19.70	25.62	-66.7	-16.67	16.7
	Cycle 12 Day 1	17	35.29	26.93	0.0	33.33	100.0	15	-6.67	19.72	-33.3	0.00	16.7
	Cycle 12 Day 22	11	34.85	31.14	0.0	33.33	100.0	9	-18.52	26.93	-66.7	-16.67	16.7
	Cycle 13 Day 1	14	33.33	31.35	0.0	33.33	100.0	13	-12.82	22.72	-50.0	0.00	16.7
	Cycle 14 Day 1	11	31.82	33.71	0.0	33.33	100.0	10	-11.67	23.64	-50.0	0.00	16.7
	Study Disc 1	83	46.59	32.38	0.0	33.33	100.0	81	-3.70	33.64	-100.0	0.00	66.7
	30 D SFU Z/P	57	41.23	25.61	0.0	33.33	100.0	55	-8.48	33.62	-100.0	0.00	66.7
	90 D SFU Z/P	50	43.33	29.55	0.0	33.33	100.0	48	-4.17	34.98	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	53.61	30.26	0.0	50.00	100.0						
	Cycle 1 Day 22	62	49.19	27.40	0.0	50.00	100.0	60	-9.17	29.82	-66.7	0.00	66.7
	Cycle 2 Day 1	79	45.15	27.50	0.0	33.33	100.0	77	-8.66	28.56	-100.0	0.00	66.7
	Cycle 2 Day 22	54	43.52	25.99	0.0	33.33	100.0	53	-12.26	24.05	-66.7	0.00	66.7
	Cycle 3 Day 1	75	41.56	25.61	0.0	33.33	100.0	73	-11.64	27.73	-100.0	0.00	66.7
	Cycle 3 Day 22	64	44.01	27.60	0.0	33.33	100.0	62	-12.90	26.72	-100.0	0.00	33.3
	Cycle 4 Day 1	65	38.46	27.31	0.0	33.33	100.0	65	-15.90	24.90	-100.0	0.00	33.3
	Cycle 4 Day 22	44	36.74	21.74	0.0	33.33	100.0	44	-17.42	25.66	-66.7	-16.67	50.0
	Cycle 5 Day 1	54	39.51	25.14	0.0	33.33	100.0	53	-12.58	31.16	-83.3	-16.67	66.7
	Cycle 5 Day 22	43	41.86	24.50	0.0	33.33	100.0	42	-14.29	31.57	-66.7	-16.67	66.7
	Cycle 6 Day 1	49	41.84	28.28	0.0	33.33	100.0	48	-11.81	35.72	-100.0	0.00	66.7
	Cycle 6 Day 22	38	38.60	21.26	0.0	33.33	83.3	37	-13.06	22.27	-66.7	0.00	16.7
	Cycle 7 Day 1	41	36.18	23.24	0.0	33.33	100.0	41	-15.04	30.46	-100.0	0.00	66.7
	Cycle 7 Day 22	27	38.89	23.57	0.0	33.33	100.0	27	-15.43	23.54	-66.7	-16.67	33.3
	Cycle 8 Day 1	27	40.12	24.13	0.0	33.33	100.0	27	-11.73	25.66	-66.7	0.00	66.7
	Cycle 8 Day 22	26	37.82	18.59	0.0	33.33	66.7	26	-10.90	22.58	-50.0	-16.67	33.3
	Cycle 9 Day 1	27	34.57	20.11	0.0	33.33	66.7	27	-17.90	19.57	-66.7	-16.67	0.0
	Cycle 9 Day 22	22	32.58	16.65	0.0	33.33	66.7	22	-15.91	18.17	-66.7	-16.67	0.0
	Cycle 10 Day 1	22	34.09	20.88	0.0	33.33	66.7	22	-16.67	18.54	-66.7	-16.67	16.7
	Cycle 10 Day 22	17	32.35	23.18	0.0	33.33	100.0	17	-14.71	21.15	-66.7	-16.67	33.3
	Cycle 11 Day 1	17	27.45	13.10	0.0	33.33	50.0	17	-22.55	25.65	-83.3	-16.67	0.0
	Cycle 11 Day 22	12	23.61	13.22	0.0	33.33	33.3	12	-18.06	22.98	-66.7	-8.33	0.0
	Cycle 12 Day 1	17	28.43	22.64	0.0	33.33	66.7	17	-19.61	19.75	-66.7	-16.67	0.0
	Cycle 12 Day 22	13	33.33	18.00	0.0	33.33	66.7	13	-10.26	23.11	-66.7	0.00	16.7
	Cycle 13 Day 1	16	30.21	17.45	0.0	33.33	66.7	16	-18.75	28.46	-66.7	0.00	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	13	32.05	17.30	0.0	33.33	66.7	13	-11.54	19.70	-66.7	0.00	0.0
	Cycle 14 Day 1	15	31.11	19.79	0.0	33.33	66.7	15	-16.67	21.82	-66.7	0.00	0.0
	Cycle 15 Day 1	12	36.11	25.46	0.0	33.33	66.7	12	-12.50	30.26	-66.7	-16.67	33.3
	Cycle 16 Day 1	12	33.33	24.62	0.0	33.33	66.7	12	-15.28	32.14	-66.7	-16.67	33.3
	Study Disc 1	46	54.35	27.76	0.0	50.00	100.0	46	-5.07	36.32	-83.3	0.00	66.7
	30 D SFU Z/P	25	53.33	27.22	0.0	50.00	100.0	24	-6.94	30.66	-66.7	0.00	50.0
	90 D SFU Z/P	34	56.37	23.93	16.7	58.33	100.0	33	2.53	32.04	-66.7	0.00	50.0
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	56.29	30.51	0.0	66.67	100.0						
	Cycle 1 Day 22	73	45.89	29.63	0.0	33.33	100.0	73	-6.85	25.13	-66.7	0.00	66.7
	Cycle 2 Day 1	79	42.62	30.86	0.0	33.33	100.0	79	-12.24	30.28	-100.0	0.00	66.7
	Cycle 2 Day 22	57	45.61	26.26	0.0	33.33	100.0	57	-11.70	31.80	-66.7	-16.67	66.7
	Cycle 3 Day 1	73	41.78	25.33	0.0	33.33	100.0	72	-13.66	31.19	-66.7	-16.67	66.7
	Cycle 3 Day 22	51	40.52	26.09	0.0	33.33	100.0	49	-16.67	23.07	-66.7	-16.67	50.0
	Cycle 4 Day 1	61	41.53	25.57	0.0	33.33	100.0	60	-14.44	23.86	-66.7	-16.67	50.0
	Cycle 4 Day 22	45	42.59	23.98	0.0	33.33	100.0	44	-15.15	27.33	-83.3	-16.67	66.7
	Cycle 5 Day 1	54	48.15	26.24	0.0	33.33	100.0	53	-7.86	28.79	-83.3	0.00	66.7
	Cycle 5 Day 22	36	42.59	29.13	0.0	33.33	100.0	35	-9.52	24.01	-66.7	0.00	50.0
	Cycle 6 Day 1	48	45.14	25.95	0.0	33.33	100.0	47	-12.41	28.12	-66.7	0.00	66.7
	Cycle 6 Day 22	32	45.83	24.68	0.0	33.33	100.0	31	-13.98	28.25	-66.7	0.00	50.0
	Cycle 7 Day 1	33	42.42	20.87	0.0	33.33	100.0	33	-18.69	26.27	-66.7	0.00	33.3
	Cycle 7 Day 22	26	41.03	20.67	0.0	33.33	100.0	26	-18.59	33.11	-83.3	0.00	66.7
	Cycle 8 Day 1	27	45.68	27.96	0.0	33.33	100.0	27	-13.58	33.66	-66.7	-16.67	83.3
	Cycle 8 Day 22	22	42.42	23.42	0.0	33.33	100.0	22	-14.39	32.24	-66.7	0.00	50.0
	Cycle 9 Day 1	20	42.50	20.57	0.0	33.33	83.3	20	-18.33	36.23	-100.0	-8.33	66.7
	Cycle 9 Day 22	18	33.33	24.25	0.0	33.33	100.0	18	-29.63	27.15	-83.3	-33.33	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	21	43.65	25.54	0.0	33.33	100.0	21	-16.67	38.01	-66.7	-16.67	66.7
	Cycle 10 Day 22	14	41.67	25.94	0.0	33.33	100.0	14	-11.90	37.23	-66.7	-8.33	66.7
	Cycle 11 Day 1	15	47.78	22.60	16.7	33.33	100.0	15	-8.89	29.46	-66.7	0.00	33.3
	Cycle 12 Day 1	15	48.89	25.56	16.7	33.33	100.0	15	-11.11	26.48	-66.7	0.00	16.7
	Cycle 13 Day 1	11	36.36	31.46	0.0	33.33	100.0	11	-19.70	31.46	-100.0	-16.67	16.7
	Cycle 14 Day 1	12	37.50	28.54	0.0	33.33	100.0	12	-18.06	26.07	-83.3	-16.67	16.7
	Cycle 15 Day 1	10	35.00	34.65	0.0	25.00	100.0	10	-25.00	33.56	-100.0	-33.33	16.7
	Study Disc 1	54	51.54	31.10	0.0	33.33	100.0	52	-7.37	32.07	-66.7	0.00	66.7
	30 D SFU Z/P	24	54.17	29.18	0.0	58.33	100.0	23	-5.07	33.12	-66.7	0.00	66.7
	90 D SFU Z/P	21	58.73	31.01	16.7	66.67	100.0	21	2.38	37.74	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	14.66	25.11	0.0	0.00	100.0						
Cycle 1 Day 22	186	11.83	21.72	0.0	0.00	100.0	176	-1.14	25.42	-100.0	0.00	66.7
Cycle 2 Day 1	216	12.50	23.25	0.0	0.00	100.0	206	-1.46	25.57	-100.0	0.00	100.0
Cycle 2 Day 22	157	10.83	22.40	0.0	0.00	100.0	150	-2.00	28.96	-100.0	0.00	100.0
Cycle 3 Day 1	200	7.33	17.42	0.0	0.00	100.0	190	-5.79	25.11	-100.0	0.00	100.0
Cycle 3 Day 22	161	11.59	21.81	0.0	0.00	100.0	152	-2.19	26.21	-100.0	0.00	100.0
Cycle 4 Day 1	177	9.04	19.62	0.0	0.00	100.0	169	-4.93	27.13	-100.0	0.00	100.0
Cycle 4 Day 22	127	11.55	22.37	0.0	0.00	100.0	122	-0.82	25.16	-100.0	0.00	66.7
Cycle 5 Day 1	155	9.89	20.87	0.0	0.00	100.0	147	-3.85	26.03	-100.0	0.00	66.7
Cycle 5 Day 22	113	12.98	26.52	0.0	0.00	100.0	106	-1.89	25.95	-100.0	0.00	100.0
Cycle 6 Day 1	124	8.06	20.10	0.0	0.00	100.0	115	-4.35	20.48	-66.7	0.00	66.7
Cycle 6 Day 22	102	8.82	19.86	0.0	0.00	100.0	97	-1.37	20.93	-66.7	0.00	66.7
Cycle 7 Day 1	110	9.39	21.72	0.0	0.00	100.0	104	-0.64	25.43	-66.7	0.00	100.0
Cycle 7 Day 22	80	9.17	20.52	0.0	0.00	100.0	74	-0.90	18.28	-33.3	0.00	66.7
Cycle 8 Day 1	81	9.88	20.71	0.0	0.00	100.0	74	0.00	23.41	-33.3	0.00	100.0
Cycle 8 Day 22	70	9.05	19.59	0.0	0.00	100.0	65	-3.08	22.61	-66.7	0.00	66.7
Cycle 9 Day 1	72	6.48	17.37	0.0	0.00	100.0	66	-5.56	18.10	-33.3	0.00	66.7
Cycle 9 Day 22	54	10.49	20.30	0.0	0.00	100.0	50	-0.67	22.83	-66.7	0.00	66.7
Cycle 10 Day 1	58	6.32	17.05	0.0	0.00	100.0	53	-3.14	21.94	-66.7	0.00	66.7
Cycle 10 Day 22	47	6.38	17.91	0.0	0.00	100.0	44	-1.52	18.96	-33.3	0.00	66.7
Cycle 11 Day 1	50	7.33	18.18	0.0	0.00	100.0	46	-2.90	19.66	-33.3	0.00	66.7
Cycle 11 Day 22	35	5.71	12.75	0.0	0.00	33.3	32	-7.29	20.27	-33.3	0.00	33.3
Cycle 12 Day 1	43	6.20	19.59	0.0	0.00	100.0	39	-5.98	20.05	-33.3	0.00	66.7
Cycle 12 Day 22	31	5.38	19.43	0.0	0.00	100.0	29	-8.05	21.19	-33.3	0.00	66.7
Cycle 13 Day 1	37	9.01	24.40	0.0	0.00	100.0	34	-4.90	21.92	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	9.09	19.14	0.0	0.00	66.7	30	-3.33	20.25	-33.3	0.00	33.3
Cycle 14 Day 1	31	6.45	20.04	0.0	0.00	100.0	30	-6.67	22.15	-33.3	0.00	66.7
Cycle 14 Day 22	24	9.72	23.01	0.0	0.00	100.0	24	-2.78	25.85	-33.3	0.00	66.7
Cycle 15 Day 1	26	10.26	22.65	0.0	0.00	100.0	26	-1.28	19.96	-33.3	0.00	66.7
Cycle 15 Day 22	21	12.70	26.82	0.0	0.00	100.0	21	-1.59	28.82	-33.3	0.00	66.7
Cycle 16 Day 1	25	6.67	13.61	0.0	0.00	33.3	25	-5.33	18.46	-33.3	0.00	33.3
Cycle 16 Day 22	19	8.77	15.08	0.0	0.00	33.3	19	-5.26	20.07	-33.3	0.00	33.3
Cycle 17 Day 1	19	8.77	18.73	0.0	0.00	66.7	19	-5.26	25.49	-33.3	0.00	66.7
Cycle 17 Day 22	14	9.52	20.37	0.0	0.00	66.7	14	-4.76	28.81	-33.3	0.00	66.7
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	-8.33	19.25	-33.3	0.00	33.3
Cycle 18 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	-6.67	26.29	-33.3	0.00	33.3
Cycle 19 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-7.69	19.97	-33.3	0.00	33.3
Cycle 19 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-9.09	21.56	-33.3	0.00	33.3
Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-5.13	18.49	-33.3	0.00	33.3
Cycle 21 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Study Disc 1	132	18.43	29.79	0.0	0.00	100.0	125	5.60	30.15	-100.0	0.00	100.0
30 D SFU Z/P	69	16.43	27.78	0.0	0.00	100.0	64	5.21	23.92	-33.3	0.00	100.0
90 D SFU Z/P	83	12.85	23.76	0.0	0.00	100.0	80	2.50	25.86	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	15.95	26.85	0.0	0.00	100.0						
Cycle 1 Day 22	211	13.74	23.58	0.0	0.00	100.0	208	-0.64	23.16	-100.0	0.00	100.0
Cycle 2 Day 1	230	10.58	21.11	0.0	0.00	100.0	223	-4.04	23.86	-100.0	0.00	100.0
Cycle 2 Day 22	185	10.99	20.98	0.0	0.00	100.0	180	-3.52	25.28	-100.0	0.00	100.0
Cycle 3 Day 1	203	9.85	20.21	0.0	0.00	100.0	196	-5.27	27.23	-100.0	0.00	100.0
Cycle 3 Day 22	156	9.62	19.31	0.0	0.00	100.0	148	-6.08	26.38	-100.0	0.00	100.0
Cycle 4 Day 1	170	7.84	17.12	0.0	0.00	100.0	161	-7.45	23.86	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	9.34	18.56	0.0	0.00	100.0	126	-5.03	26.35	-100.0	0.00	100.0
Cycle 5 Day 1	147	8.39	16.48	0.0	0.00	66.7	142	-4.69	25.60	-100.0	0.00	66.7
Cycle 5 Day 22	119	7.28	16.33	0.0	0.00	66.7	112	-4.17	21.98	-100.0	0.00	66.7
Cycle 6 Day 1	121	9.09	19.25	0.0	0.00	100.0	116	-2.59	24.14	-66.7	0.00	100.0
Cycle 6 Day 22	92	6.88	13.57	0.0	0.00	33.3	88	-5.30	22.54	-66.7	0.00	33.3
Cycle 7 Day 1	91	4.76	12.74	0.0	0.00	66.7	88	-6.82	21.54	-66.7	0.00	33.3
Cycle 7 Day 22	66	3.03	9.66	0.0	0.00	33.3	64	-6.77	18.95	-66.7	0.00	33.3
Cycle 8 Day 1	71	3.76	10.61	0.0	0.00	33.3	70	-6.19	17.30	-66.7	0.00	33.3
Cycle 8 Day 22	56	3.57	10.40	0.0	0.00	33.3	54	-5.56	19.15	-66.7	0.00	33.3
Cycle 9 Day 1	53	3.77	10.66	0.0	0.00	33.3	51	-6.54	22.13	-100.0	0.00	33.3
Cycle 9 Day 22	46	5.80	14.58	0.0	0.00	66.7	44	-4.55	23.40	-66.7	0.00	66.7
Cycle 10 Day 1	47	2.84	9.40	0.0	0.00	33.3	45	-5.93	17.82	-66.7	0.00	33.3
Cycle 10 Day 22	35	2.86	9.47	0.0	0.00	33.3	34	-4.90	14.52	-33.3	0.00	33.3
Cycle 11 Day 1	37	4.50	17.85	0.0	0.00	100.0	35	-3.81	22.54	-33.3	0.00	100.0
Cycle 11 Day 22	22	4.55	11.71	0.0	0.00	33.3	20	-3.33	18.42	-33.3	0.00	33.3
Cycle 12 Day 1	32	5.21	14.93	0.0	0.00	66.7	30	-3.33	20.25	-33.3	0.00	66.7
Cycle 12 Day 22	20	5.00	12.21	0.0	0.00	33.3	18	-7.41	18.28	-33.3	0.00	33.3
Cycle 13 Day 1	25	4.00	11.06	0.0	0.00	33.3	24	-5.56	16.05	-33.3	0.00	33.3
Cycle 13 Day 22	15	0.00	0.00	0.0	0.00	0.0	14	-9.52	15.63	-33.3	0.00	0.0
Cycle 14 Day 1	23	2.90	9.60	0.0	0.00	33.3	22	-6.06	16.70	-33.3	0.00	33.3
Cycle 14 Day 22	13	2.56	9.25	0.0	0.00	33.3	12	-11.11	16.41	-33.3	0.00	0.0
Cycle 15 Day 1	19	5.26	12.49	0.0	0.00	33.3	19	-3.51	15.29	-33.3	0.00	33.3
Cycle 16 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 17 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Study Disc 1	137	18.00	30.25	0.0	0.00	100.0	133	0.25	31.11	-100.0	0.00	100.0
Study Disc 2	10	10.00	31.62	0.0	0.00	100.0	9	-3.70	35.14	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	14.81	25.28	0.0	0.00	100.0	78	-2.99	33.20	-100.0	0.00	100.0
90 D SFU Z/P	71	12.68	24.15	0.0	0.00	100.0	69	-2.42	33.97	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	21.92	26.99	0.0	0.00	100.0						
Cycle 1 Day 22	186	26.34	26.03	0.0	33.33	100.0	176	5.68	27.01	-100.0	0.00	66.7
Cycle 2 Day 1	216	23.92	27.45	0.0	33.33	100.0	206	1.78	31.10	-100.0	0.00	100.0
Cycle 2 Day 22	157	24.42	27.58	0.0	33.33	100.0	150	3.56	26.80	-66.7	0.00	100.0
Cycle 3 Day 1	200	21.33	25.46	0.0	0.00	100.0	190	1.05	31.03	-100.0	0.00	66.7
Cycle 3 Day 22	161	24.64	24.87	0.0	33.33	100.0	152	4.39	30.85	-100.0	0.00	100.0
Cycle 4 Day 1	177	19.77	24.45	0.0	0.00	100.0	169	-0.39	30.43	-66.7	0.00	100.0
Cycle 4 Day 22	127	20.21	24.18	0.0	0.00	100.0	122	1.09	29.36	-100.0	0.00	100.0
Cycle 5 Day 1	155	22.80	25.70	0.0	33.33	100.0	147	3.17	32.25	-100.0	0.00	100.0
Cycle 5 Day 22	113	18.58	22.24	0.0	0.00	100.0	106	-0.31	28.54	-100.0	0.00	66.7
Cycle 6 Day 1	124	18.28	23.42	0.0	0.00	100.0	115	-0.87	25.92	-66.7	0.00	66.7
Cycle 6 Day 22	102	16.67	21.88	0.0	0.00	100.0	97	-2.06	26.71	-66.7	0.00	33.3
Cycle 7 Day 1	110	17.58	21.04	0.0	0.00	100.0	104	-1.28	25.41	-66.7	0.00	66.7
Cycle 7 Day 22	80	17.08	22.50	0.0	0.00	100.0	74	-0.45	27.31	-66.7	0.00	100.0
Cycle 8 Day 1	81	17.28	18.34	0.0	0.00	66.7	74	-1.35	26.14	-66.7	0.00	66.7
Cycle 8 Day 22	70	17.62	23.21	0.0	0.00	100.0	65	-2.56	26.55	-66.7	0.00	66.7
Cycle 9 Day 1	72	17.13	21.66	0.0	0.00	100.0	66	-3.03	25.97	-66.7	0.00	66.7
Cycle 9 Day 22	54	19.14	20.06	0.0	33.33	66.7	50	1.33	29.32	-66.7	0.00	66.7
Cycle 10 Day 1	58	15.52	20.91	0.0	0.00	66.7	53	-1.89	30.25	-66.7	0.00	66.7
Cycle 10 Day 22	47	14.18	18.05	0.0	0.00	66.7	44	-1.52	24.86	-66.7	0.00	33.3
Cycle 11 Day 1	50	12.67	17.68	0.0	0.00	66.7	46	-1.45	24.30	-66.7	0.00	33.3
Cycle 11 Day 22	35	14.29	16.74	0.0	0.00	33.3	32	1.04	21.56	-33.3	0.00	33.3
Cycle 12 Day 1	43	16.28	16.86	0.0	0.00	33.3	39	0.85	27.02	-66.7	0.00	33.3
Cycle 12 Day 22	31	16.13	16.93	0.0	0.00	33.3	29	4.60	23.10	-33.3	0.00	33.3
Cycle 13 Day 1	37	17.12	21.69	0.0	0.00	100.0	34	0.00	25.95	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	14.14	18.69	0.0	0.00	66.7	30	1.11	22.29	-33.3	0.00	33.3
Cycle 14 Day 1	31	16.13	24.15	0.0	0.00	100.0	30	-3.33	22.06	-33.3	0.00	33.3
Cycle 14 Day 22	24	11.11	16.05	0.0	0.00	33.3	24	-5.56	21.23	-33.3	0.00	33.3
Cycle 15 Day 1	26	11.54	16.17	0.0	0.00	33.3	26	-6.41	24.98	-66.7	0.00	33.3
Cycle 15 Day 22	21	11.11	16.10	0.0	0.00	33.3	21	-6.35	20.05	-33.3	0.00	33.3
Cycle 16 Day 1	25	10.67	15.87	0.0	0.00	33.3	25	-9.33	22.61	-66.7	0.00	33.3
Cycle 16 Day 22	19	14.04	20.23	0.0	0.00	66.7	19	-3.51	24.58	-33.3	0.00	66.7
Cycle 17 Day 1	19	15.79	17.10	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
Cycle 17 Day 22	14	11.90	16.57	0.0	0.00	33.3	14	-7.14	19.30	-33.3	0.00	33.3
Cycle 18 Day 1	16	10.42	15.96	0.0	0.00	33.3	16	-10.42	23.47	-66.7	0.00	33.3
Cycle 18 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
Cycle 19 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-12.82	21.68	-66.7	0.00	0.0
Cycle 19 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-9.09	15.57	-33.3	0.00	0.0
Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-12.82	25.60	-66.7	0.00	0.0
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-15.15	27.34	-66.7	0.00	0.0
Study Disc 1	132	29.55	31.00	0.0	33.33	100.0	125	5.07	33.08	-66.7	0.00	100.0
30 D SFU Z/P	69	28.02	26.58	0.0	33.33	100.0	64	5.21	29.23	-100.0	0.00	66.7
90 D SFU Z/P	83	24.10	25.14	0.0	33.33	100.0	80	2.50	31.72	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	22.70	26.83	0.0	33.33	100.0						
Cycle 1 Day 22	211	27.17	26.00	0.0	33.33	100.0	208	4.33	27.17	-100.0	0.00	100.0
Cycle 2 Day 1	230	23.48	25.87	0.0	33.33	100.0	223	0.45	28.03	-100.0	0.00	100.0
Cycle 2 Day 22	185	25.41	25.95	0.0	33.33	100.0	180	1.11	29.67	-100.0	0.00	100.0
Cycle 3 Day 1	203	21.67	24.39	0.0	33.33	100.0	196	-1.53	29.68	-100.0	0.00	66.7
Cycle 3 Day 22	156	23.93	25.90	0.0	33.33	100.0	148	1.13	29.46	-100.0	0.00	66.7
Cycle 4 Day 1	170	22.16	25.88	0.0	33.33	100.0	161	-0.62	29.22	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	22.22	23.90	0.0	33.33	100.0	126	1.59	29.17	-100.0	0.00	66.7
Cycle 5 Day 1	147	21.09	25.61	0.0	0.00	100.0	142	0.94	27.49	-100.0	0.00	66.7
Cycle 5 Day 22	119	18.49	23.65	0.0	0.00	100.0	112	-0.60	26.08	-100.0	0.00	66.7
Cycle 6 Day 1	121	18.46	26.16	0.0	0.00	100.0	116	-0.57	29.81	-100.0	0.00	66.7
Cycle 6 Day 22	92	15.58	20.64	0.0	0.00	66.7	88	-3.79	25.98	-100.0	0.00	33.3
Cycle 7 Day 1	91	14.29	22.30	0.0	0.00	100.0	88	-4.17	28.95	-100.0	0.00	66.7
Cycle 7 Day 22	66	14.14	19.45	0.0	0.00	66.7	64	-5.21	30.41	-100.0	0.00	33.3
Cycle 8 Day 1	71	15.49	23.79	0.0	0.00	100.0	70	-5.71	27.79	-100.0	0.00	100.0
Cycle 8 Day 22	56	17.26	20.09	0.0	0.00	66.7	54	-1.85	32.00	-100.0	0.00	66.7
Cycle 9 Day 1	53	15.09	23.17	0.0	0.00	100.0	51	-2.61	32.55	-100.0	0.00	66.7
Cycle 9 Day 22	46	15.22	22.99	0.0	0.00	100.0	44	-3.03	33.58	-100.0	0.00	33.3
Cycle 10 Day 1	47	14.18	21.70	0.0	0.00	100.0	45	-2.96	29.15	-100.0	0.00	33.3
Cycle 10 Day 22	35	17.14	24.75	0.0	0.00	100.0	34	-3.92	31.53	-100.0	0.00	66.7
Cycle 11 Day 1	37	15.32	25.57	0.0	0.00	100.0	35	-4.76	30.40	-100.0	0.00	33.3
Cycle 11 Day 22	22	15.15	22.37	0.0	0.00	66.7	20	-3.33	23.94	-66.7	0.00	33.3
Cycle 12 Day 1	32	16.67	25.40	0.0	0.00	100.0	30	-3.33	29.49	-100.0	0.00	33.3
Cycle 12 Day 22	20	23.33	30.78	0.0	0.00	100.0	18	0.00	28.01	-66.7	0.00	33.3
Cycle 13 Day 1	25	20.00	28.87	0.0	0.00	100.0	24	-1.39	33.30	-100.0	0.00	33.3
Cycle 13 Day 22	15	24.44	34.43	0.0	0.00	100.0	14	-4.76	38.91	-100.0	0.00	33.3
Cycle 14 Day 1	23	15.94	26.34	0.0	0.00	100.0	22	-4.55	33.01	-100.0	0.00	33.3
Cycle 14 Day 22	13	25.64	30.89	0.0	33.33	100.0	12	0.00	24.62	-33.3	0.00	33.3
Cycle 15 Day 1	19	10.53	27.34	0.0	0.00	100.0	19	-7.02	23.78	-66.7	0.00	33.3
Cycle 16 Day 1	11	9.09	21.56	0.0	0.00	66.7	11	-9.09	21.56	-33.3	0.00	33.3
Cycle 17 Day 1	10	16.67	28.33	0.0	0.00	66.7	10	0.00	22.22	-33.3	0.00	33.3
Study Disc 1	137	27.98	31.63	0.0	33.33	100.0	133	3.76	34.97	-100.0	0.00	100.0
Study Disc 2	10	36.67	45.68	0.0	16.67	100.0	9	25.93	27.78	0.0	33.33	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	24.69	29.71	0.0	33.33	100.0	78	4.70	35.11	-100.0	0.00	100.0
90 D SFU Z/P	71	26.76	29.61	0.0	33.33	100.0	69	5.31	32.15	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	12.06	23.32	0.0	0.00	100.0						
Cycle 1 Day 22	186	20.97	25.63	0.0	0.00	100.0	176	10.80	29.66	-100.0	0.00	100.0
Cycle 2 Day 1	216	22.99	28.95	0.0	0.00	100.0	206	12.62	29.49	-66.7	0.00	100.0
Cycle 2 Day 22	157	25.05	30.11	0.0	33.33	100.0	150	15.78	33.60	-66.7	0.00	100.0
Cycle 3 Day 1	200	24.50	30.53	0.0	0.00	100.0	190	14.56	34.52	-100.0	0.00	100.0
Cycle 3 Day 22	161	31.26	31.55	0.0	33.33	100.0	152	21.93	31.66	-66.7	16.67	100.0
Cycle 4 Day 1	177	27.31	31.80	0.0	33.33	100.0	169	17.75	35.46	-66.7	0.00	100.0
Cycle 4 Day 22	127	28.87	31.53	0.0	33.33	100.0	122	20.49	32.48	-66.7	0.00	100.0
Cycle 5 Day 1	155	29.89	29.95	0.0	33.33	100.0	147	19.73	31.88	-66.7	0.00	100.0
Cycle 5 Day 22	113	28.02	30.07	0.0	33.33	100.0	106	19.50	28.31	-66.7	0.00	100.0
Cycle 6 Day 1	124	22.85	28.31	0.0	0.00	100.0	115	12.75	28.13	-33.3	0.00	100.0
Cycle 6 Day 22	102	20.59	28.55	0.0	0.00	100.0	97	10.31	30.18	-33.3	0.00	100.0
Cycle 7 Day 1	110	17.27	25.43	0.0	0.00	100.0	104	8.01	24.79	-33.3	0.00	100.0
Cycle 7 Day 22	80	20.42	27.30	0.0	0.00	100.0	74	9.91	25.72	-33.3	0.00	100.0
Cycle 8 Day 1	81	17.70	26.40	0.0	0.00	100.0	74	6.31	23.20	-33.3	0.00	100.0
Cycle 8 Day 22	70	15.24	26.43	0.0	0.00	100.0	65	2.56	21.50	-33.3	0.00	100.0
Cycle 9 Day 1	72	14.35	25.53	0.0	0.00	100.0	66	2.02	20.15	-33.3	0.00	100.0
Cycle 9 Day 22	54	20.99	29.17	0.0	0.00	100.0	50	10.67	27.31	-33.3	0.00	100.0
Cycle 10 Day 1	58	16.09	25.93	0.0	0.00	100.0	53	5.66	25.09	-33.3	0.00	100.0
Cycle 10 Day 22	47	14.18	24.81	0.0	0.00	100.0	44	4.55	22.26	-33.3	0.00	100.0
Cycle 11 Day 1	50	14.00	25.28	0.0	0.00	100.0	46	4.35	26.86	-66.7	0.00	100.0
Cycle 11 Day 22	35	15.24	24.71	0.0	0.00	100.0	32	4.17	20.30	-33.3	0.00	66.7
Cycle 12 Day 1	43	17.05	27.58	0.0	0.00	100.0	39	3.42	26.26	-66.7	0.00	100.0
Cycle 12 Day 22	31	21.51	27.95	0.0	0.00	100.0	29	11.49	27.13	-33.3	0.00	100.0
Cycle 13 Day 1	37	12.61	22.70	0.0	0.00	100.0	34	3.92	19.70	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	15.15	25.13	0.0	0.00	100.0	30	6.67	23.81	-33.3	0.00	66.7
Cycle 14 Day 1	31	12.90	26.77	0.0	0.00	100.0	30	2.22	26.16	-33.3	0.00	100.0
Cycle 14 Day 22	24	16.67	21.98	0.0	0.00	66.7	24	9.72	25.02	-33.3	0.00	66.7
Cycle 15 Day 1	26	11.54	22.98	0.0	0.00	100.0	26	2.56	29.70	-66.7	0.00	100.0
Cycle 15 Day 22	21	17.46	29.10	0.0	0.00	100.0	21	9.52	30.08	-33.3	0.00	100.0
Cycle 16 Day 1	25	10.67	18.56	0.0	0.00	66.7	25	4.00	20.00	-33.3	0.00	33.3
Cycle 16 Day 22	19	12.28	22.80	0.0	0.00	66.7	19	1.75	26.00	-66.7	0.00	66.7
Cycle 17 Day 1	19	8.77	18.73	0.0	0.00	66.7	19	-1.75	26.00	-66.7	0.00	33.3
Cycle 17 Day 22	14	19.05	25.20	0.0	0.00	66.7	14	4.76	31.64	-66.7	0.00	66.7
Cycle 18 Day 1	16	8.33	14.91	0.0	0.00	33.3	16	-4.17	20.64	-33.3	0.00	33.3
Cycle 18 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 19 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 19 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 20 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 21 Day 1	11	18.18	31.14	0.0	0.00	100.0	11	6.06	20.10	-33.3	0.00	33.3
Study Disc 1	132	32.58	34.82	0.0	33.33	100.0	125	19.73	34.16	-100.0	0.00	100.0
30 D SFU Z/P	69	23.19	29.87	0.0	0.00	100.0	64	14.58	28.41	-33.3	0.00	100.0
90 D SFU Z/P	83	25.70	29.14	0.0	33.33	100.0	80	15.42	29.02	-33.3	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	11.54	22.07	0.0	0.00	100.0						
Cycle 1 Day 22	211	19.27	27.16	0.0	0.00	100.0	208	8.17	27.46	-100.0	0.00	100.0
Cycle 2 Day 1	230	15.80	24.06	0.0	0.00	100.0	223	4.19	28.69	-100.0	0.00	100.0
Cycle 2 Day 22	185	22.16	27.28	0.0	0.00	100.0	180	10.56	31.01	-100.0	0.00	100.0
Cycle 3 Day 1	203	19.70	25.59	0.0	0.00	100.0	196	9.35	30.53	-100.0	0.00	100.0
Cycle 3 Day 22	156	24.57	28.11	0.0	33.33	100.0	148	13.51	31.31	-100.0	0.00	100.0
Cycle 4 Day 1	170	25.10	28.51	0.0	33.33	100.0	161	15.94	34.78	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	27.78	30.31	0.0	33.33	100.0	126	16.14	35.21	-100.0	0.00	100.0
Cycle 5 Day 1	147	24.04	27.25	0.0	33.33	100.0	142	15.26	30.14	-100.0	0.00	100.0
Cycle 5 Day 22	119	23.81	28.50	0.0	0.00	100.0	112	16.07	30.67	-100.0	0.00	100.0
Cycle 6 Day 1	121	22.04	26.72	0.0	0.00	100.0	116	14.94	26.50	-33.3	0.00	100.0
Cycle 6 Day 22	92	18.84	25.34	0.0	0.00	100.0	88	10.61	29.27	-100.0	0.00	100.0
Cycle 7 Day 1	91	13.92	22.81	0.0	0.00	100.0	88	7.58	23.01	-66.7	0.00	66.7
Cycle 7 Day 22	66	16.16	22.07	0.0	0.00	100.0	64	10.42	24.40	-33.3	0.00	66.7
Cycle 8 Day 1	71	15.02	23.09	0.0	0.00	100.0	70	10.00	21.50	-33.3	0.00	66.7
Cycle 8 Day 22	56	16.07	22.01	0.0	0.00	100.0	54	11.73	21.63	-33.3	0.00	66.7
Cycle 9 Day 1	53	15.09	28.17	0.0	0.00	100.0	51	10.46	27.88	-33.3	0.00	100.0
Cycle 9 Day 22	46	13.04	26.74	0.0	0.00	100.0	44	7.58	24.76	-33.3	0.00	100.0
Cycle 10 Day 1	47	9.93	18.28	0.0	0.00	66.7	45	6.67	19.59	-33.3	0.00	66.7
Cycle 10 Day 22	35	10.48	19.42	0.0	0.00	66.7	34	7.84	20.20	-33.3	0.00	66.7
Cycle 11 Day 1	37	6.31	15.39	0.0	0.00	66.7	35	3.81	17.66	-33.3	0.00	66.7
Cycle 11 Day 22	22	9.09	23.42	0.0	0.00	100.0	20	8.33	26.21	-33.3	0.00	100.0
Cycle 12 Day 1	32	9.37	19.37	0.0	0.00	66.7	30	6.67	18.36	-33.3	0.00	66.7
Cycle 12 Day 22	20	15.00	22.88	0.0	0.00	66.7	18	11.11	25.57	-33.3	0.00	66.7
Cycle 13 Day 1	25	9.33	24.57	0.0	0.00	100.0	24	6.94	24.04	-33.3	0.00	100.0
Cycle 13 Day 22	15	22.22	29.99	0.0	0.00	100.0	14	19.05	31.25	0.0	0.00	100.0
Cycle 14 Day 1	23	14.49	26.26	0.0	0.00	100.0	22	10.61	26.00	-33.3	0.00	100.0
Cycle 14 Day 22	13	17.95	25.88	0.0	0.00	66.7	12	13.89	26.43	0.0	0.00	66.7
Cycle 15 Day 1	19	10.53	22.37	0.0	0.00	66.7	19	7.02	21.02	-33.3	0.00	66.7
Cycle 16 Day 1	11	12.12	22.47	0.0	0.00	66.7	11	12.12	22.47	0.0	0.00	66.7
Cycle 17 Day 1	10	13.33	23.31	0.0	0.00	66.7	10	13.33	23.31	0.0	0.00	66.7
Study Disc 1	137	26.76	31.79	0.0	33.33	100.0	133	14.04	34.87	-100.0	0.00	100.0
Study Disc 2	10	20.00	35.83	0.0	0.00	100.0	9	22.22	37.27	0.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	23.05	26.69	0.0	33.33	100.0	78	14.10	32.91	-100.0	0.00	100.0
90 D SFU Z/P	71	21.60	28.23	0.0	0.00	100.0	69	11.59	32.25	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	22.57	29.62	0.0	0.00	100.0						
Cycle 1 Day 22	186	26.70	28.54	0.0	33.33	100.0	176	3.60	25.06	-100.0	0.00	66.7
Cycle 2 Day 1	216	25.31	29.94	0.0	33.33	100.0	206	3.56	26.91	-66.7	0.00	100.0
Cycle 2 Day 22	157	26.11	29.07	0.0	33.33	100.0	150	5.11	26.96	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.33	26.25	0.0	33.33	100.0	190	4.21	25.54	-100.0	0.00	66.7
Cycle 3 Day 22	161	29.61	29.11	0.0	33.33	100.0	152	7.46	25.21	-66.7	0.00	100.0
Cycle 4 Day 1	177	23.16	27.70	0.0	33.33	100.0	169	1.58	24.07	-66.7	0.00	66.7
Cycle 4 Day 22	127	28.61	29.61	0.0	33.33	100.0	122	9.29	27.53	-66.7	0.00	100.0
Cycle 5 Day 1	155	27.10	28.63	0.0	33.33	100.0	147	6.12	28.14	-66.7	0.00	100.0
Cycle 5 Day 22	113	29.50	28.44	0.0	33.33	100.0	106	6.60	30.31	-100.0	0.00	100.0
Cycle 6 Day 1	124	25.54	28.86	0.0	33.33	100.0	115	5.80	30.67	-100.0	0.00	100.0
Cycle 6 Day 22	102	22.55	25.76	0.0	33.33	100.0	97	2.41	26.89	-100.0	0.00	100.0
Cycle 7 Day 1	110	20.61	27.08	0.0	0.00	100.0	104	0.32	28.82	-66.7	0.00	100.0
Cycle 7 Day 22	80	24.17	24.86	0.0	33.33	100.0	74	3.60	28.97	-66.7	0.00	100.0
Cycle 8 Day 1	81	20.16	23.97	0.0	0.00	100.0	74	-1.80	27.53	-100.0	0.00	100.0
Cycle 8 Day 22	70	24.76	28.20	0.0	33.33	100.0	65	-0.51	30.90	-100.0	0.00	66.7
Cycle 9 Day 1	72	19.91	22.14	0.0	33.33	100.0	66	-4.55	30.32	-100.0	0.00	66.7
Cycle 9 Day 22	54	21.60	26.03	0.0	16.67	100.0	50	-2.00	32.58	-100.0	0.00	100.0
Cycle 10 Day 1	58	20.11	24.93	0.0	0.00	100.0	53	-1.89	34.23	-100.0	0.00	100.0
Cycle 10 Day 22	47	19.15	26.69	0.0	0.00	100.0	44	-1.52	31.30	-100.0	0.00	100.0
Cycle 11 Day 1	50	18.67	27.90	0.0	0.00	100.0	46	-4.35	34.14	-100.0	0.00	100.0
Cycle 11 Day 22	35	18.10	21.91	0.0	0.00	66.7	32	-10.42	29.86	-100.0	0.00	33.3
Cycle 12 Day 1	43	20.16	25.34	0.0	0.00	100.0	39	-3.42	29.41	-100.0	0.00	66.7
Cycle 12 Day 22	31	20.43	26.77	0.0	0.00	100.0	29	-1.15	35.05	-100.0	0.00	66.7
Cycle 13 Day 1	37	18.02	23.03	0.0	0.00	100.0	34	-3.92	31.53	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	16.16	20.62	0.0	0.00	66.7	30	-6.67	29.56	-100.0	0.00	33.3
Cycle 14 Day 1	31	17.20	25.63	0.0	0.00	100.0	30	-5.56	30.43	-100.0	0.00	66.7
Cycle 14 Day 22	24	22.22	28.94	0.0	0.00	100.0	24	0.00	34.05	-100.0	0.00	66.7
Cycle 15 Day 1	26	15.38	25.35	0.0	0.00	100.0	26	-3.85	28.79	-100.0	0.00	66.7
Cycle 15 Day 22	21	14.29	22.54	0.0	0.00	66.7	21	-9.52	31.87	-100.0	0.00	33.3
Cycle 16 Day 1	25	12.00	18.95	0.0	0.00	66.7	25	-8.00	27.69	-100.0	0.00	33.3
Cycle 16 Day 22	19	14.04	20.23	0.0	0.00	66.7	19	-10.53	29.51	-100.0	0.00	33.3
Cycle 17 Day 1	19	15.79	28.04	0.0	0.00	100.0	19	-7.02	36.14	-100.0	0.00	66.7
Cycle 17 Day 22	14	19.05	31.25	0.0	0.00	100.0	14	-2.38	35.72	-33.3	0.00	66.7
Cycle 18 Day 1	16	10.42	20.07	0.0	0.00	66.7	16	-10.42	20.07	-33.3	0.00	33.3
Cycle 18 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	-16.67	17.57	-33.3	-16.67	0.0
Cycle 19 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-10.26	21.01	-33.3	0.00	33.3
Cycle 19 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-15.15	17.41	-33.3	0.00	0.0
Cycle 20 Day 1	13	10.26	21.01	0.0	0.00	66.7	13	-5.13	26.69	-33.3	0.00	66.7
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-9.09	15.57	-33.3	0.00	0.0
Study Disc 1	132	33.59	32.56	0.0	33.33	100.0	125	10.93	31.33	-100.0	0.00	100.0
30 D SFU Z/P	69	30.43	30.65	0.0	33.33	100.0	64	9.90	29.50	-100.0	0.00	100.0
90 D SFU Z/P	83	29.72	29.45	0.0	33.33	100.0	80	7.50	33.11	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	24.90	30.80	0.0	0.00	100.0						
Cycle 1 Day 22	211	24.17	28.73	0.0	33.33	100.0	208	-0.96	26.60	-100.0	0.00	100.0
Cycle 2 Day 1	230	24.78	29.21	0.0	33.33	100.0	223	0.00	31.00	-100.0	0.00	100.0
Cycle 2 Day 22	185	25.41	27.75	0.0	33.33	100.0	180	2.78	30.08	-66.7	0.00	100.0
Cycle 3 Day 1	203	23.15	27.26	0.0	33.33	100.0	196	-0.51	29.33	-100.0	0.00	100.0
Cycle 3 Day 22	156	22.44	25.16	0.0	33.33	100.0	148	-0.90	28.02	-100.0	0.00	100.0
Cycle 4 Day 1	170	20.78	25.37	0.0	0.00	100.0	161	-4.35	28.90	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	21.21	24.81	0.0	0.00	100.0	126	-3.44	26.94	-100.0	0.00	66.7
Cycle 5 Day 1	147	21.54	25.82	0.0	0.00	100.0	142	-2.58	26.06	-100.0	0.00	66.7
Cycle 5 Day 22	119	21.85	26.90	0.0	0.00	100.0	112	-2.08	34.45	-100.0	0.00	66.7
Cycle 6 Day 1	121	22.87	26.54	0.0	33.33	100.0	116	-2.30	28.73	-100.0	0.00	66.7
Cycle 6 Day 22	92	22.10	26.74	0.0	0.00	100.0	88	-4.17	29.39	-66.7	0.00	66.7
Cycle 7 Day 1	91	20.15	25.28	0.0	0.00	100.0	88	-3.79	31.74	-100.0	0.00	66.7
Cycle 7 Day 22	66	18.69	24.90	0.0	0.00	100.0	64	-5.21	33.18	-100.0	0.00	100.0
Cycle 8 Day 1	71	21.13	27.16	0.0	0.00	100.0	70	-3.33	29.57	-100.0	0.00	66.7
Cycle 8 Day 22	56	16.67	21.08	0.0	0.00	66.7	54	-7.41	27.98	-66.7	0.00	33.3
Cycle 9 Day 1	53	12.58	18.75	0.0	0.00	66.7	51	-9.15	30.61	-100.0	0.00	33.3
Cycle 9 Day 22	46	12.32	20.32	0.0	0.00	66.7	44	-12.88	29.83	-100.0	0.00	33.3
Cycle 10 Day 1	47	14.18	21.70	0.0	0.00	66.7	45	-7.41	30.89	-100.0	0.00	66.7
Cycle 10 Day 22	35	10.48	17.66	0.0	0.00	66.7	34	-11.76	29.45	-100.0	0.00	33.3
Cycle 11 Day 1	37	10.81	19.33	0.0	0.00	66.7	35	-8.57	31.67	-100.0	0.00	66.7
Cycle 11 Day 22	22	10.61	18.93	0.0	0.00	66.7	20	-10.00	28.82	-66.7	0.00	33.3
Cycle 12 Day 1	32	15.62	22.38	0.0	0.00	66.7	30	-6.67	28.23	-66.7	0.00	33.3
Cycle 12 Day 22	20	21.67	24.84	0.0	16.67	66.7	18	-7.41	29.27	-66.7	0.00	33.3
Cycle 13 Day 1	25	16.00	21.77	0.0	0.00	66.7	24	-5.56	28.94	-66.7	0.00	33.3
Cycle 13 Day 22	15	17.78	24.77	0.0	0.00	66.7	14	-7.14	26.73	-66.7	0.00	33.3
Cycle 14 Day 1	23	14.49	19.66	0.0	0.00	66.7	22	-9.09	29.42	-66.7	0.00	33.3
Cycle 14 Day 22	13	20.51	21.68	0.0	33.33	66.7	12	-11.11	29.59	-66.7	0.00	33.3
Cycle 15 Day 1	19	14.04	20.23	0.0	0.00	66.7	19	-10.53	33.43	-66.7	0.00	33.3
Cycle 16 Day 1	11	18.18	22.92	0.0	0.00	66.7	11	-3.03	31.46	-66.7	0.00	33.3
Cycle 17 Day 1	10	20.00	23.31	0.0	16.67	66.7	10	0.00	15.71	-33.3	0.00	33.3
Study Disc 1	137	25.79	31.57	0.0	33.33	100.0	133	1.00	34.56	-100.0	0.00	100.0
Study Disc 2	10	30.00	42.89	0.0	0.00	100.0	9	0.00	33.33	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	30.04	28.68	0.0	33.33	100.0	78	5.98	29.79	-66.7	0.00	100.0
90 D SFU Z/P	71	36.15	33.69	0.0	33.33	100.0	69	10.63	29.42	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	23.29	27.09	0.0	33.33	100.0						
	Cycle 1 Day 22	123	29.00	28.93	0.0	33.33	100.0	117	4.84	25.24	-100.0	0.00	66.7
	Cycle 2 Day 1	137	27.49	29.95	0.0	33.33	100.0	132	2.78	26.39	-66.7	0.00	100.0
	Cycle 2 Day 22	104	28.53	30.25	0.0	33.33	100.0	100	4.67	26.39	-100.0	0.00	100.0
	Cycle 3 Day 1	133	25.31	26.32	0.0	33.33	100.0	127	3.15	24.64	-100.0	0.00	66.7
	Cycle 3 Day 22	107	31.15	28.33	0.0	33.33	100.0	102	6.86	23.14	-33.3	0.00	100.0
	Cycle 4 Day 1	112	26.19	29.49	0.0	33.33	100.0	108	2.16	24.23	-66.7	0.00	66.7
	Cycle 4 Day 22	84	32.14	31.24	0.0	33.33	100.0	80	9.58	27.66	-66.7	0.00	100.0
	Cycle 5 Day 1	103	30.10	30.43	0.0	33.33	100.0	98	7.82	29.81	-66.7	0.00	100.0
	Cycle 5 Day 22	74	33.33	29.71	0.0	33.33	100.0	69	10.63	27.71	-33.3	0.00	100.0
	Cycle 6 Day 1	81	26.75	30.92	0.0	33.33	100.0	76	6.58	28.29	-33.3	0.00	100.0
	Cycle 6 Day 22	62	24.73	27.62	0.0	33.33	100.0	59	4.52	25.86	-33.3	0.00	100.0
	Cycle 7 Day 1	70	23.81	29.02	0.0	33.33	100.0	67	1.99	30.08	-66.7	0.00	100.0
	Cycle 7 Day 22	56	26.19	26.75	0.0	33.33	100.0	51	4.58	29.83	-66.7	0.00	100.0
	Cycle 8 Day 1	52	18.59	23.26	0.0	0.00	100.0	48	-2.08	26.99	-100.0	0.00	100.0
	Cycle 8 Day 22	42	24.60	26.61	0.0	33.33	100.0	39	0.00	30.59	-100.0	0.00	66.7
	Cycle 9 Day 1	40	19.17	22.50	0.0	16.67	100.0	36	-6.48	29.62	-100.0	0.00	66.7
	Cycle 9 Day 22	34	24.51	28.79	0.0	33.33	100.0	31	1.08	31.60	-66.7	0.00	100.0
	Cycle 10 Day 1	36	21.30	26.61	0.0	0.00	100.0	33	-4.04	35.12	-100.0	0.00	100.0
	Cycle 10 Day 22	31	22.58	29.04	0.0	0.00	100.0	29	-1.15	36.17	-100.0	0.00	100.0
	Cycle 11 Day 1	31	20.43	29.41	0.0	0.00	100.0	29	-8.05	37.43	-100.0	0.00	100.0
	Cycle 11 Day 22	23	15.94	22.18	0.0	0.00	66.7	21	-15.87	32.69	-100.0	0.00	33.3
	Cycle 12 Day 1	24	19.44	23.91	0.0	16.67	100.0	22	-7.58	34.01	-100.0	0.00	66.7
	Cycle 12 Day 22	20	20.00	27.36	0.0	0.00	100.0	18	-7.41	38.87	-100.0	0.00	66.7
	Cycle 13 Day 1	23	17.39	24.35	0.0	0.00	100.0	22	-7.58	35.53	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	22	16.67	19.92	0.0	0.00	66.7	20	-10.00	32.62	-100.0	0.00	33.3
	Cycle 14 Day 1	19	17.54	28.04	0.0	0.00	100.0	18	-11.11	36.16	-100.0	0.00	66.7
	Cycle 14 Day 22	13	25.64	33.76	0.0	0.00	100.0	13	-2.56	41.86	-100.0	0.00	66.7
	Cycle 15 Day 1	16	18.75	27.13	0.0	0.00	100.0	16	-4.17	34.16	-100.0	0.00	66.7
	Cycle 15 Day 22	14	14.29	21.54	0.0	0.00	66.7	14	-11.90	33.61	-100.0	0.00	33.3
	Cycle 16 Day 1	16	10.42	15.96	0.0	0.00	33.3	16	-12.50	29.50	-100.0	0.00	33.3
	Cycle 16 Day 22	13	15.38	17.30	0.0	0.00	33.3	13	-12.82	32.03	-100.0	0.00	33.3
	Cycle 17 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	-18.18	31.14	-100.0	0.00	0.0
	Study Disc 1	89	36.70	32.58	0.0	33.33	100.0	85	12.94	29.14	-100.0	0.00	100.0
	30 D SFU Z/P	44	32.58	31.74	0.0	33.33	100.0	41	10.57	26.29	-33.3	0.00	100.0
	90 D SFU Z/P	52	34.62	29.49	0.0	33.33	100.0	51	12.42	24.00	-33.3	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	26.02	31.99	0.0	16.67	100.0						
	Cycle 1 Day 22	133	24.56	29.56	0.0	33.33	100.0	131	-1.78	25.26	-100.0	0.00	100.0
	Cycle 2 Day 1	147	25.62	31.95	0.0	0.00	100.0	143	-0.70	31.27	-100.0	0.00	100.0
	Cycle 2 Day 22	117	23.65	28.05	0.0	33.33	100.0	113	1.47	28.66	-66.7	0.00	100.0
	Cycle 3 Day 1	128	22.92	27.35	0.0	16.67	100.0	125	-1.07	28.69	-100.0	0.00	66.7
	Cycle 3 Day 22	102	22.88	25.68	0.0	33.33	100.0	98	-2.04	26.57	-100.0	0.00	66.7
	Cycle 4 Day 1	107	21.81	26.74	0.0	0.00	100.0	102	-4.90	26.70	-66.7	0.00	66.7
	Cycle 4 Day 22	86	20.16	24.13	0.0	0.00	100.0	83	-3.61	24.97	-100.0	0.00	33.3
	Cycle 5 Day 1	95	22.81	27.19	0.0	0.00	100.0	93	-1.79	23.24	-100.0	0.00	33.3
	Cycle 5 Day 22	79	17.72	23.17	0.0	0.00	100.0	75	-7.11	28.63	-100.0	0.00	66.7
	Cycle 6 Day 1	80	22.92	26.83	0.0	33.33	100.0	78	-2.99	27.49	-100.0	0.00	66.7
	Cycle 6 Day 22	61	21.31	26.55	0.0	0.00	100.0	59	-3.95	27.04	-66.7	0.00	66.7
	Cycle 7 Day 1	61	19.13	25.43	0.0	0.00	100.0	58	-4.02	31.27	-100.0	0.00	66.7
	Cycle 7 Day 22	43	16.28	22.27	0.0	0.00	66.7	41	-5.69	31.54	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 8 Day 1	48	21.53	27.06	0.0	0.00	100.0	47	-2.84	29.35	-66.7	0.00	66.7
	Cycle 8 Day 22	36	13.89	21.64	0.0	0.00	66.7	34	-7.84	27.29	-66.7	0.00	33.3
	Cycle 9 Day 1	33	11.11	18.00	0.0	0.00	66.7	31	-8.60	28.50	-66.7	0.00	33.3
	Cycle 9 Day 22	28	9.52	17.82	0.0	0.00	66.7	26	-14.10	23.42	-66.7	0.00	33.3
	Cycle 10 Day 1	30	12.22	18.54	0.0	0.00	66.7	28	-7.14	27.75	-66.7	0.00	66.7
	Cycle 10 Day 22	23	8.70	14.97	0.0	0.00	33.3	22	-7.58	22.84	-66.7	0.00	33.3
	Cycle 11 Day 1	22	10.61	18.93	0.0	0.00	66.7	20	-3.33	28.41	-66.7	0.00	66.7
	Cycle 11 Day 22	14	7.14	14.19	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
	Cycle 12 Day 1	18	11.11	16.17	0.0	0.00	33.3	16	-6.25	21.84	-33.3	0.00	33.3
	Cycle 12 Day 22	11	15.15	17.41	0.0	0.00	33.3	9	-3.70	20.03	-33.3	0.00	33.3
	Cycle 13 Day 1	13	12.82	16.88	0.0	0.00	33.3	12	-5.56	27.83	-66.7	0.00	33.3
	Cycle 14 Day 1	11	15.15	17.41	0.0	0.00	33.3	10	-6.67	30.63	-66.7	0.00	33.3
	Study Disc 1	88	25.76	31.45	0.0	33.33	100.0	85	-0.39	34.31	-100.0	0.00	100.0
	30 D SFU Z/P	46	28.99	28.64	0.0	33.33	100.0	44	2.27	24.27	-66.7	0.00	100.0
	90 D SFU Z/P	41	30.08	31.45	0.0	33.33	100.0	40	6.67	21.62	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	21.25	33.89	0.0	0.00	100.0						
	Cycle 1 Day 22	63	22.22	27.44	0.0	0.00	100.0	59	1.13	24.73	-66.7	0.00	66.7
	Cycle 2 Day 1	79	21.52	29.74	0.0	0.00	100.0	74	4.95	27.96	-66.7	0.00	100.0
	Cycle 2 Day 22	53	21.38	26.23	0.0	0.00	100.0	50	6.00	28.32	-66.7	0.00	66.7
	Cycle 3 Day 1	67	22.39	26.20	0.0	33.33	100.0	63	6.35	27.34	-66.7	0.00	66.7
	Cycle 3 Day 22	54	26.54	30.63	0.0	33.33	100.0	50	8.67	29.21	-66.7	0.00	66.7
	Cycle 4 Day 1	65	17.95	23.63	0.0	0.00	100.0	61	0.55	23.95	-66.7	0.00	33.3
	Cycle 4 Day 22	43	21.71	25.08	0.0	0.00	66.7	42	8.73	27.60	-66.7	0.00	66.7
	Cycle 5 Day 1	52	21.15	23.83	0.0	16.67	66.7	49	2.72	24.38	-66.7	0.00	66.7
	Cycle 5 Day 22	39	22.22	24.58	0.0	33.33	66.7	37	-0.90	33.78	-100.0	0.00	66.7
	Cycle 6 Day 1	43	23.26	24.70	0.0	33.33	100.0	39	4.27	35.19	-100.0	0.00	100.0
	Cycle 6 Day 22	40	19.17	22.50	0.0	0.00	66.7	38	-0.88	28.46	-100.0	0.00	33.3
	Cycle 7 Day 1	40	15.00	22.58	0.0	0.00	100.0	37	-2.70	26.50	-66.7	0.00	66.7
	Cycle 7 Day 22	24	19.44	19.45	0.0	33.33	66.7	23	1.45	27.48	-66.7	0.00	33.3
	Cycle 8 Day 1	29	22.99	25.36	0.0	33.33	100.0	26	-1.28	29.03	-66.7	0.00	33.3
	Cycle 8 Day 22	28	25.00	30.93	0.0	16.67	100.0	26	-1.28	31.95	-100.0	0.00	33.3
	Cycle 9 Day 1	32	20.83	22.00	0.0	33.33	66.7	30	-2.22	31.48	-66.7	0.00	66.7
	Cycle 9 Day 22	20	16.67	20.23	0.0	0.00	66.7	19	-7.02	34.39	-100.0	0.00	33.3
	Cycle 10 Day 1	22	18.18	22.37	0.0	0.00	66.7	20	1.67	33.29	-100.0	0.00	66.7
	Cycle 10 Day 22	16	12.50	20.64	0.0	0.00	66.7	15	-2.22	19.79	-33.3	0.00	33.3
	Cycle 11 Day 1	19	15.79	25.74	0.0	0.00	100.0	17	1.96	27.56	-33.3	0.00	66.7
	Cycle 11 Day 22	12	22.22	21.71	0.0	33.33	66.7	11	0.00	21.08	-33.3	0.00	33.3
	Cycle 12 Day 1	19	21.05	27.69	0.0	0.00	100.0	17	1.96	21.96	-33.3	0.00	33.3
	Cycle 12 Day 22	11	21.21	26.97	0.0	0.00	66.7	11	9.09	26.21	-33.3	0.00	66.7
	Cycle 13 Day 1	14	19.05	21.54	0.0	16.67	66.7	12	2.78	22.29	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	11	15.15	22.92	0.0	0.00	66.7	10	0.00	22.22	-33.3	0.00	33.3
	Cycle 14 Day 1	12	16.67	22.47	0.0	0.00	66.7	12	2.78	17.16	-33.3	0.00	33.3
	Cycle 14 Day 22	11	18.18	22.92	0.0	0.00	66.7	11	3.03	23.35	-33.3	0.00	33.3
	Cycle 15 Day 1	10	10.00	22.50	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Study Disc 1	43	27.13	31.92	0.0	33.33	100.0	40	6.67	35.57	-66.7	0.00	100.0
	30 D SFU Z/P	25	26.67	28.87	0.0	33.33	100.0	23	8.70	35.13	-100.0	0.00	66.7
	90 D SFU Z/P	31	21.51	27.95	0.0	0.00	100.0	29	-1.15	44.08	-100.0	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	22.94	28.65	0.0	0.00	100.0						
	Cycle 1 Day 22	78	23.50	27.45	0.0	16.67	100.0	77	0.43	28.86	-100.0	0.00	66.7
	Cycle 2 Day 1	83	23.29	23.70	0.0	33.33	100.0	80	1.25	30.67	-66.7	0.00	66.7
	Cycle 2 Day 22	68	28.43	27.17	0.0	33.33	100.0	67	4.98	32.44	-66.7	0.00	100.0
	Cycle 3 Day 1	75	23.56	27.28	0.0	33.33	100.0	71	0.47	30.60	-66.7	0.00	100.0
	Cycle 3 Day 22	54	21.60	24.36	0.0	33.33	100.0	50	1.33	30.83	-100.0	0.00	100.0
	Cycle 4 Day 1	63	19.05	22.97	0.0	0.00	100.0	59	-3.39	32.57	-100.0	0.00	100.0
	Cycle 4 Day 22	46	23.19	26.17	0.0	16.67	66.7	43	-3.10	30.70	-100.0	0.00	66.7
	Cycle 5 Day 1	52	19.23	23.19	0.0	0.00	66.7	49	-4.08	30.91	-66.7	0.00	66.7
	Cycle 5 Day 22	40	30.00	31.85	0.0	33.33	100.0	37	8.11	42.60	-100.0	0.00	66.7
	Cycle 6 Day 1	41	22.76	26.29	0.0	33.33	100.0	38	-0.88	31.47	-66.7	0.00	66.7
	Cycle 6 Day 22	31	23.66	27.48	0.0	33.33	100.0	29	-4.60	34.18	-66.7	0.00	66.7
	Cycle 7 Day 1	30	22.22	25.27	0.0	16.67	66.7	30	-3.33	33.16	-66.7	0.00	66.7
	Cycle 7 Day 22	23	23.19	29.19	0.0	33.33	100.0	23	-4.35	36.66	-66.7	0.00	100.0
	Cycle 8 Day 1	23	20.29	27.96	0.0	0.00	100.0	23	-4.35	30.66	-100.0	0.00	33.3
	Cycle 8 Day 22	20	21.67	19.57	0.0	33.33	66.7	20	-6.67	29.81	-66.7	0.00	33.3
	Cycle 9 Day 1	20	15.00	20.16	0.0	0.00	66.7	20	-10.00	34.37	-100.0	0.00	33.3
	Cycle 9 Day 22	18	16.67	23.57	0.0	0.00	66.7	18	-11.11	37.92	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	17	17.65	26.66	0.0	0.00	66.7	17	-7.84	36.38	-100.0	0.00	33.3
	Cycle 10 Day 22	12	13.89	22.29	0.0	0.00	66.7	12	-19.44	38.82	-100.0	0.00	33.3
	Cycle 11 Day 1	15	11.11	20.57	0.0	0.00	66.7	15	-15.56	35.34	-100.0	0.00	33.3
	Cycle 12 Day 1	14	21.43	28.06	0.0	0.00	66.7	14	-7.14	35.03	-66.7	0.00	33.3
	Cycle 13 Day 1	12	19.44	26.43	0.0	0.00	66.7	12	-5.56	31.25	-66.7	0.00	33.3
	Cycle 14 Day 1	12	13.89	22.29	0.0	0.00	66.7	12	-11.11	29.59	-66.7	0.00	33.3
	Cycle 15 Day 1	11	15.15	22.92	0.0	0.00	66.7	11	-12.12	30.81	-66.7	0.00	33.3
	Study Disc 1	49	25.85	32.11	0.0	33.33	100.0	48	3.47	35.22	-66.7	0.00	100.0
	30 D SFU Z/P	35	31.43	29.09	0.0	33.33	100.0	34	10.78	35.51	-66.7	0.00	100.0
	90 D SFU Z/P	30	44.44	35.38	0.0	33.33	100.0	29	16.09	37.40	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.65	17.36	0.0	0.00	100.0						
Cycle 1 Day 22	186	8.42	16.46	0.0	0.00	100.0	176	0.95	21.51	-100.0	0.00	66.7
Cycle 2 Day 1	216	9.10	17.74	0.0	0.00	66.7	206	1.46	21.91	-100.0	0.00	66.7
Cycle 2 Day 22	157	8.49	18.45	0.0	0.00	100.0	150	1.56	19.44	-66.7	0.00	100.0
Cycle 3 Day 1	200	7.33	16.08	0.0	0.00	100.0	190	-0.18	20.72	-100.0	0.00	66.7
Cycle 3 Day 22	161	11.18	20.73	0.0	0.00	100.0	152	3.73	25.02	-66.7	0.00	100.0
Cycle 4 Day 1	177	6.97	14.92	0.0	0.00	66.7	169	-0.59	21.66	-100.0	0.00	66.7
Cycle 4 Day 22	127	8.40	18.29	0.0	0.00	100.0	122	1.64	23.41	-100.0	0.00	100.0
Cycle 5 Day 1	155	10.32	19.94	0.0	0.00	100.0	147	3.63	24.09	-66.7	0.00	100.0
Cycle 5 Day 22	113	8.55	17.69	0.0	0.00	66.7	106	2.20	21.71	-66.7	0.00	66.7
Cycle 6 Day 1	124	6.99	14.89	0.0	0.00	66.7	115	-0.29	18.47	-66.7	0.00	66.7
Cycle 6 Day 22	102	6.86	17.13	0.0	0.00	100.0	97	-1.37	18.58	-66.7	0.00	33.3
Cycle 7 Day 1	110	5.15	13.69	0.0	0.00	66.7	104	-0.32	17.06	-66.7	0.00	33.3
Cycle 7 Day 22	80	6.67	14.43	0.0	0.00	66.7	74	0.45	19.50	-66.7	0.00	66.7
Cycle 8 Day 1	81	7.41	16.67	0.0	0.00	100.0	74	1.35	16.03	-33.3	0.00	33.3
Cycle 8 Day 22	70	5.71	13.87	0.0	0.00	66.7	65	-2.05	15.45	-66.7	0.00	33.3
Cycle 9 Day 1	72	4.63	11.61	0.0	0.00	33.3	66	-2.53	15.81	-66.7	0.00	33.3
Cycle 9 Day 22	54	6.17	13.07	0.0	0.00	33.3	50	0.67	17.16	-66.7	0.00	33.3
Cycle 10 Day 1	58	2.87	9.44	0.0	0.00	33.3	53	-1.89	16.56	-66.7	0.00	33.3
Cycle 10 Day 22	47	2.13	8.24	0.0	0.00	33.3	44	-1.52	14.30	-33.3	0.00	33.3
Cycle 11 Day 1	50	2.67	9.13	0.0	0.00	33.3	46	-0.72	13.13	-33.3	0.00	33.3
Cycle 11 Day 22	35	4.76	14.33	0.0	0.00	66.7	32	-2.08	16.80	-33.3	0.00	33.3
Cycle 12 Day 1	43	1.55	7.10	0.0	0.00	33.3	39	-1.71	10.68	-33.3	0.00	33.3
Cycle 12 Day 22	31	4.30	11.36	0.0	0.00	33.3	29	0.00	15.43	-33.3	0.00	33.3
Cycle 13 Day 1	37	3.60	10.49	0.0	0.00	33.3	34	0.00	16.41	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	5.05	12.14	0.0	0.00	33.3	30	0.00	15.16	-33.3	0.00	33.3
Cycle 14 Day 1	31	4.30	11.36	0.0	0.00	33.3	30	0.00	15.16	-33.3	0.00	33.3
Cycle 14 Day 22	24	4.17	11.26	0.0	0.00	33.3	24	-1.39	15.48	-33.3	0.00	33.3
Cycle 15 Day 1	26	5.13	12.26	0.0	0.00	33.3	26	0.00	16.33	-33.3	0.00	33.3
Cycle 15 Day 22	21	3.17	10.03	0.0	0.00	33.3	21	-3.17	14.55	-33.3	0.00	33.3
Cycle 16 Day 1	25	5.33	12.47	0.0	0.00	33.3	25	0.00	16.67	-33.3	0.00	33.3
Cycle 16 Day 22	19	5.26	12.49	0.0	0.00	33.3	19	-1.75	17.48	-33.3	0.00	33.3
Cycle 17 Day 1	19	5.26	12.49	0.0	0.00	33.3	19	0.00	19.25	-33.3	0.00	33.3
Cycle 17 Day 22	14	7.14	14.19	0.0	0.00	33.3	14	0.00	22.65	-33.3	0.00	33.3
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	0.00	21.08	-33.3	0.00	33.3
Cycle 18 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 19 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
Cycle 19 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	2.56	9.25	0.0	0.00	33.3
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	6.06	13.48	0.0	0.00	33.3
Study Disc 1	132	16.67	28.98	0.0	0.00	100.0	125	9.07	28.20	-33.3	0.00	100.0
30 D SFU Z/P	69	14.98	25.91	0.0	0.00	100.0	64	7.29	25.52	-33.3	0.00	100.0
90 D SFU Z/P	83	10.44	21.42	0.0	0.00	100.0	80	2.92	25.54	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	9.08	20.93	0.0	0.00	100.0						
Cycle 1 Day 22	211	7.27	19.24	0.0	0.00	100.0	208	-2.40	19.65	-100.0	0.00	66.7
Cycle 2 Day 1	230	6.09	16.53	0.0	0.00	100.0	223	-3.44	24.57	-100.0	0.00	100.0
Cycle 2 Day 22	185	7.21	17.26	0.0	0.00	100.0	180	-2.41	24.16	-100.0	0.00	100.0
Cycle 3 Day 1	203	5.25	15.01	0.0	0.00	100.0	196	-2.89	22.59	-100.0	0.00	100.0
Cycle 3 Day 22	156	6.20	15.52	0.0	0.00	100.0	148	-2.25	21.88	-100.0	0.00	66.7
Cycle 4 Day 1	170	5.10	14.05	0.0	0.00	66.7	161	-3.11	21.34	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	6.82	16.85	0.0	0.00	100.0	126	0.26	21.70	-100.0	0.00	66.7
Cycle 5 Day 1	147	4.54	12.73	0.0	0.00	66.7	142	-2.82	19.65	-100.0	0.00	33.3
Cycle 5 Day 22	119	5.32	14.38	0.0	0.00	66.7	112	-2.08	21.59	-100.0	0.00	66.7
Cycle 6 Day 1	121	5.79	15.92	0.0	0.00	100.0	116	-1.15	20.59	-100.0	0.00	66.7
Cycle 6 Day 22	92	2.90	9.44	0.0	0.00	33.3	88	-2.65	19.06	-100.0	0.00	33.3
Cycle 7 Day 1	91	2.56	8.93	0.0	0.00	33.3	88	-2.65	17.67	-100.0	0.00	33.3
Cycle 7 Day 22	66	3.03	12.71	0.0	0.00	66.7	64	-3.12	20.33	-100.0	0.00	66.7
Cycle 8 Day 1	71	2.35	8.59	0.0	0.00	33.3	70	-4.29	16.95	-100.0	0.00	33.3
Cycle 8 Day 22	56	1.19	6.24	0.0	0.00	33.3	54	-6.17	21.55	-100.0	0.00	33.3
Cycle 9 Day 1	53	3.14	9.84	0.0	0.00	33.3	51	-3.92	19.60	-100.0	0.00	33.3
Cycle 9 Day 22	46	2.90	9.50	0.0	0.00	33.3	44	-5.30	20.26	-100.0	0.00	33.3
Cycle 10 Day 1	47	1.42	6.80	0.0	0.00	33.3	45	-4.44	18.26	-100.0	0.00	0.0
Cycle 10 Day 22	35	1.90	7.85	0.0	0.00	33.3	34	-2.94	19.01	-100.0	0.00	33.3
Cycle 11 Day 1	37	2.70	9.22	0.0	0.00	33.3	35	-1.90	19.71	-100.0	0.00	33.3
Cycle 11 Day 22	22	1.52	7.11	0.0	0.00	33.3	20	1.67	7.45	0.0	0.00	33.3
Cycle 12 Day 1	32	1.04	5.89	0.0	0.00	33.3	30	-3.33	18.26	-100.0	0.00	0.0
Cycle 12 Day 22	20	1.67	7.45	0.0	0.00	33.3	18	0.00	0.00	0.0	0.00	0.0
Cycle 13 Day 1	25	1.33	6.67	0.0	0.00	33.3	24	-4.17	20.41	-100.0	0.00	0.0
Cycle 13 Day 22	15	4.44	11.73	0.0	0.00	33.3	14	-4.76	28.81	-100.0	0.00	33.3
Cycle 14 Day 1	23	1.45	6.95	0.0	0.00	33.3	22	-4.55	21.32	-100.0	0.00	0.0
Cycle 14 Day 22	13	5.13	12.52	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
Cycle 15 Day 1	19	0.00	0.00	0.0	0.00	0.0	19	-1.75	7.65	-33.3	0.00	0.0
Cycle 16 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	0.00	0.00	0.0	0.00	0.0
Cycle 17 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
Study Disc 1	137	11.68	24.78	0.0	0.00	100.0	133	1.75	26.37	-100.0	0.00	100.0
Study Disc 2	10	20.00	42.16	0.0	0.00	100.0	9	18.52	37.68	0.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	8.23	20.09	0.0	0.00	100.0	78	-0.43	22.47	-100.0	0.00	66.7
90 D SFU Z/P	71	7.04	17.74	0.0	0.00	100.0	69	0.00	23.57	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	7.63	17.08	0.0	0.00	100.0						
	Cycle 1 Day 22	123	8.67	15.88	0.0	0.00	66.7	117	2.56	20.60	-100.0	0.00	66.7
	Cycle 2 Day 1	137	8.76	17.28	0.0	0.00	66.7	132	0.51	22.93	-100.0	0.00	66.7
	Cycle 2 Day 22	104	8.01	16.42	0.0	0.00	66.7	100	0.00	17.73	-66.7	0.00	66.7
	Cycle 3 Day 1	133	7.02	16.44	0.0	0.00	100.0	127	-0.79	21.19	-100.0	0.00	66.7
	Cycle 3 Day 22	107	11.21	19.93	0.0	0.00	66.7	102	3.92	26.66	-66.7	0.00	66.7
	Cycle 4 Day 1	112	7.14	15.13	0.0	0.00	66.7	108	-0.93	24.73	-100.0	0.00	66.7
	Cycle 4 Day 22	84	8.73	18.74	0.0	0.00	100.0	80	1.25	25.68	-100.0	0.00	100.0
	Cycle 5 Day 1	103	11.00	21.08	0.0	0.00	100.0	98	4.76	26.65	-66.7	0.00	100.0
	Cycle 5 Day 22	74	7.21	15.87	0.0	0.00	66.7	69	2.42	19.23	-33.3	0.00	66.7
	Cycle 6 Day 1	81	6.17	14.05	0.0	0.00	66.7	76	0.88	18.84	-66.7	0.00	66.7
	Cycle 6 Day 22	62	4.30	11.27	0.0	0.00	33.3	59	-0.56	16.94	-33.3	0.00	33.3
	Cycle 7 Day 1	70	3.33	10.07	0.0	0.00	33.3	67	-1.49	17.82	-66.7	0.00	33.3
	Cycle 7 Day 22	56	5.95	14.36	0.0	0.00	66.7	51	0.65	20.54	-66.7	0.00	66.7
	Cycle 8 Day 1	52	7.05	17.88	0.0	0.00	100.0	48	2.08	15.99	-33.3	0.00	33.3
	Cycle 8 Day 22	42	3.17	9.90	0.0	0.00	33.3	39	-1.71	15.20	-33.3	0.00	33.3
	Cycle 9 Day 1	40	4.17	11.16	0.0	0.00	33.3	36	-1.85	15.83	-33.3	0.00	33.3
	Cycle 9 Day 22	34	5.88	12.90	0.0	0.00	33.3	31	1.08	16.06	-33.3	0.00	33.3
	Cycle 10 Day 1	36	2.78	9.34	0.0	0.00	33.3	33	-2.02	14.29	-33.3	0.00	33.3
	Cycle 10 Day 22	31	2.15	8.32	0.0	0.00	33.3	29	-2.30	15.25	-33.3	0.00	33.3
	Cycle 11 Day 1	31	4.30	11.36	0.0	0.00	33.3	29	0.00	15.43	-33.3	0.00	33.3
	Cycle 11 Day 22	23	2.90	9.60	0.0	0.00	33.3	21	-3.17	17.97	-33.3	0.00	33.3
	Cycle 12 Day 1	24	1.39	6.80	0.0	0.00	33.3	22	-3.03	14.21	-33.3	0.00	33.3
	Cycle 12 Day 22	20	3.33	10.26	0.0	0.00	33.3	18	-1.85	17.98	-33.3	0.00	33.3
	Cycle 13 Day 1	23	5.80	12.92	0.0	0.00	33.3	22	1.52	19.18	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	22	6.06	13.16	0.0	0.00	33.3	20	0.00	15.29	-33.3	0.00	33.3
	Cycle 14 Day 1	19	5.26	12.49	0.0	0.00	33.3	18	0.00	19.80	-33.3	0.00	33.3
	Cycle 14 Day 22	13	5.13	12.52	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
	Cycle 15 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	0.00	21.08	-33.3	0.00	33.3
	Cycle 15 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
	Cycle 16 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	-2.08	19.12	-33.3	0.00	33.3
	Cycle 16 Day 22	13	5.13	12.52	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
	Cycle 17 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	0.00	21.08	-33.3	0.00	33.3
	Study Disc 1	89	17.23	28.03	0.0	0.00	100.0	85	9.02	25.92	-33.3	0.00	66.7
	30 D SFU Z/P	44	12.88	25.13	0.0	0.00	100.0	41	4.07	22.60	-33.3	0.00	100.0
	90 D SFU Z/P	52	11.54	21.78	0.0	0.00	100.0	51	4.58	24.06	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	9.76	23.35	0.0	0.00	100.0						
	Cycle 1 Day 22	133	5.01	16.66	0.0	0.00	100.0	131	-5.09	18.71	-100.0	0.00	33.3
	Cycle 2 Day 1	147	4.76	15.11	0.0	0.00	100.0	143	-6.06	25.53	-100.0	0.00	100.0
	Cycle 2 Day 22	117	5.41	15.76	0.0	0.00	100.0	113	-4.42	26.17	-100.0	0.00	100.0
	Cycle 3 Day 1	128	4.43	12.81	0.0	0.00	66.7	125	-4.80	23.07	-100.0	0.00	66.7
	Cycle 3 Day 22	102	3.92	10.79	0.0	0.00	33.3	98	-5.44	20.69	-100.0	0.00	33.3
	Cycle 4 Day 1	107	2.80	9.30	0.0	0.00	33.3	102	-6.54	22.51	-100.0	0.00	33.3
	Cycle 4 Day 22	86	4.65	11.62	0.0	0.00	33.3	83	-2.41	20.68	-100.0	0.00	33.3
	Cycle 5 Day 1	95	2.11	9.49	0.0	0.00	66.7	93	-6.09	20.82	-100.0	0.00	33.3
	Cycle 5 Day 22	79	3.38	11.44	0.0	0.00	66.7	75	-4.44	21.46	-100.0	0.00	33.3
	Cycle 6 Day 1	80	2.50	10.30	0.0	0.00	66.7	78	-4.27	21.05	-100.0	0.00	66.7
	Cycle 6 Day 22	61	2.73	9.22	0.0	0.00	33.3	59	-3.95	21.52	-100.0	0.00	33.3
	Cycle 7 Day 1	61	0.55	4.27	0.0	0.00	33.3	58	-5.17	18.52	-100.0	0.00	0.0
	Cycle 7 Day 22	43	1.55	7.10	0.0	0.00	33.3	41	-5.69	20.95	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 8 Day 1	48	1.39	6.73	0.0	0.00	33.3	47	-5.67	18.80	-100.0	0.00	0.0
	Cycle 8 Day 22	36	1.85	7.74	0.0	0.00	33.3	34	-6.86	25.66	-100.0	0.00	33.3
	Cycle 9 Day 1	33	1.01	5.80	0.0	0.00	33.3	31	-7.53	22.29	-100.0	0.00	0.0
	Cycle 9 Day 22	28	2.38	8.74	0.0	0.00	33.3	26	-7.69	25.49	-100.0	0.00	33.3
	Cycle 10 Day 1	30	0.00	0.00	0.0	0.00	0.0	28	-7.14	22.87	-100.0	0.00	0.0
	Cycle 10 Day 22	23	0.00	0.00	0.0	0.00	0.0	22	-6.06	22.15	-100.0	0.00	0.0
	Cycle 11 Day 1	22	0.00	0.00	0.0	0.00	0.0	20	-6.67	23.20	-100.0	0.00	0.0
	Cycle 11 Day 22	14	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	18	0.00	0.00	0.0	0.00	0.0	16	-6.25	25.00	-100.0	0.00	0.0
	Cycle 12 Day 22	11	0.00	0.00	0.0	0.00	0.0	9	0.00	0.00	0.0	0.00	0.0
	Cycle 13 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	-8.33	28.87	-100.0	0.00	0.0
	Cycle 14 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	-10.00	31.62	-100.0	0.00	0.0
	Study Disc 1	88	8.33	20.37	0.0	0.00	100.0	85	-1.96	23.20	-100.0	0.00	66.7
	30 D SFU Z/P	46	7.25	19.77	0.0	0.00	100.0	44	-3.03	22.53	-100.0	0.00	66.7
	90 D SFU Z/P	41	4.88	11.93	0.0	0.00	33.3	40	-3.33	21.08	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	7.69	17.97	0.0	0.00	100.0						
	Cycle 1 Day 22	63	7.94	17.67	0.0	0.00	100.0	59	-2.26	23.05	-100.0	0.00	66.7
	Cycle 2 Day 1	79	9.70	18.61	0.0	0.00	66.7	74	3.15	20.02	-66.7	0.00	66.7
	Cycle 2 Day 22	53	9.43	22.05	0.0	0.00	100.0	50	4.67	22.35	-33.3	0.00	100.0
	Cycle 3 Day 1	67	7.96	15.45	0.0	0.00	66.7	63	1.06	19.83	-66.7	0.00	66.7
	Cycle 3 Day 22	54	11.11	22.43	0.0	0.00	100.0	50	3.33	21.56	-33.3	0.00	100.0
	Cycle 4 Day 1	65	6.67	14.67	0.0	0.00	66.7	61	0.00	14.91	-33.3	0.00	33.3
	Cycle 4 Day 22	43	7.75	17.57	0.0	0.00	66.7	42	2.38	18.61	-33.3	0.00	66.7
	Cycle 5 Day 1	52	8.97	17.61	0.0	0.00	66.7	49	1.36	17.95	-33.3	0.00	66.7
	Cycle 5 Day 22	39	11.11	20.71	0.0	0.00	66.7	37	1.80	25.99	-66.7	0.00	66.7
	Cycle 6 Day 1	43	8.53	16.42	0.0	0.00	66.7	39	-2.56	17.75	-66.7	0.00	33.3
	Cycle 6 Day 22	40	10.83	23.13	0.0	0.00	100.0	38	-2.63	21.06	-66.7	0.00	33.3
	Cycle 7 Day 1	40	8.33	18.10	0.0	0.00	66.7	37	1.80	15.61	-33.3	0.00	33.3
	Cycle 7 Day 22	24	8.33	14.74	0.0	0.00	33.3	23	0.00	17.41	-33.3	0.00	33.3
	Cycle 8 Day 1	29	8.05	14.52	0.0	0.00	33.3	26	0.00	16.33	-33.3	0.00	33.3
	Cycle 8 Day 22	28	9.52	17.82	0.0	0.00	66.7	26	-2.56	16.12	-66.7	0.00	33.3
	Cycle 9 Day 1	32	5.21	12.30	0.0	0.00	33.3	30	-3.33	16.02	-66.7	0.00	33.3
	Cycle 9 Day 22	20	6.67	13.68	0.0	0.00	33.3	19	0.00	19.25	-66.7	0.00	33.3
	Cycle 10 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	-1.67	20.16	-66.7	0.00	33.3
	Cycle 10 Day 22	16	2.08	8.33	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
	Cycle 11 Day 1	19	0.00	0.00	0.0	0.00	0.0	17	-1.96	8.08	-33.3	0.00	0.0
	Cycle 11 Day 22	12	8.33	20.72	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
	Cycle 12 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Cycle 13 Day 1	14	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	0.00	0.00	0.0	0.00	0.0
	Cycle 14 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	43	15.50	31.16	0.0	0.00	100.0	40	9.17	32.89	-33.3	0.00	100.0
	30 D SFU Z/P	25	18.67	27.35	0.0	0.00	66.7	23	13.04	29.71	-33.3	0.00	66.7
	90 D SFU Z/P	31	8.60	21.03	0.0	0.00	100.0	29	0.00	28.17	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	7.89	15.85	0.0	0.00	66.7						
	Cycle 1 Day 22	78	11.11	22.58	0.0	0.00	100.0	77	2.16	20.48	-33.3	0.00	66.7
	Cycle 2 Day 1	83	8.43	18.66	0.0	0.00	100.0	80	1.25	22.15	-66.7	0.00	66.7
	Cycle 2 Day 22	68	10.29	19.32	0.0	0.00	100.0	67	1.00	20.08	-33.3	0.00	66.7
	Cycle 3 Day 1	75	6.67	18.17	0.0	0.00	100.0	71	0.47	21.45	-33.3	0.00	100.0
	Cycle 3 Day 22	54	10.49	21.30	0.0	0.00	100.0	50	4.00	22.98	-33.3	0.00	66.7
	Cycle 4 Day 1	63	8.99	19.13	0.0	0.00	66.7	59	2.82	17.82	-33.3	0.00	66.7
	Cycle 4 Day 22	46	10.87	23.36	0.0	0.00	100.0	43	5.43	22.92	-33.3	0.00	66.7
	Cycle 5 Day 1	52	8.97	16.32	0.0	0.00	66.7	49	3.40	15.58	-33.3	0.00	33.3
	Cycle 5 Day 22	40	9.17	18.47	0.0	0.00	66.7	37	2.70	21.34	-33.3	0.00	66.7
	Cycle 6 Day 1	41	12.20	22.06	0.0	0.00	100.0	38	5.26	18.22	-33.3	0.00	66.7
	Cycle 6 Day 22	31	3.23	10.02	0.0	0.00	33.3	29	0.00	12.60	-33.3	0.00	33.3
	Cycle 7 Day 1	30	6.67	13.56	0.0	0.00	33.3	30	2.22	14.99	-33.3	0.00	33.3
	Cycle 7 Day 22	23	5.80	19.21	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	66.7
	Cycle 8 Day 1	23	4.35	11.48	0.0	0.00	33.3	23	-1.45	12.22	-33.3	0.00	33.3
	Cycle 8 Day 22	20	0.00	0.00	0.0	0.00	0.0	20	-5.00	12.21	-33.3	0.00	0.0
	Cycle 9 Day 1	20	6.67	13.68	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
	Cycle 9 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	-1.85	7.86	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	17	3.92	11.07	0.0	0.00	33.3	17	0.00	0.00	0.0	0.00	0.0
	Cycle 10 Day 22	12	5.56	12.97	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Cycle 11 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	4.44	11.73	0.0	0.00	33.3
	Cycle 12 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	0.00	0.00	0.0	0.00	0.0
	Cycle 13 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	0.00	0.00	0.0	0.00	0.0
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Study Disc 1	49	17.69	30.51	0.0	0.00	100.0	48	8.33	30.36	-33.3	0.00	100.0
	30 D SFU Z/P	35	9.52	20.72	0.0	0.00	100.0	34	2.94	22.27	-33.3	0.00	66.7
	90 D SFU Z/P	30	10.00	23.41	0.0	0.00	100.0	29	4.60	26.31	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.00	18.24	0.0	0.00	100.0						
Cycle 1 Day 22	186	8.24	17.78	0.0	0.00	100.0	176	1.52	17.75	-66.7	0.00	66.7
Cycle 2 Day 1	216	6.33	14.94	0.0	0.00	100.0	206	-0.49	17.26	-100.0	0.00	66.7
Cycle 2 Day 22	157	4.67	13.85	0.0	0.00	100.0	150	-2.67	19.12	-100.0	0.00	66.7
Cycle 3 Day 1	200	5.17	14.98	0.0	0.00	100.0	190	-1.23	18.90	-100.0	0.00	100.0
Cycle 3 Day 22	161	8.90	16.57	0.0	0.00	66.7	152	2.19	19.81	-66.7	0.00	66.7
Cycle 4 Day 1	177	5.46	13.82	0.0	0.00	66.7	169	-0.99	17.22	-66.7	0.00	66.7
Cycle 4 Day 22	127	6.56	14.57	0.0	0.00	66.7	122	1.09	18.15	-66.7	0.00	66.7
Cycle 5 Day 1	155	7.31	16.24	0.0	0.00	66.7	147	0.45	18.70	-66.7	0.00	66.7
Cycle 5 Day 22	113	7.67	16.67	0.0	0.00	66.7	106	0.00	16.59	-66.7	0.00	66.7
Cycle 6 Day 1	124	6.99	16.06	0.0	0.00	66.7	115	-1.45	18.41	-66.7	0.00	33.3
Cycle 6 Day 22	102	5.56	15.62	0.0	0.00	100.0	97	-1.72	16.92	-66.7	0.00	66.7
Cycle 7 Day 1	110	3.94	12.56	0.0	0.00	66.7	104	-3.21	17.70	-66.7	0.00	33.3
Cycle 7 Day 22	80	7.50	14.98	0.0	0.00	66.7	74	0.00	17.45	-66.7	0.00	33.3
Cycle 8 Day 1	81	7.41	13.94	0.0	0.00	33.3	74	-0.90	19.09	-66.7	0.00	33.3
Cycle 8 Day 22	70	5.71	13.87	0.0	0.00	66.7	65	-2.56	16.98	-66.7	0.00	33.3
Cycle 9 Day 1	72	4.63	11.61	0.0	0.00	33.3	66	-3.54	14.48	-33.3	0.00	33.3
Cycle 9 Day 22	54	5.56	14.11	0.0	0.00	66.7	50	-1.33	17.77	-66.7	0.00	33.3
Cycle 10 Day 1	58	3.45	10.24	0.0	0.00	33.3	53	-1.26	15.96	-66.7	0.00	33.3
Cycle 10 Day 22	47	2.13	8.24	0.0	0.00	33.3	44	-1.52	16.00	-66.7	0.00	33.3
Cycle 11 Day 1	50	3.33	10.10	0.0	0.00	33.3	46	0.00	17.21	-66.7	0.00	33.3
Cycle 11 Day 22	35	5.71	12.75	0.0	0.00	33.3	32	0.00	20.74	-66.7	0.00	33.3
Cycle 12 Day 1	43	4.65	11.69	0.0	0.00	33.3	39	0.00	17.10	-66.7	0.00	33.3
Cycle 12 Day 22	31	3.23	10.02	0.0	0.00	33.3	29	-1.15	18.86	-66.7	0.00	33.3
Cycle 13 Day 1	37	3.60	10.49	0.0	0.00	33.3	34	-0.98	17.38	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	5.05	12.14	0.0	0.00	33.3	30	1.11	20.50	-66.7	0.00	33.3
Cycle 14 Day 1	31	2.15	8.32	0.0	0.00	33.3	30	-2.22	17.36	-66.7	0.00	33.3
Cycle 14 Day 22	24	0.00	0.00	0.0	0.00	0.0	24	-5.56	16.05	-66.7	0.00	0.0
Cycle 15 Day 1	26	3.85	10.86	0.0	0.00	33.3	26	0.00	13.33	-33.3	0.00	33.3
Cycle 15 Day 22	21	1.59	7.27	0.0	0.00	33.3	21	-3.17	10.03	-33.3	0.00	0.0
Cycle 16 Day 1	25	5.33	12.47	0.0	0.00	33.3	25	0.00	13.61	-33.3	0.00	33.3
Cycle 16 Day 22	19	3.51	10.51	0.0	0.00	33.3	19	-1.75	13.49	-33.3	0.00	33.3
Cycle 17 Day 1	19	3.51	10.51	0.0	0.00	33.3	19	-3.51	18.90	-66.7	0.00	33.3
Cycle 17 Day 22	14	9.52	15.63	0.0	0.00	33.3	14	0.00	26.15	-66.7	0.00	33.3
Cycle 18 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	-2.08	22.67	-66.7	0.00	33.3
Cycle 18 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 19 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	5.13	12.52	0.0	0.00	33.3
Cycle 19 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	2.56	9.25	0.0	0.00	33.3
Cycle 21 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Study Disc 1	132	11.87	24.06	0.0	0.00	100.0	125	3.20	24.11	-66.7	0.00	100.0
30 D SFU Z/P	69	10.63	22.50	0.0	0.00	100.0	64	1.56	21.76	-33.3	0.00	66.7
90 D SFU Z/P	83	12.05	19.88	0.0	0.00	100.0	80	2.92	19.98	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	6.10	15.65	0.0	0.00	100.0						
Cycle 1 Day 22	211	5.37	15.35	0.0	0.00	100.0	208	-1.28	16.98	-66.7	0.00	100.0
Cycle 2 Day 1	230	4.49	13.00	0.0	0.00	66.7	223	-1.05	13.93	-66.7	0.00	66.7
Cycle 2 Day 22	185	5.23	15.63	0.0	0.00	100.0	180	-1.30	16.29	-66.7	0.00	100.0
Cycle 3 Day 1	203	5.75	14.64	0.0	0.00	66.7	196	-0.34	15.47	-66.7	0.00	66.7
Cycle 3 Day 22	156	4.27	12.40	0.0	0.00	66.7	148	-2.93	16.46	-66.7	0.00	33.3
Cycle 4 Day 1	170	4.90	12.90	0.0	0.00	66.7	161	-1.86	16.77	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	5.81	13.34	0.0	0.00	66.7	126	-0.26	17.64	-66.7	0.00	33.3
Cycle 5 Day 1	147	4.76	11.70	0.0	0.00	33.3	142	-2.11	15.99	-66.7	0.00	33.3
Cycle 5 Day 22	119	6.44	14.57	0.0	0.00	66.7	112	-0.30	18.17	-66.7	0.00	66.7
Cycle 6 Day 1	121	6.34	14.47	0.0	0.00	66.7	116	0.29	17.85	-66.7	0.00	66.7
Cycle 6 Day 22	92	2.17	8.28	0.0	0.00	33.3	88	-3.41	14.33	-66.7	0.00	33.3
Cycle 7 Day 1	91	2.20	8.32	0.0	0.00	33.3	88	-3.41	13.41	-66.7	0.00	33.3
Cycle 7 Day 22	66	2.02	8.01	0.0	0.00	33.3	64	-3.13	15.39	-66.7	0.00	33.3
Cycle 8 Day 1	71	3.76	12.02	0.0	0.00	66.7	70	-0.95	13.87	-66.7	0.00	33.3
Cycle 8 Day 22	56	4.17	11.12	0.0	0.00	33.3	54	-1.23	14.43	-66.7	0.00	33.3
Cycle 9 Day 1	53	1.89	7.78	0.0	0.00	33.3	51	-3.27	15.28	-66.7	0.00	33.3
Cycle 9 Day 22	46	1.45	6.87	0.0	0.00	33.3	44	-3.79	16.42	-66.7	0.00	33.3
Cycle 10 Day 1	47	0.71	4.86	0.0	0.00	33.3	45	-5.19	15.82	-66.7	0.00	33.3
Cycle 10 Day 22	35	0.95	5.63	0.0	0.00	33.3	34	-4.90	16.68	-66.7	0.00	33.3
Cycle 11 Day 1	37	0.00	0.00	0.0	0.00	0.0	35	-5.71	15.09	-66.7	0.00	0.0
Cycle 11 Day 22	22	3.03	9.81	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 12 Day 1	32	0.00	0.00	0.0	0.00	0.0	30	-2.22	8.46	-33.3	0.00	0.0
Cycle 12 Day 22	20	5.00	12.21	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
Cycle 13 Day 1	25	0.00	0.00	0.0	0.00	0.0	24	-2.78	9.41	-33.3	0.00	0.0
Cycle 13 Day 22	15	2.22	8.61	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
Cycle 14 Day 1	23	1.45	6.95	0.0	0.00	33.3	22	-1.52	7.11	-33.3	0.00	0.0
Cycle 14 Day 22	13	0.00	0.00	0.0	0.00	0.0	12	-5.56	12.97	-33.3	0.00	0.0
Cycle 15 Day 1	19	1.75	7.65	0.0	0.00	33.3	19	-1.75	13.49	-33.3	0.00	33.3
Cycle 16 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
Cycle 17 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
Study Disc 1	137	9.00	19.60	0.0	0.00	100.0	133	2.01	22.00	-66.7	0.00	100.0
Study Disc 2	10	16.67	32.39	0.0	0.00	100.0	9	11.11	37.27	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	6.17	13.03	0.0	0.00	33.3	78	-0.85	16.09	-66.7	0.00	33.3
90 D SFU Z/P	71	7.04	16.82	0.0	0.00	66.7	69	0.97	23.55	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	5.82	15.56	0.0	0.00	100.0						
	Cycle 1 Day 22	123	7.05	16.11	0.0	0.00	100.0	117	1.71	17.42	-66.7	0.00	66.7
	Cycle 2 Day 1	137	5.84	14.52	0.0	0.00	100.0	132	-0.51	18.41	-100.0	0.00	33.3
	Cycle 2 Day 22	104	4.49	13.98	0.0	0.00	100.0	100	-2.67	17.52	-66.7	0.00	33.3
	Cycle 3 Day 1	133	5.26	16.33	0.0	0.00	100.0	127	-1.31	19.43	-100.0	0.00	100.0
	Cycle 3 Day 22	107	9.35	17.01	0.0	0.00	66.7	102	2.94	21.55	-66.7	0.00	66.7
	Cycle 4 Day 1	112	5.95	14.30	0.0	0.00	66.7	108	-0.62	17.64	-66.7	0.00	66.7
	Cycle 4 Day 22	84	6.35	15.06	0.0	0.00	66.7	80	0.42	18.75	-66.7	0.00	66.7
	Cycle 5 Day 1	103	7.12	16.60	0.0	0.00	66.7	98	0.68	19.72	-66.7	0.00	66.7
	Cycle 5 Day 22	74	5.41	14.63	0.0	0.00	66.7	69	-1.45	15.59	-66.7	0.00	33.3
	Cycle 6 Day 1	81	6.58	16.18	0.0	0.00	66.7	76	-1.32	18.41	-66.7	0.00	33.3
	Cycle 6 Day 22	62	5.38	16.19	0.0	0.00	100.0	59	-1.13	18.53	-66.7	0.00	66.7
	Cycle 7 Day 1	70	1.90	7.79	0.0	0.00	33.3	67	-3.98	16.94	-66.7	0.00	33.3
	Cycle 7 Day 22	56	5.95	12.88	0.0	0.00	33.3	51	-0.65	16.98	-66.7	0.00	33.3
	Cycle 8 Day 1	52	5.77	12.73	0.0	0.00	33.3	48	-0.69	18.82	-66.7	0.00	33.3
	Cycle 8 Day 22	42	3.17	9.90	0.0	0.00	33.3	39	-2.56	14.07	-33.3	0.00	33.3
	Cycle 9 Day 1	40	4.17	11.16	0.0	0.00	33.3	36	-1.85	11.11	-33.3	0.00	33.3
	Cycle 9 Day 22	34	5.88	15.29	0.0	0.00	66.7	31	2.15	11.97	-33.3	0.00	33.3
	Cycle 10 Day 1	36	3.70	10.62	0.0	0.00	33.3	33	1.01	13.14	-33.3	0.00	33.3
	Cycle 10 Day 22	31	1.08	5.99	0.0	0.00	33.3	29	-1.15	10.85	-33.3	0.00	33.3
	Cycle 11 Day 1	31	4.30	11.36	0.0	0.00	33.3	29	2.30	15.25	-33.3	0.00	33.3
	Cycle 11 Day 22	23	7.25	14.06	0.0	0.00	33.3	21	3.17	17.97	-33.3	0.00	33.3
	Cycle 12 Day 1	24	6.94	13.83	0.0	0.00	33.3	22	3.03	14.21	-33.3	0.00	33.3
	Cycle 12 Day 22	20	3.33	10.26	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
	Cycle 13 Day 1	23	4.35	11.48	0.0	0.00	33.3	22	1.52	12.50	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	22	4.55	11.71	0.0	0.00	33.3	20	3.33	14.91	-33.3	0.00	33.3
	Cycle 14 Day 1	19	1.75	7.65	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
	Cycle 14 Day 22	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.25	-33.3	0.00	0.0
	Cycle 15 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	2.08	14.75	-33.3	0.00	33.3
	Cycle 15 Day 22	14	0.00	0.00	0.0	0.00	0.0	14	-2.38	8.91	-33.3	0.00	0.0
	Cycle 16 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	2.08	14.75	-33.3	0.00	33.3
	Cycle 16 Day 22	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 17 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Study Disc 1	89	10.86	21.77	0.0	0.00	100.0	85	2.35	24.01	-66.7	0.00	100.0
	30 D SFU Z/P	44	8.33	21.72	0.0	0.00	100.0	41	-1.63	18.18	-33.3	0.00	66.7
	90 D SFU Z/P	52	12.18	18.70	0.0	0.00	66.7	51	3.92	20.71	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	4.47	13.07	0.0	0.00	66.7						
	Cycle 1 Day 22	133	3.26	10.75	0.0	0.00	66.7	131	-1.78	12.62	-66.7	0.00	33.3
	Cycle 2 Day 1	147	3.40	11.53	0.0	0.00	66.7	143	-1.17	11.47	-66.7	0.00	33.3
	Cycle 2 Day 22	117	4.84	14.69	0.0	0.00	100.0	113	-0.29	16.36	-66.7	0.00	100.0
	Cycle 3 Day 1	128	5.47	13.73	0.0	0.00	66.7	125	0.53	15.25	-66.7	0.00	66.7
	Cycle 3 Day 22	102	1.63	7.23	0.0	0.00	33.3	98	-3.74	16.50	-66.7	0.00	33.3
	Cycle 4 Day 1	107	3.12	10.77	0.0	0.00	66.7	102	-1.96	15.43	-66.7	0.00	33.3
	Cycle 4 Day 22	86	4.26	11.20	0.0	0.00	33.3	83	0.00	17.27	-66.7	0.00	33.3
	Cycle 5 Day 1	95	2.46	8.75	0.0	0.00	33.3	93	-2.51	14.10	-66.7	0.00	33.3
	Cycle 5 Day 22	79	5.06	12.04	0.0	0.00	33.3	75	0.44	17.75	-66.7	0.00	33.3
	Cycle 6 Day 1	80	3.75	10.60	0.0	0.00	33.3	78	-1.28	15.61	-66.7	0.00	33.3
	Cycle 6 Day 22	61	2.19	8.32	0.0	0.00	33.3	59	-3.39	13.41	-66.7	0.00	33.3
	Cycle 7 Day 1	61	1.64	7.27	0.0	0.00	33.3	58	-4.02	12.61	-66.7	0.00	0.0
	Cycle 7 Day 22	43	0.78	5.08	0.0	0.00	33.3	41	-4.07	15.27	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 8 Day 1	48	2.78	11.57	0.0	0.00	66.7	47	-2.13	12.82	-66.7	0.00	33.3
	Cycle 8 Day 22	36	1.85	7.74	0.0	0.00	33.3	34	-2.94	12.63	-66.7	0.00	0.0
	Cycle 9 Day 1	33	2.02	8.08	0.0	0.00	33.3	31	-3.23	15.76	-66.7	0.00	33.3
	Cycle 9 Day 22	28	1.19	6.30	0.0	0.00	33.3	26	-3.85	17.20	-66.7	0.00	33.3
	Cycle 10 Day 1	30	0.00	0.00	0.0	0.00	0.0	28	-5.95	15.85	-66.7	0.00	0.0
	Cycle 10 Day 22	23	0.00	0.00	0.0	0.00	0.0	22	-6.06	16.70	-66.7	0.00	0.0
	Cycle 11 Day 1	22	0.00	0.00	0.0	0.00	0.0	20	-6.67	17.44	-66.7	0.00	0.0
	Cycle 11 Day 22	14	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	18	0.00	0.00	0.0	0.00	0.0	16	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 22	11	3.03	10.05	0.0	0.00	33.3	9	3.70	11.11	0.0	0.00	33.3
	Cycle 13 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 14 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	88	5.30	14.19	0.0	0.00	66.7	85	-0.39	18.89	-66.7	0.00	66.7
	30 D SFU Z/P	46	4.35	11.35	0.0	0.00	33.3	44	-0.76	13.43	-66.7	0.00	33.3
	90 D SFU Z/P	41	4.88	14.07	0.0	0.00	66.7	40	0.00	19.97	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	9.16	22.26	0.0	0.00	100.0						
	Cycle 1 Day 22	63	10.58	20.59	0.0	0.00	100.0	59	1.13	18.53	-33.3	0.00	66.7
	Cycle 2 Day 1	79	7.17	15.72	0.0	0.00	66.7	74	-0.45	15.10	-33.3	0.00	66.7
	Cycle 2 Day 22	53	5.03	13.71	0.0	0.00	66.7	50	-2.67	22.17	-100.0	0.00	66.7
	Cycle 3 Day 1	67	4.98	11.97	0.0	0.00	33.3	63	-1.06	17.93	-66.7	0.00	33.3
	Cycle 3 Day 22	54	8.02	15.78	0.0	0.00	66.7	50	0.67	15.78	-33.3	0.00	33.3
	Cycle 4 Day 1	65	4.62	13.01	0.0	0.00	66.7	61	-1.64	16.58	-66.7	0.00	66.7
	Cycle 4 Day 22	43	6.98	13.72	0.0	0.00	33.3	42	2.38	17.10	-33.3	0.00	33.3
	Cycle 5 Day 1	52	7.69	15.64	0.0	0.00	66.7	49	0.00	16.67	-66.7	0.00	33.3
	Cycle 5 Day 22	39	11.97	19.48	0.0	0.00	66.7	37	2.70	18.22	-33.3	0.00	66.7
	Cycle 6 Day 1	43	7.75	16.00	0.0	0.00	66.7	39	-1.71	18.65	-66.7	0.00	33.3
	Cycle 6 Day 22	40	5.83	14.88	0.0	0.00	66.7	38	-2.63	14.25	-33.3	0.00	33.3
	Cycle 7 Day 1	40	7.50	17.68	0.0	0.00	66.7	37	-1.80	19.16	-66.7	0.00	33.3
	Cycle 7 Day 22	24	11.11	18.82	0.0	0.00	66.7	23	1.45	18.74	-33.3	0.00	33.3
	Cycle 8 Day 1	29	10.34	15.69	0.0	0.00	33.3	26	-1.28	19.96	-66.7	0.00	33.3
	Cycle 8 Day 22	28	9.52	17.82	0.0	0.00	66.7	26	-2.56	20.92	-66.7	0.00	33.3
	Cycle 9 Day 1	32	5.21	12.30	0.0	0.00	33.3	30	-5.56	17.69	-33.3	0.00	33.3
	Cycle 9 Day 22	20	5.00	12.21	0.0	0.00	33.3	19	-7.02	23.78	-66.7	0.00	33.3
	Cycle 10 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	-5.00	19.57	-66.7	0.00	33.3
	Cycle 10 Day 22	16	4.17	11.39	0.0	0.00	33.3	15	-2.22	23.46	-66.7	0.00	33.3
	Cycle 11 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	-3.92	20.01	-66.7	0.00	33.3
	Cycle 11 Day 22	12	2.78	9.62	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
	Cycle 12 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	-3.92	20.01	-66.7	0.00	33.3
	Cycle 12 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
	Cycle 13 Day 1	14	2.38	8.91	0.0	0.00	33.3	12	-5.56	23.92	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-3.33	29.19	-66.7	0.00	33.3
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-5.56	23.92	-66.7	0.00	33.3
	Cycle 14 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
	Cycle 15 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Study Disc 1	43	13.95	28.39	0.0	0.00	100.0	40	5.00	24.52	-33.3	0.00	100.0
	30 D SFU Z/P	25	14.67	23.73	0.0	0.00	66.7	23	7.25	26.51	-33.3	0.00	66.7
	90 D SFU Z/P	31	11.83	22.02	0.0	0.00	100.0	29	1.15	18.86	-66.7	0.00	33.3
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	8.96	19.12	0.0	0.00	100.0						
	Cycle 1 Day 22	78	8.97	20.58	0.0	0.00	100.0	77	-0.43	22.62	-66.7	0.00	100.0
	Cycle 2 Day 1	83	6.43	15.14	0.0	0.00	66.7	80	-0.83	17.57	-33.3	0.00	66.7
	Cycle 2 Day 22	68	5.88	17.22	0.0	0.00	100.0	67	-2.99	16.13	-33.3	0.00	33.3
	Cycle 3 Day 1	75	6.22	16.16	0.0	0.00	66.7	71	-1.88	15.82	-33.3	0.00	33.3
	Cycle 3 Day 22	54	9.26	17.63	0.0	0.00	66.7	50	-1.33	16.44	-33.3	0.00	33.3
	Cycle 4 Day 1	63	7.94	15.51	0.0	0.00	66.7	59	-1.69	19.00	-33.3	0.00	33.3
	Cycle 4 Day 22	46	8.70	16.38	0.0	0.00	66.7	43	-0.78	18.53	-33.3	0.00	33.3
	Cycle 5 Day 1	52	8.97	14.93	0.0	0.00	33.3	49	-1.36	19.20	-66.7	0.00	33.3
	Cycle 5 Day 22	40	9.17	18.47	0.0	0.00	66.7	37	-1.80	19.16	-33.3	0.00	66.7
	Cycle 6 Day 1	41	11.38	19.16	0.0	0.00	66.7	38	3.51	21.63	-33.3	0.00	66.7
	Cycle 6 Day 22	31	2.15	8.32	0.0	0.00	33.3	29	-3.45	16.29	-33.3	0.00	33.3
	Cycle 7 Day 1	30	3.33	10.17	0.0	0.00	33.3	30	-2.22	14.99	-33.3	0.00	33.3
	Cycle 7 Day 22	23	4.35	11.48	0.0	0.00	33.3	23	-1.45	15.82	-33.3	0.00	33.3
	Cycle 8 Day 1	23	5.80	12.92	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
	Cycle 8 Day 22	20	8.33	14.81	0.0	0.00	33.3	20	1.67	17.01	-33.3	0.00	33.3
	Cycle 9 Day 1	20	1.67	7.45	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
	Cycle 9 Day 22	18	1.85	7.86	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	17	1.96	8.08	0.0	0.00	33.3	17	-3.92	16.17	-33.3	0.00	33.3
	Cycle 10 Day 22	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
	Cycle 11 Day 1	15	0.00	0.00	0.0	0.00	0.0	15	-4.44	11.73	-33.3	0.00	0.0
	Cycle 12 Day 1	14	0.00	0.00	0.0	0.00	0.0	14	-4.76	12.10	-33.3	0.00	0.0
	Cycle 13 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-5.56	12.97	-33.3	0.00	0.0
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Study Disc 1	49	15.65	25.55	0.0	0.00	100.0	48	6.25	26.32	-66.7	0.00	100.0
	30 D SFU Z/P	35	8.57	14.78	0.0	0.00	33.3	34	-0.98	19.22	-66.7	0.00	33.3
	90 D SFU Z/P	30	10.00	19.87	0.0	0.00	66.7	29	2.30	28.07	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	12.06	19.69	0.0	0.00	100.0						
Cycle 1 Day 22	186	15.23	21.67	0.0	0.00	100.0	176	4.17	23.27	-66.7	0.00	100.0
Cycle 2 Day 1	216	13.89	21.39	0.0	0.00	100.0	206	2.75	23.47	-66.7	0.00	100.0
Cycle 2 Day 22	157	12.53	20.81	0.0	0.00	100.0	150	2.22	20.31	-33.3	0.00	100.0
Cycle 3 Day 1	200	15.50	22.88	0.0	0.00	100.0	190	4.74	26.24	-66.7	0.00	100.0
Cycle 3 Day 22	161	14.49	19.99	0.0	0.00	100.0	152	3.29	24.19	-66.7	0.00	66.7
Cycle 4 Day 1	177	13.18	20.15	0.0	0.00	100.0	169	1.97	23.77	-66.7	0.00	100.0
Cycle 4 Day 22	127	11.02	17.84	0.0	0.00	100.0	122	1.37	18.87	-66.7	0.00	66.7
Cycle 5 Day 1	155	11.61	19.95	0.0	0.00	100.0	147	1.81	20.93	-66.7	0.00	66.7
Cycle 5 Day 22	113	11.21	19.22	0.0	0.00	100.0	106	0.94	20.81	-66.7	0.00	66.7
Cycle 6 Day 1	124	11.02	18.88	0.0	0.00	100.0	115	-0.29	22.29	-66.7	0.00	66.7
Cycle 6 Day 22	102	10.13	16.77	0.0	0.00	66.7	97	-1.03	18.91	-33.3	0.00	66.7
Cycle 7 Day 1	110	11.52	18.85	0.0	0.00	100.0	104	0.32	19.43	-33.3	0.00	100.0
Cycle 7 Day 22	80	9.58	15.18	0.0	0.00	33.3	74	-2.25	18.57	-33.3	0.00	33.3
Cycle 8 Day 1	81	11.93	16.92	0.0	0.00	66.7	74	0.00	20.64	-66.7	0.00	66.7
Cycle 8 Day 22	70	10.48	15.59	0.0	0.00	33.3	65	0.00	15.59	-33.3	0.00	33.3
Cycle 9 Day 1	72	8.80	14.79	0.0	0.00	33.3	66	-3.54	17.67	-33.3	0.00	33.3
Cycle 9 Day 22	54	10.49	19.23	0.0	0.00	100.0	50	0.67	22.83	-33.3	0.00	100.0
Cycle 10 Day 1	58	6.90	13.62	0.0	0.00	33.3	53	-3.14	16.36	-33.3	0.00	33.3
Cycle 10 Day 22	47	7.09	13.79	0.0	0.00	33.3	44	-1.52	16.00	-33.3	0.00	33.3
Cycle 11 Day 1	50	6.67	13.47	0.0	0.00	33.3	46	-1.45	17.15	-33.3	0.00	33.3
Cycle 11 Day 22	35	8.57	16.85	0.0	0.00	66.7	32	0.00	16.93	-33.3	0.00	33.3
Cycle 12 Day 1	43	9.30	19.69	0.0	0.00	100.0	39	-0.85	16.20	-33.3	0.00	33.3
Cycle 12 Day 22	31	5.38	12.46	0.0	0.00	33.3	29	1.15	10.85	-33.3	0.00	33.3
Cycle 13 Day 1	37	7.21	13.91	0.0	0.00	33.3	34	0.98	15.32	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	7.07	13.84	0.0	0.00	33.3	30	2.22	14.99	-33.3	0.00	33.3
Cycle 14 Day 1	31	6.45	13.39	0.0	0.00	33.3	30	0.00	15.16	-33.3	0.00	33.3
Cycle 14 Day 22	24	2.78	9.41	0.0	0.00	33.3	24	-4.17	11.26	-33.3	0.00	0.0
Cycle 15 Day 1	26	10.26	22.65	0.0	0.00	100.0	26	2.56	26.54	-33.3	0.00	100.0
Cycle 15 Day 22	21	4.76	11.95	0.0	0.00	33.3	21	-3.17	14.55	-33.3	0.00	33.3
Cycle 16 Day 1	25	6.67	13.61	0.0	0.00	33.3	25	0.00	16.67	-33.3	0.00	33.3
Cycle 16 Day 22	19	7.02	13.96	0.0	0.00	33.3	19	0.00	15.71	-33.3	0.00	33.3
Cycle 17 Day 1	19	8.77	15.08	0.0	0.00	33.3	19	1.75	17.48	-33.3	0.00	33.3
Cycle 17 Day 22	14	7.14	14.19	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
Cycle 18 Day 1	16	8.33	14.91	0.0	0.00	33.3	16	0.00	17.21	-33.3	0.00	33.3
Cycle 18 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 19 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
Cycle 19 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
Cycle 21 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
Study Disc 1	132	17.42	23.47	0.0	0.00	100.0	125	3.20	25.20	-66.7	0.00	66.7
30 D SFU Z/P	69	16.43	24.67	0.0	0.00	100.0	64	-1.04	29.08	-66.7	0.00	66.7
90 D SFU Z/P	83	14.06	20.24	0.0	0.00	100.0	80	2.50	22.98	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	16.73	22.85	0.0	0.00	100.0						
Cycle 1 Day 22	211	14.06	21.76	0.0	0.00	100.0	208	-3.04	21.14	-66.7	0.00	100.0
Cycle 2 Day 1	230	13.19	19.82	0.0	0.00	100.0	223	-4.19	24.56	-100.0	0.00	66.7
Cycle 2 Day 22	185	13.51	20.94	0.0	0.00	100.0	180	-3.70	27.04	-100.0	0.00	100.0
Cycle 3 Day 1	203	12.32	19.52	0.0	0.00	100.0	196	-5.78	24.12	-100.0	0.00	66.7
Cycle 3 Day 22	156	13.68	21.38	0.0	0.00	100.0	148	-4.28	23.74	-66.7	0.00	66.7
Cycle 4 Day 1	170	11.76	18.99	0.0	0.00	66.7	161	-7.04	23.40	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	13.64	22.92	0.0	0.00	100.0	126	-4.23	23.85	-66.7	0.00	66.7
Cycle 5 Day 1	147	10.88	18.78	0.0	0.00	66.7	142	-5.40	22.33	-66.7	0.00	33.3
Cycle 5 Day 22	119	13.17	20.46	0.0	0.00	100.0	112	-3.57	23.83	-66.7	0.00	66.7
Cycle 6 Day 1	121	12.95	20.35	0.0	0.00	100.0	116	-2.87	23.08	-66.7	0.00	66.7
Cycle 6 Day 22	92	11.23	19.94	0.0	0.00	100.0	88	-5.30	23.10	-66.7	0.00	66.7
Cycle 7 Day 1	91	9.16	17.26	0.0	0.00	66.7	88	-4.17	18.78	-66.7	0.00	33.3
Cycle 7 Day 22	66	5.56	13.82	0.0	0.00	66.7	64	-8.33	19.70	-66.7	0.00	33.3
Cycle 8 Day 1	71	8.92	16.86	0.0	0.00	66.7	70	-3.33	19.78	-66.7	0.00	33.3
Cycle 8 Day 22	56	7.74	16.81	0.0	0.00	66.7	54	-6.79	21.84	-66.7	0.00	33.3
Cycle 9 Day 1	53	12.58	19.86	0.0	0.00	66.7	51	-1.31	24.91	-66.7	0.00	33.3
Cycle 9 Day 22	46	9.42	16.72	0.0	0.00	66.7	44	-3.03	23.64	-66.7	0.00	33.3
Cycle 10 Day 1	47	11.35	21.17	0.0	0.00	66.7	45	-3.70	23.81	-66.7	0.00	33.3
Cycle 10 Day 22	35	12.38	21.52	0.0	0.00	66.7	34	-3.92	26.92	-66.7	0.00	66.7
Cycle 11 Day 1	37	9.01	16.94	0.0	0.00	66.7	35	-5.71	23.55	-66.7	0.00	33.3
Cycle 11 Day 22	22	12.12	21.93	0.0	0.00	66.7	20	0.00	21.63	-33.3	0.00	33.3
Cycle 12 Day 1	32	11.46	23.36	0.0	0.00	100.0	30	-2.22	24.66	-66.7	0.00	33.3
Cycle 12 Day 22	20	13.33	19.94	0.0	0.00	66.7	18	-1.85	21.30	-33.3	0.00	33.3
Cycle 13 Day 1	25	8.00	17.43	0.0	0.00	66.7	24	-8.33	22.52	-66.7	0.00	33.3
Cycle 13 Day 22	15	17.78	27.79	0.0	0.00	100.0	14	-4.76	31.64	-66.7	0.00	33.3
Cycle 14 Day 1	23	14.49	16.90	0.0	0.00	33.3	22	0.00	27.22	-66.7	0.00	33.3
Cycle 14 Day 22	13	15.38	22.01	0.0	0.00	66.7	12	-2.78	26.43	-33.3	0.00	33.3
Cycle 15 Day 1	19	14.04	20.23	0.0	0.00	66.7	19	3.51	21.93	-33.3	0.00	33.3
Cycle 16 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 17 Day 1	10	10.00	16.10	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Study Disc 1	137	16.55	24.63	0.0	0.00	100.0	133	-2.26	25.36	-66.7	0.00	66.7
Study Disc 2	10	20.00	32.20	0.0	0.00	100.0	9	3.70	26.06	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	12.76	20.12	0.0	0.00	66.7	78	-6.41	25.80	-66.7	0.00	66.7
90 D SFU Z/P	71	12.21	18.03	0.0	0.00	66.7	69	-3.86	20.24	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	5.45	14.00	0.0	0.00	66.7						
Cycle 1 Day 22	186	8.06	16.64	0.0	0.00	66.7	176	3.03	19.93	-66.7	0.00	66.7
Cycle 2 Day 1	216	6.33	15.95	0.0	0.00	100.0	206	0.81	16.28	-66.7	0.00	66.7
Cycle 2 Day 22	157	6.58	15.76	0.0	0.00	100.0	150	0.89	16.81	-66.7	0.00	66.7
Cycle 3 Day 1	200	5.00	12.83	0.0	0.00	66.7	190	-0.18	15.52	-66.7	0.00	66.7
Cycle 3 Day 22	161	5.80	13.21	0.0	0.00	66.7	152	0.66	16.93	-66.7	0.00	66.7
Cycle 4 Day 1	177	6.03	13.81	0.0	0.00	66.7	169	0.59	16.05	-33.3	0.00	66.7
Cycle 4 Day 22	127	7.35	18.26	0.0	0.00	100.0	122	2.19	19.04	-33.3	0.00	100.0
Cycle 5 Day 1	155	4.52	12.06	0.0	0.00	66.7	147	-0.68	15.34	-33.3	0.00	66.7
Cycle 5 Day 22	113	6.78	16.76	0.0	0.00	100.0	106	0.94	16.24	-33.3	0.00	66.7
Cycle 6 Day 1	124	5.65	15.75	0.0	0.00	100.0	115	-0.29	16.22	-33.3	0.00	66.7
Cycle 6 Day 22	102	4.90	13.59	0.0	0.00	66.7	97	-1.72	16.92	-33.3	0.00	66.7
Cycle 7 Day 1	110	4.24	13.63	0.0	0.00	100.0	104	-1.28	17.94	-33.3	0.00	100.0
Cycle 7 Day 22	80	5.00	13.10	0.0	0.00	66.7	74	-1.35	16.03	-33.3	0.00	66.7
Cycle 8 Day 1	81	7.41	17.48	0.0	0.00	100.0	74	1.80	20.56	-33.3	0.00	100.0
Cycle 8 Day 22	70	4.29	11.24	0.0	0.00	33.3	65	-2.05	15.45	-33.3	0.00	33.3
Cycle 9 Day 1	72	2.78	9.28	0.0	0.00	33.3	66	-3.03	12.71	-33.3	0.00	33.3
Cycle 9 Day 22	54	3.70	10.57	0.0	0.00	33.3	50	-1.33	15.00	-33.3	0.00	33.3
Cycle 10 Day 1	58	4.60	11.59	0.0	0.00	33.3	53	-0.63	12.21	-33.3	0.00	33.3
Cycle 10 Day 22	47	2.13	8.24	0.0	0.00	33.3	44	-0.76	13.43	-33.3	0.00	33.3
Cycle 11 Day 1	50	4.00	10.94	0.0	0.00	33.3	46	0.72	13.13	-33.3	0.00	33.3
Cycle 11 Day 22	35	1.90	7.85	0.0	0.00	33.3	32	-2.08	14.51	-33.3	0.00	33.3
Cycle 12 Day 1	43	3.10	9.80	0.0	0.00	33.3	39	-1.71	13.13	-33.3	0.00	33.3
Cycle 12 Day 22	31	2.15	8.32	0.0	0.00	33.3	29	-1.15	10.85	-33.3	0.00	33.3
Cycle 13 Day 1	37	3.60	10.49	0.0	0.00	33.3	34	0.00	14.21	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	1.01	5.80	0.0	0.00	33.3	30	-2.22	12.17	-33.3	0.00	33.3
Cycle 14 Day 1	31	2.15	8.32	0.0	0.00	33.3	30	-1.11	13.79	-33.3	0.00	33.3
Cycle 14 Day 22	24	1.39	6.80	0.0	0.00	33.3	24	-1.39	11.95	-33.3	0.00	33.3
Cycle 15 Day 1	26	5.13	12.26	0.0	0.00	33.3	26	1.28	14.85	-33.3	0.00	33.3
Cycle 15 Day 22	21	4.76	11.95	0.0	0.00	33.3	21	1.59	12.81	-33.3	0.00	33.3
Cycle 16 Day 1	25	1.33	6.67	0.0	0.00	33.3	25	-2.67	13.33	-33.3	0.00	33.3
Cycle 16 Day 22	19	1.75	7.65	0.0	0.00	33.3	19	-3.51	15.29	-33.3	0.00	33.3
Cycle 17 Day 1	19	5.26	12.49	0.0	0.00	33.3	19	0.00	15.71	-33.3	0.00	33.3
Cycle 17 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
Cycle 18 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	-2.08	8.33	-33.3	0.00	0.0
Cycle 18 Day 22	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
Cycle 19 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.25	-33.3	0.00	0.0
Cycle 19 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
Cycle 20 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.25	-33.3	0.00	0.0
Cycle 21 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
Study Disc 1	132	12.88	23.53	0.0	0.00	100.0	125	6.13	24.82	-66.7	0.00	100.0
30 D SFU Z/P	69	10.14	20.85	0.0	0.00	100.0	64	2.08	22.91	-66.7	0.00	66.7
90 D SFU Z/P	83	7.23	15.66	0.0	0.00	66.7	80	0.83	19.10	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	5.97	15.28	0.0	0.00	100.0						
Cycle 1 Day 22	211	7.27	17.21	0.0	0.00	100.0	208	1.60	14.56	-66.7	0.00	66.7
Cycle 2 Day 1	230	5.07	14.22	0.0	0.00	100.0	223	-0.75	15.96	-66.7	0.00	66.7
Cycle 2 Day 22	185	6.85	17.41	0.0	0.00	100.0	180	0.93	15.93	-33.3	0.00	66.7
Cycle 3 Day 1	203	4.27	12.11	0.0	0.00	66.7	196	-0.34	15.09	-33.3	0.00	66.7
Cycle 3 Day 22	156	4.91	13.01	0.0	0.00	66.7	148	0.23	15.31	-66.7	0.00	66.7
Cycle 4 Day 1	170	4.90	11.84	0.0	0.00	33.3	161	-0.21	14.67	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	5.05	12.68	0.0	0.00	66.7	126	-0.53	17.88	-66.7	0.00	66.7
Cycle 5 Day 1	147	5.67	15.30	0.0	0.00	100.0	142	1.17	17.94	-66.7	0.00	100.0
Cycle 5 Day 22	119	6.44	16.96	0.0	0.00	100.0	112	1.49	19.70	-66.7	0.00	66.7
Cycle 6 Day 1	121	5.23	14.28	0.0	0.00	66.7	116	1.15	16.41	-66.7	0.00	66.7
Cycle 6 Day 22	92	4.71	12.68	0.0	0.00	66.7	88	0.76	15.14	-66.7	0.00	66.7
Cycle 7 Day 1	91	2.93	9.49	0.0	0.00	33.3	88	0.00	13.37	-66.7	0.00	33.3
Cycle 7 Day 22	66	3.03	11.29	0.0	0.00	66.7	64	0.00	14.55	-66.7	0.00	66.7
Cycle 8 Day 1	71	4.69	12.97	0.0	0.00	66.7	70	3.33	12.88	-33.3	0.00	66.7
Cycle 8 Day 22	56	2.98	11.51	0.0	0.00	66.7	54	1.23	12.89	-33.3	0.00	66.7
Cycle 9 Day 1	53	2.52	8.89	0.0	0.00	33.3	51	0.65	10.52	-33.3	0.00	33.3
Cycle 9 Day 22	46	1.45	6.87	0.0	0.00	33.3	44	0.00	10.17	-33.3	0.00	33.3
Cycle 10 Day 1	47	2.84	9.40	0.0	0.00	33.3	45	0.74	8.67	-33.3	0.00	33.3
Cycle 10 Day 22	35	2.86	9.47	0.0	0.00	33.3	34	0.98	10.00	-33.3	0.00	33.3
Cycle 11 Day 1	37	1.80	7.64	0.0	0.00	33.3	35	0.00	8.08	-33.3	0.00	33.3
Cycle 11 Day 22	22	3.03	9.81	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 12 Day 1	32	2.08	8.20	0.0	0.00	33.3	30	0.00	8.75	-33.3	0.00	33.3
Cycle 12 Day 22	20	5.00	12.21	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
Cycle 13 Day 1	25	2.67	9.23	0.0	0.00	33.3	24	0.00	9.83	-33.3	0.00	33.3
Cycle 13 Day 22	15	2.22	8.61	0.0	0.00	33.3	14	0.00	0.00	0.0	0.00	0.0
Cycle 14 Day 1	23	4.35	11.48	0.0	0.00	33.3	22	3.03	14.21	-33.3	0.00	33.3
Cycle 14 Day 22	13	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
Cycle 15 Day 1	19	1.75	7.65	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
Cycle 16 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
Cycle 17 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Study Disc 1	137	8.03	16.92	0.0	0.00	66.7	133	2.01	20.42	-66.7	0.00	66.7
Study Disc 2	10	16.67	23.57	0.0	0.00	66.7	9	7.41	14.70	0.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	6.17	15.01	0.0	0.00	66.7	78	2.14	15.51	-66.7	0.00	66.7
90 D SFU Z/P	71	6.57	14.50	0.0	0.00	66.7	69	4.35	13.90	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	4.62	12.66	0.0	0.00	66.7						
	Cycle 1 Day 22	123	9.49	17.35	0.0	0.00	66.7	117	5.70	18.20	-33.3	0.00	66.7
	Cycle 2 Day 1	137	6.08	16.28	0.0	0.00	100.0	132	1.77	16.64	-33.3	0.00	66.7
	Cycle 2 Day 22	104	6.09	15.93	0.0	0.00	100.0	100	1.00	15.32	-33.3	0.00	66.7
	Cycle 3 Day 1	133	5.26	13.51	0.0	0.00	66.7	127	0.79	15.41	-33.3	0.00	66.7
	Cycle 3 Day 22	107	6.23	13.84	0.0	0.00	66.7	102	1.96	17.44	-33.3	0.00	66.7
	Cycle 4 Day 1	112	5.65	12.57	0.0	0.00	33.3	108	0.62	15.10	-33.3	0.00	33.3
	Cycle 4 Day 22	84	6.75	16.99	0.0	0.00	100.0	80	1.67	19.05	-33.3	0.00	100.0
	Cycle 5 Day 1	103	4.21	11.12	0.0	0.00	33.3	98	-0.68	15.12	-33.3	0.00	33.3
	Cycle 5 Day 22	74	6.76	16.53	0.0	0.00	100.0	69	0.48	15.65	-33.3	0.00	33.3
	Cycle 6 Day 1	81	4.94	15.01	0.0	0.00	100.0	76	-1.32	15.81	-33.3	0.00	33.3
	Cycle 6 Day 22	62	3.23	11.63	0.0	0.00	66.7	59	-3.95	17.60	-33.3	0.00	66.7
	Cycle 7 Day 1	70	4.29	14.93	0.0	0.00	100.0	67	-1.00	20.08	-33.3	0.00	100.0
	Cycle 7 Day 22	56	5.36	13.89	0.0	0.00	66.7	51	-0.65	16.98	-33.3	0.00	66.7
	Cycle 8 Day 1	52	7.05	17.88	0.0	0.00	100.0	48	1.39	21.70	-33.3	0.00	100.0
	Cycle 8 Day 22	42	2.38	8.69	0.0	0.00	33.3	39	-5.13	14.38	-33.3	0.00	33.3
	Cycle 9 Day 1	40	2.50	8.89	0.0	0.00	33.3	36	-4.63	14.15	-33.3	0.00	33.3
	Cycle 9 Day 22	34	4.90	11.98	0.0	0.00	33.3	31	-1.08	16.06	-33.3	0.00	33.3
	Cycle 10 Day 1	36	3.70	10.62	0.0	0.00	33.3	33	-2.02	14.29	-33.3	0.00	33.3
	Cycle 10 Day 22	31	3.23	10.02	0.0	0.00	33.3	29	-1.15	16.63	-33.3	0.00	33.3
	Cycle 11 Day 1	31	4.30	11.36	0.0	0.00	33.3	29	0.00	15.43	-33.3	0.00	33.3
	Cycle 11 Day 22	23	2.90	9.60	0.0	0.00	33.3	21	-3.17	17.97	-33.3	0.00	33.3
	Cycle 12 Day 1	24	1.39	6.80	0.0	0.00	33.3	22	-3.03	14.21	-33.3	0.00	33.3
	Cycle 12 Day 22	20	3.33	10.26	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Cycle 13 Day 1	23	2.90	9.60	0.0	0.00	33.3	22	-1.52	16.19	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	22	1.52	7.11	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
	Cycle 14 Day 1	19	1.75	7.65	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
	Cycle 14 Day 22	13	2.56	9.25	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
	Cycle 15 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	0.00	17.21	-33.3	0.00	33.3
	Cycle 15 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
	Cycle 16 Day 1	16	0.00	0.00	0.0	0.00	0.0	16	-6.25	13.44	-33.3	0.00	0.0
	Cycle 16 Day 22	13	0.00	0.00	0.0	0.00	0.0	13	-7.69	14.62	-33.3	0.00	0.0
	Cycle 17 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Study Disc 1	89	12.73	22.76	0.0	0.00	100.0	85	7.45	23.22	-33.3	0.00	100.0
	30 D SFU Z/P	44	10.61	21.29	0.0	0.00	100.0	41	4.07	22.60	-33.3	0.00	66.7
	90 D SFU Z/P	52	7.69	15.64	0.0	0.00	66.7	51	2.61	18.67	-33.3	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	4.88	13.94	0.0	0.00	100.0						
	Cycle 1 Day 22	133	6.27	15.43	0.0	0.00	66.7	131	1.53	14.83	-66.7	0.00	66.7
	Cycle 2 Day 1	147	3.85	12.04	0.0	0.00	66.7	143	-1.17	13.94	-66.7	0.00	66.7
	Cycle 2 Day 22	117	4.84	15.33	0.0	0.00	100.0	113	0.29	15.10	-33.3	0.00	66.7
	Cycle 3 Day 1	128	2.60	9.91	0.0	0.00	66.7	125	-0.80	13.02	-33.3	0.00	66.7
	Cycle 3 Day 22	102	4.90	13.59	0.0	0.00	66.7	98	1.02	13.92	-33.3	0.00	66.7
	Cycle 4 Day 1	107	2.18	8.28	0.0	0.00	33.3	102	-0.98	9.90	-33.3	0.00	33.3
	Cycle 4 Day 22	86	3.10	9.74	0.0	0.00	33.3	83	0.40	13.27	-33.3	0.00	33.3
	Cycle 5 Day 1	95	3.51	13.29	0.0	0.00	100.0	93	0.72	13.88	-33.3	0.00	100.0
	Cycle 5 Day 22	79	3.80	14.11	0.0	0.00	100.0	75	0.44	12.84	-33.3	0.00	66.7
	Cycle 6 Day 1	80	3.33	12.55	0.0	0.00	66.7	78	1.28	11.32	-33.3	0.00	66.7
	Cycle 6 Day 22	61	2.19	8.32	0.0	0.00	33.3	59	0.56	7.56	-33.3	0.00	33.3
	Cycle 7 Day 1	61	1.64	7.27	0.0	0.00	33.3	58	1.15	8.75	-33.3	0.00	33.3
	Cycle 7 Day 22	43	0.78	5.08	0.0	0.00	33.3	41	0.00	7.45	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 8 Day 1	48	1.39	6.73	0.0	0.00	33.3	47	0.71	8.48	-33.3	0.00	33.3
	Cycle 8 Day 22	36	0.00	0.00	0.0	0.00	0.0	34	-0.98	5.72	-33.3	0.00	0.0
	Cycle 9 Day 1	33	1.01	5.80	0.0	0.00	33.3	31	1.08	5.99	0.0	0.00	33.3
	Cycle 9 Day 22	28	0.00	0.00	0.0	0.00	0.0	26	0.00	0.00	0.0	0.00	0.0
	Cycle 10 Day 1	30	0.00	0.00	0.0	0.00	0.0	28	0.00	0.00	0.0	0.00	0.0
	Cycle 10 Day 22	23	1.45	6.95	0.0	0.00	33.3	22	1.52	7.11	0.0	0.00	33.3
	Cycle 11 Day 1	22	0.00	0.00	0.0	0.00	0.0	20	0.00	0.00	0.0	0.00	0.0
	Cycle 11 Day 22	14	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	18	0.00	0.00	0.0	0.00	0.0	16	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 22	11	0.00	0.00	0.0	0.00	0.0	9	0.00	0.00	0.0	0.00	0.0
	Cycle 13 Day 1	13	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 14 Day 1	11	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	88	6.06	14.77	0.0	0.00	66.7	85	0.39	18.18	-66.7	0.00	66.7
	30 D SFU Z/P	46	3.62	12.63	0.0	0.00	66.7	44	-2.27	13.25	-66.7	0.00	33.3
	90 D SFU Z/P	41	4.07	11.04	0.0	0.00	33.3	40	1.67	10.54	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	6.96	16.11	0.0	0.00	66.7						
	Cycle 1 Day 22	63	5.29	14.91	0.0	0.00	66.7	59	-2.26	22.20	-66.7	0.00	66.7
	Cycle 2 Day 1	79	6.75	15.45	0.0	0.00	66.7	74	-0.90	15.58	-66.7	0.00	33.3
	Cycle 2 Day 22	53	7.55	15.53	0.0	0.00	66.7	50	0.67	19.62	-66.7	0.00	33.3
	Cycle 3 Day 1	67	4.48	11.45	0.0	0.00	33.3	63	-2.12	15.70	-66.7	0.00	33.3
	Cycle 3 Day 22	54	4.94	11.95	0.0	0.00	33.3	50	-2.00	15.66	-66.7	0.00	33.3
	Cycle 4 Day 1	65	6.67	15.81	0.0	0.00	66.7	61	0.55	17.73	-33.3	0.00	66.7
	Cycle 4 Day 22	43	8.53	20.69	0.0	0.00	100.0	42	3.17	19.21	-33.3	0.00	66.7
	Cycle 5 Day 1	52	5.13	13.82	0.0	0.00	66.7	49	-0.68	15.94	-33.3	0.00	66.7
	Cycle 5 Day 22	39	6.84	17.40	0.0	0.00	66.7	37	1.80	17.47	-33.3	0.00	66.7
	Cycle 6 Day 1	43	6.98	17.15	0.0	0.00	66.7	39	1.71	17.01	-33.3	0.00	66.7
	Cycle 6 Day 22	40	7.50	15.99	0.0	0.00	66.7	38	1.75	15.40	-33.3	0.00	33.3
	Cycle 7 Day 1	40	4.17	11.16	0.0	0.00	33.3	37	-1.80	13.49	-33.3	0.00	33.3
	Cycle 7 Day 22	24	4.17	11.26	0.0	0.00	33.3	23	-2.90	13.90	-33.3	0.00	33.3
	Cycle 8 Day 1	29	8.05	17.03	0.0	0.00	66.7	26	2.56	18.67	-33.3	0.00	66.7
	Cycle 8 Day 22	28	7.14	13.93	0.0	0.00	33.3	26	2.56	16.12	-33.3	0.00	33.3
	Cycle 9 Day 1	32	3.12	9.87	0.0	0.00	33.3	30	-1.11	10.66	-33.3	0.00	33.3
	Cycle 9 Day 22	20	1.67	7.45	0.0	0.00	33.3	19	-1.75	13.49	-33.3	0.00	33.3
	Cycle 10 Day 1	22	6.06	13.16	0.0	0.00	33.3	20	1.67	7.45	0.0	0.00	33.3
	Cycle 10 Day 22	16	0.00	0.00	0.0	0.00	0.0	15	0.00	0.00	0.0	0.00	0.0
	Cycle 11 Day 1	19	3.51	10.51	0.0	0.00	33.3	17	1.96	8.08	0.0	0.00	33.3
	Cycle 11 Day 22	12	0.00	0.00	0.0	0.00	0.0	11	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	19	5.26	12.49	0.0	0.00	33.3	17	0.00	11.79	-33.3	0.00	33.3
	Cycle 12 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	0.00	0.00	0.0	0.00	0.0
	Cycle 13 Day 1	14	4.76	12.10	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	11	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Cycle 14 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Cycle 14 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Study Disc 1	43	13.18	25.34	0.0	0.00	100.0	40	3.33	28.04	-66.7	0.00	100.0
	30 D SFU Z/P	25	9.33	20.46	0.0	0.00	66.7	23	-1.45	23.52	-66.7	0.00	33.3
	90 D SFU Z/P	31	6.45	15.91	0.0	0.00	66.7	29	-2.30	19.78	-66.7	0.00	33.3
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	7.89	17.31	0.0	0.00	66.7						
	Cycle 1 Day 22	78	8.97	19.86	0.0	0.00	100.0	77	1.73	14.20	-33.3	0.00	33.3
	Cycle 2 Day 1	83	7.23	17.30	0.0	0.00	100.0	80	0.00	19.12	-66.7	0.00	66.7
	Cycle 2 Day 22	68	10.29	20.16	0.0	0.00	100.0	67	1.99	17.29	-33.3	0.00	33.3
	Cycle 3 Day 1	75	7.11	14.80	0.0	0.00	66.7	71	0.47	18.25	-33.3	0.00	66.7
	Cycle 3 Day 22	54	4.94	11.95	0.0	0.00	33.3	50	-1.33	17.77	-66.7	0.00	33.3
	Cycle 4 Day 1	63	9.52	15.18	0.0	0.00	33.3	59	1.13	20.50	-66.7	0.00	33.3
	Cycle 4 Day 22	46	8.70	16.38	0.0	0.00	66.7	43	-2.33	24.55	-66.7	0.00	66.7
	Cycle 5 Day 1	52	9.62	17.88	0.0	0.00	66.7	49	2.04	23.97	-66.7	0.00	66.7
	Cycle 5 Day 22	40	11.67	20.74	0.0	0.00	66.7	37	3.60	29.17	-66.7	0.00	66.7
	Cycle 6 Day 1	41	8.94	16.71	0.0	0.00	66.7	38	0.88	23.87	-66.7	0.00	66.7
	Cycle 6 Day 22	31	9.68	17.62	0.0	0.00	66.7	29	1.15	24.37	-66.7	0.00	66.7
	Cycle 7 Day 1	30	5.56	12.63	0.0	0.00	33.3	30	-2.22	19.44	-66.7	0.00	33.3
	Cycle 7 Day 22	23	7.25	17.28	0.0	0.00	66.7	23	0.00	22.47	-66.7	0.00	66.7
	Cycle 8 Day 1	23	11.59	19.09	0.0	0.00	66.7	23	8.70	18.03	0.0	0.00	66.7
	Cycle 8 Day 22	20	8.33	18.34	0.0	0.00	66.7	20	5.00	19.57	-33.3	0.00	66.7
	Cycle 9 Day 1	20	5.00	12.21	0.0	0.00	33.3	20	0.00	15.29	-33.3	0.00	33.3
	Cycle 9 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	0.00	16.17	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 10 Day 1	17	7.84	14.57	0.0	0.00	33.3	17	1.96	14.29	-33.3	0.00	33.3
	Cycle 10 Day 22	12	5.56	12.97	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 11 Day 1	15	4.44	11.73	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
	Cycle 12 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
	Cycle 13 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 14 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	5.56	19.25	-33.3	0.00	33.3
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Study Disc 1	49	11.56	19.90	0.0	0.00	66.7	48	4.86	23.81	-66.7	0.00	66.7
	30 D SFU Z/P	35	9.52	17.29	0.0	0.00	66.7	34	7.84	16.53	0.0	0.00	66.7
	90 D SFU Z/P	30	10.00	17.83	0.0	0.00	66.7	29	8.05	17.03	0.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	29.70	32.47	0.0	33.33	100.0						
Cycle 1 Day 22	186	32.08	32.95	0.0	33.33	100.0	176	0.95	28.60	-66.7	0.00	100.0
Cycle 2 Day 1	216	29.94	31.97	0.0	33.33	100.0	206	-0.65	31.23	-100.0	0.00	100.0
Cycle 2 Day 22	157	29.51	31.12	0.0	33.33	100.0	150	0.00	30.41	-66.7	0.00	100.0
Cycle 3 Day 1	200	26.50	30.13	0.0	33.33	100.0	190	-2.46	31.14	-100.0	0.00	66.7
Cycle 3 Day 22	161	28.57	32.03	0.0	33.33	100.0	152	-1.75	31.59	-100.0	0.00	100.0
Cycle 4 Day 1	177	24.48	29.36	0.0	0.00	100.0	169	-5.72	29.32	-100.0	0.00	100.0
Cycle 4 Day 22	127	27.03	31.35	0.0	33.33	100.0	122	-2.19	32.84	-100.0	0.00	100.0
Cycle 5 Day 1	155	26.67	30.25	0.0	33.33	100.0	147	-2.72	35.22	-100.0	0.00	100.0
Cycle 5 Day 22	113	26.25	29.70	0.0	33.33	100.0	106	-5.03	33.43	-100.0	0.00	100.0
Cycle 6 Day 1	124	22.31	27.46	0.0	0.00	100.0	115	-4.06	30.64	-100.0	0.00	100.0
Cycle 6 Day 22	102	20.92	28.50	0.0	0.00	100.0	97	-6.87	32.96	-100.0	0.00	100.0
Cycle 7 Day 1	110	16.97	26.62	0.0	0.00	100.0	104	-9.62	31.05	-100.0	0.00	66.7
Cycle 7 Day 22	80	19.58	28.41	0.0	0.00	100.0	74	-7.21	33.23	-100.0	0.00	66.7
Cycle 8 Day 1	81	17.28	26.41	0.0	0.00	100.0	74	-9.46	30.98	-100.0	0.00	66.7
Cycle 8 Day 22	70	18.10	25.81	0.0	0.00	100.0	65	-9.74	33.71	-100.0	0.00	66.7
Cycle 9 Day 1	72	12.96	24.10	0.0	0.00	100.0	66	-13.13	30.87	-100.0	0.00	66.7
Cycle 9 Day 22	54	17.28	29.49	0.0	0.00	100.0	50	-8.00	34.05	-100.0	0.00	100.0
Cycle 10 Day 1	58	13.79	26.52	0.0	0.00	100.0	53	-8.18	30.60	-66.7	0.00	66.7
Cycle 10 Day 22	47	13.48	26.61	0.0	0.00	100.0	44	-11.36	29.59	-66.7	0.00	66.7
Cycle 11 Day 1	50	13.33	26.94	0.0	0.00	100.0	46	-11.59	33.12	-66.7	0.00	100.0
Cycle 11 Day 22	35	12.38	25.67	0.0	0.00	100.0	32	-16.67	26.77	-66.7	0.00	33.3
Cycle 12 Day 1	43	13.95	28.39	0.0	0.00	100.0	39	-11.97	31.98	-66.7	0.00	100.0
Cycle 12 Day 22	31	9.68	23.08	0.0	0.00	100.0	29	-12.64	25.84	-66.7	0.00	33.3
Cycle 13 Day 1	37	10.81	23.64	0.0	0.00	100.0	34	-14.71	26.20	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	11.11	27.22	0.0	0.00	100.0	30	-12.22	26.96	-66.7	0.00	66.7
Cycle 14 Day 1	31	13.98	28.25	0.0	0.00	100.0	30	-12.22	28.34	-66.7	0.00	66.7
Cycle 14 Day 22	24	15.28	25.97	0.0	0.00	100.0	24	-9.72	31.82	-66.7	0.00	66.7
Cycle 15 Day 1	26	11.54	24.84	0.0	0.00	100.0	26	-10.26	27.92	-66.7	0.00	66.7
Cycle 15 Day 22	21	11.11	24.34	0.0	0.00	100.0	21	-12.70	26.82	-66.7	0.00	33.3
Cycle 16 Day 1	25	6.67	21.52	0.0	0.00	100.0	25	-18.67	23.73	-66.7	-33.33	33.3
Cycle 16 Day 22	19	15.79	30.16	0.0	0.00	100.0	19	-14.04	33.91	-66.7	-33.33	66.7
Cycle 17 Day 1	19	12.28	25.36	0.0	0.00	100.0	19	-14.04	23.08	-33.3	-33.33	33.3
Cycle 17 Day 22	14	14.29	31.25	0.0	0.00	100.0	14	-9.52	30.46	-33.3	-16.67	66.7
Cycle 18 Day 1	16	10.42	26.44	0.0	0.00	100.0	16	-16.67	24.34	-33.3	-33.33	33.3
Cycle 18 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	-20.00	23.31	-33.3	-33.33	33.3
Cycle 19 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-23.08	16.01	-33.3	-33.33	0.0
Cycle 19 Day 22	11	12.12	22.47	0.0	0.00	66.7	11	-12.12	30.81	-33.3	-33.33	66.7
Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-17.95	22.01	-33.3	-33.33	33.3
Cycle 21 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-18.18	22.92	-33.3	-33.33	33.3
Study Disc 1	132	35.86	33.36	0.0	33.33	100.0	125	5.87	34.41	-100.0	0.00	66.7
30 D SFU Z/P	69	34.78	33.55	0.0	33.33	100.0	64	6.77	32.08	-100.0	0.00	100.0
90 D SFU Z/P	83	24.10	29.59	0.0	0.00	100.0	80	-3.33	38.83	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	34.24	31.38	0.0	33.33	100.0						
Cycle 1 Day 22	211	31.12	32.45	0.0	33.33	100.0	208	-2.72	28.34	-100.0	0.00	100.0
Cycle 2 Day 1	230	26.23	27.74	0.0	33.33	100.0	223	-7.92	28.33	-100.0	0.00	66.7
Cycle 2 Day 22	185	28.29	30.67	0.0	33.33	100.0	180	-6.11	30.41	-100.0	0.00	66.7
Cycle 3 Day 1	203	23.97	28.63	0.0	33.33	100.0	196	-9.35	30.34	-100.0	0.00	66.7
Cycle 3 Day 22	156	24.57	30.79	0.0	0.00	100.0	148	-9.46	29.62	-100.0	0.00	66.7
Cycle 4 Day 1	170	20.00	27.71	0.0	0.00	100.0	161	-13.87	29.71	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	20.45	27.52	0.0	0.00	100.0	126	-12.17	29.09	-100.0	0.00	66.7
Cycle 5 Day 1	147	21.32	28.92	0.0	0.00	100.0	142	-11.50	28.08	-100.0	0.00	66.7
Cycle 5 Day 22	119	19.61	26.19	0.0	0.00	100.0	112	-12.80	32.03	-100.0	0.00	100.0
Cycle 6 Day 1	121	19.28	27.47	0.0	0.00	100.0	116	-10.34	30.27	-100.0	0.00	100.0
Cycle 6 Day 22	92	17.03	26.38	0.0	0.00	100.0	88	-15.91	31.15	-100.0	0.00	33.3
Cycle 7 Day 1	91	12.82	22.65	0.0	0.00	100.0	88	-16.67	28.14	-100.0	0.00	33.3
Cycle 7 Day 22	66	10.10	20.23	0.0	0.00	100.0	64	-20.83	31.15	-100.0	-16.67	33.3
Cycle 8 Day 1	71	14.08	21.57	0.0	0.00	100.0	70	-13.33	26.25	-66.7	0.00	33.3
Cycle 8 Day 22	56	11.90	20.53	0.0	0.00	100.0	54	-16.05	24.86	-100.0	0.00	33.3
Cycle 9 Day 1	53	11.95	21.77	0.0	0.00	100.0	51	-14.38	24.27	-66.7	0.00	33.3
Cycle 9 Day 22	46	8.70	20.41	0.0	0.00	100.0	44	-20.45	27.10	-100.0	0.00	33.3
Cycle 10 Day 1	47	9.22	17.99	0.0	0.00	66.7	45	-17.04	29.83	-100.0	0.00	33.3
Cycle 10 Day 22	35	7.62	16.34	0.0	0.00	66.7	34	-22.55	26.87	-100.0	-33.33	33.3
Cycle 11 Day 1	37	8.11	16.49	0.0	0.00	66.7	35	-17.14	29.56	-100.0	0.00	66.7
Cycle 11 Day 22	22	10.61	23.87	0.0	0.00	100.0	20	-21.67	29.17	-100.0	-33.33	33.3
Cycle 12 Day 1	32	10.42	17.84	0.0	0.00	66.7	30	-18.89	27.24	-100.0	-33.33	33.3
Cycle 12 Day 22	20	13.33	27.36	0.0	0.00	100.0	18	-24.07	33.93	-100.0	-33.33	33.3
Cycle 13 Day 1	25	6.67	13.61	0.0	0.00	33.3	24	-23.61	33.30	-100.0	-16.67	33.3
Cycle 13 Day 22	15	8.89	15.26	0.0	0.00	33.3	14	-26.19	23.31	-66.7	-33.33	0.0
Cycle 14 Day 1	23	5.80	12.92	0.0	0.00	33.3	22	-21.21	31.78	-100.0	0.00	33.3
Cycle 14 Day 22	13	10.26	16.01	0.0	0.00	33.3	12	-25.00	28.87	-100.0	-33.33	0.0
Cycle 15 Day 1	19	8.77	18.73	0.0	0.00	66.7	19	-22.81	35.23	-100.0	-33.33	33.3
Cycle 16 Day 1	11	15.15	22.92	0.0	0.00	66.7	11	-12.12	34.23	-66.7	0.00	33.3
Cycle 17 Day 1	10	10.00	16.10	0.0	0.00	33.3	10	-13.33	28.11	-66.7	0.00	33.3
Study Disc 1	137	25.79	30.52	0.0	33.33	100.0	133	-6.77	34.02	-100.0	0.00	100.0
Study Disc 2	10	36.67	36.68	0.0	33.33	100.0	9	0.00	33.33	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	81	23.05	28.69	0.0	0.00	100.0	78	-10.26	34.11	-100.0	0.00	100.0
90 D SFU Z/P	71	26.29	35.60	0.0	0.00	100.0	69	-8.70	38.20	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	64	15.62	26.54	0.0	0.00	100.0						
Cycle 1 Day 22	61	26.78	33.23	0.0	0.00	100.0	24	11.11	25.38	0.0	0.00	100.0
Cycle 2 Day 1	98	24.15	30.57	0.0	0.00	100.0	38	0.88	27.39	-66.7	0.00	66.7
Cycle 2 Day 22	84	24.60	31.52	0.0	0.00	100.0	33	4.04	32.01	-66.7	0.00	100.0
Cycle 3 Day 1	106	28.93	31.23	0.0	33.33	100.0	34	8.82	26.35	-33.3	0.00	66.7
Cycle 3 Day 22	96	28.82	28.04	0.0	33.33	100.0	29	10.34	25.36	-66.7	0.00	66.7
Cycle 4 Day 1	99	28.28	30.63	0.0	33.33	100.0	31	9.68	23.08	-33.3	0.00	66.7
Cycle 4 Day 22	81	26.75	29.54	0.0	33.33	100.0	26	11.54	22.98	-33.3	0.00	66.7
Cycle 5 Day 1	89	28.09	27.93	0.0	33.33	100.0	27	6.17	24.52	-33.3	0.00	66.7
Cycle 5 Day 22	62	32.80	32.78	0.0	33.33	100.0	19	10.53	27.34	-33.3	0.00	66.7
Cycle 6 Day 1	73	22.83	27.71	0.0	0.00	100.0	23	8.70	25.06	-33.3	0.00	66.7
Cycle 6 Day 22	54	20.99	25.32	0.0	0.00	100.0	16	4.17	23.96	-33.3	0.00	66.7
Cycle 7 Day 1	56	23.21	27.65	0.0	16.67	100.0	15	2.22	23.46	-33.3	0.00	33.3
Cycle 7 Day 22	43	18.60	23.35	0.0	0.00	100.0	16	2.08	19.12	-33.3	0.00	33.3
Cycle 8 Day 1	47	19.86	23.73	0.0	0.00	100.0	18	5.56	17.15	-33.3	0.00	33.3
Cycle 8 Day 22	34	19.61	24.78	0.0	0.00	100.0	11	9.09	15.57	0.0	0.00	33.3
Cycle 9 Day 1	34	17.65	23.55	0.0	0.00	100.0	10	0.00	15.71	-33.3	0.00	33.3
Cycle 9 Day 22	26	26.92	24.98	0.0	33.33	100.0	8	16.67	17.82	0.0	16.67	33.3
Cycle 10 Day 1	28	25.00	28.15	0.0	33.33	100.0	6	16.67	34.96	-33.3	16.67	66.7
Cycle 10 Day 22	21	28.57	32.12	0.0	33.33	100.0	5	20.00	18.26	0.0	33.33	33.3
Cycle 11 Day 1	23	24.64	32.13	0.0	0.00	100.0	7	19.05	17.82	0.0	33.33	33.3
Cycle 11 Day 22	17	21.57	20.21	0.0	33.33	66.7	5	20.00	18.26	0.0	33.33	33.3
Cycle 12 Day 1	19	26.32	28.50	0.0	33.33	100.0	6	22.22	27.22	0.0	16.67	66.7
Cycle 12 Day 22	16	18.75	27.13	0.0	0.00	100.0	5	20.00	44.72	0.0	0.00	100.0
Cycle 13 Day 1	21	17.46	24.99	0.0	0.00	66.7	7	9.52	16.27	0.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	18	24.07	25.06	0.0	33.33	66.7	4	16.67	19.25	0.0	16.67	33.3
Cycle 14 Day 1	17	19.61	23.74	0.0	0.00	66.7	6	11.11	17.21	0.0	0.00	33.3
Cycle 14 Day 22	12	25.00	32.18	0.0	16.67	100.0	4	41.67	41.94	0.0	33.33	100.0
Cycle 15 Day 1	13	28.21	29.96	0.0	33.33	100.0	6	27.78	38.97	0.0	16.67	100.0
Cycle 15 Day 22	10	13.33	23.31	0.0	0.00	66.7	3	22.22	19.25	0.0	33.33	33.3
Cycle 16 Day 1	12	19.44	22.29	0.0	16.67	66.7	4	16.67	19.25	0.0	16.67	33.3
Study Disc 1	56	31.55	30.10	0.0	33.33	100.0	16	20.83	31.91	-33.3	16.67	100.0
30 D SFU Z/P	30	26.67	26.84	0.0	33.33	100.0	5	-13.33	50.55	-100.0	0.00	33.3
90 D SFU Z/P	50	30.67	25.94	0.0	33.33	100.0	13	23.08	34.39	-66.7	33.33	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	66	14.14	29.27	0.0	0.00	100.0						
Cycle 1 Day 22	85	20.78	28.63	0.0	0.00	100.0	41	4.07	29.05	-66.7	0.00	100.0
Cycle 2 Day 1	107	18.69	25.57	0.0	0.00	100.0	43	3.10	28.00	-66.7	0.00	66.7
Cycle 2 Day 22	89	19.48	24.00	0.0	0.00	100.0	29	3.45	24.14	-66.7	0.00	33.3
Cycle 3 Day 1	99	22.22	26.51	0.0	33.33	100.0	37	2.70	30.81	-66.7	0.00	66.7
Cycle 3 Day 22	80	25.42	27.17	0.0	33.33	100.0	28	0.00	27.22	-66.7	0.00	33.3
Cycle 4 Day 1	87	24.14	25.26	0.0	33.33	100.0	30	7.78	34.67	-100.0	0.00	66.7
Cycle 4 Day 22	67	24.38	26.32	0.0	33.33	100.0	22	10.61	21.54	-33.3	0.00	66.7
Cycle 5 Day 1	80	27.50	29.42	0.0	33.33	100.0	24	9.72	26.88	-66.7	0.00	66.7
Cycle 5 Day 22	58	22.41	28.19	0.0	0.00	100.0	16	0.00	38.49	-66.7	0.00	66.7
Cycle 6 Day 1	58	27.59	30.03	0.0	33.33	100.0	18	9.26	29.83	-66.7	0.00	66.7
Cycle 6 Day 22	43	20.93	26.25	0.0	0.00	100.0	12	5.56	42.24	-100.0	0.00	66.7
Cycle 7 Day 1	43	21.71	22.87	0.0	33.33	66.7	12	5.56	34.33	-66.7	0.00	66.7
Cycle 7 Day 22	28	17.86	21.24	0.0	0.00	66.7	7	-4.76	44.84	-100.0	0.00	33.3
Cycle 8 Day 1	32	19.79	23.74	0.0	0.00	66.7	9	-7.41	36.43	-100.0	0.00	33.3
Cycle 8 Day 22	24	13.89	19.45	0.0	0.00	66.7	6	0.00	36.51	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 9 Day 1	22	15.15	26.68	0.0	0.00	100.0	5	-13.33	50.55	-100.0	0.00	33.3
Cycle 9 Day 22	21	9.52	15.43	0.0	0.00	33.3	4	-16.67	57.74	-100.0	0.00	33.3
Cycle 10 Day 1	18	16.67	26.20	0.0	0.00	100.0	4	-16.67	57.74	-100.0	0.00	33.3
Cycle 10 Day 22	12	8.33	15.08	0.0	0.00	33.3	3	-22.22	69.39	-100.0	0.00	33.3
Cycle 11 Day 1	13	15.38	29.24	0.0	0.00	100.0	3	-22.22	69.39	-100.0	0.00	33.3
Cycle 12 Day 1	10	20.00	23.31	0.0	16.67	66.7	2	33.33	0.00	33.3	33.33	33.3
Study Disc 1	58	23.56	27.22	0.0	33.33	100.0	26	6.41	24.98	-66.7	0.00	66.7
30 D SFU Z/P	34	33.33	28.43	0.0	33.33	100.0	10	13.33	17.21	0.0	0.00	33.3
90 D SFU Z/P	40	30.83	31.48	0.0	33.33	100.0	12	16.67	17.41	0.0	16.67	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

Table 301.1.3004.20.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	154 (54.4%)	138 (48.9%)	
Number of patients censored	129 (45.6%)	144 (51.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.9 [1.7, 4.3]	5.3 [4.2, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.285 [1.018, 1.621]
Log-rank test			
Two-sided stratified log-rank p-value			0.0340

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.20.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	96 (53.0)	3.0 [1.4, 4.9]	181	80 (44.2)	8.7 [4.9, 14.3]	1.442 [1.071, 1.942]	0.0155	0.2061
>65 years	102	58 (56.9)	2.9 [1.5, 4.7]	101	58 (57.4)	3.0 [1.4, 4.9]	1.070 [0.743, 1.539]	0.7084	
Sex									
Male	176	90 (51.1)	3.9 [2.6, 5.8]	175	95 (54.3)	4.6 [2.5, 6.4]	1.001 [0.750, 1.335]	0.9899	0.0028
Female	107	64 (59.8)	1.4 [1.0, 2.9]	107	43 (40.2)	11.1 [4.8, 24.3]	2.076 [1.404, 3.071]	0.0002	
Region									
Asia	88	51 (58.0)	3.9 [2.4, 8.0]	89	47 (52.8)	6.1 [3.2, 9.4]	1.118 [0.752, 1.664]	0.5749	0.3083
Non-Asia	195	103 (52.8)	2.3 [1.4, 3.8]	193	91 (47.2)	4.9 [3.5, 10.4]	1.419 [1.069, 1.884]	0.0153	
Number of Organs with Metastatic Sites									
0-2	219	114 (52.1)	3.3 [2.1, 5.1]	219	109 (49.8)	5.3 [4.1, 8.7]	1.219 [0.937, 1.585]	0.1415	0.3151
>=3	64	40 (62.5)	1.7 [1.4, 3.6]	63	29 (46.0)	6.3 [2.2, 11.1]	1.622 [1.003, 2.624]	0.0462	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.21.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	139 (49.1%)	117 (41.5%)	
Number of patients censored	144 (50.9%)	165 (58.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.0, 6.1]	8.0 [5.5, 12.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.237 [0.965, 1.586]
Log-rank test			
Two-sided stratified log-rank p-value			0.0946

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.21.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	87 (48.1)	5.1 [2.3, 7.5]	181	71 (39.2)	11.1 [4.9, 16.3]	1.309 [0.956, 1.792]	0.0918	0.6392
>65 years	102	52 (51.0)	4.9 [2.3, 8.5]	101	46 (45.5)	7.2 [2.2, 14.0]	1.164 [0.782, 1.731]	0.4396	
Sex									
Male	176	89 (50.6)	5.1 [3.0, 6.1]	175	80 (45.7)	7.2 [3.7, 11.1]	1.111 [0.821, 1.502]	0.4899	0.1990
Female	107	50 (46.7)	3.7 [1.4, 8.6]	107	37 (34.6)	16.4 [6.2, NC]	1.581 [1.032, 2.422]	0.0332	
Region									
Asia	88	48 (54.5)	5.7 [3.0, 14.9]	89	39 (43.8)	8.1 [5.5, 16.3]	1.150 [0.751, 1.760]	0.5154	0.7394
Non-Asia	195	91 (46.7)	3.6 [2.3, 6.0]	193	78 (40.4)	8.0 [3.7, 11.1]	1.286 [0.950, 1.741]	0.1030	
Number of Organs with Metastatic Sites									
0-2	219	111 (50.7)	4.9 [2.3, 6.0]	219	93 (42.5)	8.0 [4.4, 15.1]	1.274 [0.967, 1.679]	0.0815	0.7621
>=3	64	28 (43.8)	5.3 [1.5, NC]	63	24 (38.1)	8.0 [4.2, 11.1]	1.185 [0.682, 2.059]	0.5529	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.22.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	137 (48.4%)	126 (44.7%)	
Number of patients censored	146 (51.6%)	156 (55.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.9, 7.8]	7.9 [5.3, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.098 [0.856, 1.408]
Log-rank test			
Two-sided stratified log-rank p-value			0.4626

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.22.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	89 (49.2)	4.7 [3.2, 8.2]	181	74 (40.9)	10.4 [5.3, 15.1]	1.244 [0.912, 1.698]	0.1684	0.2510
>65 years	102	48 (47.1)	5.7 [3.0, 9.2]	101	52 (51.5)	5.6 [3.1, 9.2]	0.950 [0.640, 1.410]	0.7973	
Sex									
Male	176	79 (44.9)	5.8 [4.4, 9.5]	175	85 (48.6)	6.3 [3.9, 9.4]	0.932 [0.686, 1.266]	0.6546	0.0355
Female	107	58 (54.2)	3.1 [2.1, 7.8]	107	41 (38.3)	10.1 [4.4, 31.3]	1.568 [1.045, 2.351]	0.0289	
Region									
Asia	88	51 (58.0)	4.9 [3.0, 9.5]	89	40 (44.9)	8.1 [5.5, 31.3]	1.343 [0.886, 2.038]	0.1654	0.3376
Non-Asia	195	86 (44.1)	5.1 [3.4, 8.3]	193	86 (44.6)	6.4 [3.7, 10.1]	1.018 [0.754, 1.374]	0.9084	
Number of Organs with Metastatic Sites									
0-2	219	114 (52.1)	4.6 [3.1, 6.8]	219	103 (47.0)	7.2 [4.2, 12.3]	1.152 [0.881, 1.506]	0.3002	0.6323
>=3	64	23 (35.9)	8.5 [3.8, NC]	63	23 (36.5)	9.2 [5.5, NC]	0.994 [0.558, 1.774]	0.9811	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.23.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	142 (50.2%)	117 (41.5%)	
Number of patients censored	141 (49.8%)	165 (58.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.6 [3.5, 8.5]	9.2 [6.4, 12.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.247 [0.973, 1.598]
Log-rank test			
Two-sided stratified log-rank p-value			0.0807

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.23.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	92 (50.8)	5.7 [3.2, 8.5]	181	73 (40.3)	10.1 [6.4, 14.3]	1.303 [0.956, 1.776]	0.0924	0.7039
>65 years	102	50 (49.0)	5.1 [1.7, 10.5]	101	44 (43.6)	8.6 [4.6, 18.3]	1.159 [0.772, 1.739]	0.4659	
Sex									
Male	176	86 (48.9)	5.1 [3.3, 8.5]	175	77 (44.0)	8.5 [4.6, 11.1]	1.097 [0.806, 1.494]	0.5420	0.1452
Female	107	56 (52.3)	5.8 [1.8, 10.3]	107	40 (37.4)	12.3 [7.2, 18.4]	1.599 [1.064, 2.403]	0.0228	
Region									
Asia	88	51 (58.0)	4.9 [1.7, 12.3]	89	49 (55.1)	8.1 [3.7, 10.4]	0.990 [0.662, 1.480]	0.9542	0.1553
Non-Asia	195	91 (46.7)	5.9 [3.3, 8.5]	193	68 (35.2)	10.0 [8.0, 19.8]	1.439 [1.051, 1.972]	0.0219	
Number of Organs with Metastatic Sites									
0-2	219	111 (50.7)	5.1 [2.8, 8.5]	219	96 (43.8)	8.6 [6.2, 14.3]	1.187 [0.901, 1.564]	0.2201	0.3516
>=3	64	31 (48.4)	6.2 [1.8, 10.3]	63	21 (33.3)	10.0 [6.2, NC]	1.538 [0.881, 2.684]	0.1276	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.24.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	128 (45.2%)	120 (42.6%)	
Number of patients censored	155 (54.8%)	162 (57.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.8 [4.5, 10.0]	8.5 [5.1, 12.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.023 [0.795, 1.317]
Log-rank test			
Two-sided stratified log-rank p-value			0.8546

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.24.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	84 (46.4)	7.4 [4.4, 10.4]	181	78 (43.1)	7.1 [4.4, 13.4]	1.008 [0.740, 1.373]	0.9597	0.9765
>65 years	102	44 (43.1)	6.5 [3.5, NC]	101	42 (41.6)	9.5 [5.0, 17.4]	1.029 [0.673, 1.572]	0.8887	
Sex									
Male	176	79 (44.9)	6.8 [4.4, 10.1]	175	71 (40.6)	8.8 [5.6, 15.0]	1.104 [0.800, 1.522]	0.5402	0.4433
Female	107	49 (45.8)	7.4 [3.7, 18.9]	107	49 (45.8)	6.3 [3.5, 14.3]	0.896 [0.603, 1.333]	0.5859	
Region									
Asia	88	48 (54.5)	5.7 [3.0, 10.7]	89	43 (48.3)	7.9 [4.0, 18.3]	1.069 [0.705, 1.620]	0.7516	0.8311
Non-Asia	195	80 (41.0)	7.4 [4.4, 10.1]	193	77 (39.9)	8.8 [4.9, 14.0]	0.991 [0.724, 1.355]	0.9608	
Number of Organs with Metastatic Sites									
0-2	219	100 (45.7)	7.4 [4.5, 10.4]	219	97 (44.3)	7.9 [4.7, 13.4]	0.965 [0.729, 1.278]	0.8072	0.4707
>=3	64	28 (43.8)	6.5 [3.0, NC]	63	23 (36.5)	9.3 [5.6, NC]	1.224 [0.705, 2.125]	0.4712	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.25.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	119 (42.0%)	114 (40.4%)	
Number of patients censored	164 (58.0%)	168 (59.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.3 [4.8, 8.1]	6.3 [3.9, 9.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.934 [0.720, 1.212]
Log-rank test			
Two-sided stratified log-rank p-value			0.6090

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.25.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	80 (44.2)	5.7 [3.5, 8.0]	181	68 (37.6)	7.5 [3.6, 12.9]	1.146 [0.827, 1.587]	0.4032	0.0726
>65 years	102	39 (38.2)	8.0 [5.7, NC]	101	46 (45.5)	5.6 [1.7, 12.3]	0.713 [0.464, 1.094]	0.1203	
Sex									
Male	176	65 (36.9)	6.9 [5.1, NC]	175	74 (42.3)	5.5 [2.7, 9.0]	0.755 [0.541, 1.054]	0.1001	0.0179
Female	107	54 (50.5)	5.4 [2.6, 7.5]	107	40 (37.4)	6.5 [3.6, 27.1]	1.401 [0.927, 2.116]	0.1077	
Region									
Asia	88	48 (54.5)	6.6 [3.8, 10.3]	89	42 (47.2)	8.1 [5.5, 16.3]	1.005 [0.660, 1.530]	0.9803	0.5472
Non-Asia	195	71 (36.4)	6.2 [3.9, 9.0]	193	72 (37.3)	4.2 [2.2, 9.0]	0.879 [0.633, 1.221]	0.4489	
Number of Organs with Metastatic Sites									
0-2	219	101 (46.1)	5.8 [3.8, 7.5]	219	91 (41.6)	6.3 [3.6, 12.3]	1.034 [0.778, 1.374]	0.8151	0.1470
>=3	64	18 (28.1)	NC [4.8, NC]	63	23 (36.5)	6.5 [1.6, NC]	0.625 [0.337, 1.159]	0.1330	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.26.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	91 (32.2%)	87 (30.9%)	
Number of patients censored	192 (67.8%)	195 (69.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	26.8 [13.3, NC]	29.1 [12.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.051 [0.782, 1.414]
Log-rank test			
Two-sided stratified log-rank p-value			0.7368

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.26.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	60 (33.1)	26.8 [8.0, NC]	181	51 (28.2)	NC [12.3, NC]	1.194 [0.822, 1.734]	0.3524	0.2793
>65 years	102	31 (30.4)	NC [8.3, NC]	101	36 (35.6)	29.1 [7.4, 29.1]	0.854 [0.528, 1.382]	0.5271	
Sex									
Male	176	63 (35.8)	13.3 [5.8, NC]	175	57 (32.6)	NC [8.1, NC]	1.157 [0.808, 1.655]	0.4226	0.4627
Female	107	28 (26.2)	26.8 [26.8, NC]	107	30 (28.0)	29.1 [12.0, NC]	0.912 [0.544, 1.528]	0.7262	
Region									
Asia	88	37 (42.0)	17.2 [5.4, NC]	89	34 (38.2)	12.3 [6.3, NC]	1.068 [0.669, 1.703]	0.7825	0.9105
Non-Asia	195	54 (27.7)	NC [13.3, NC]	193	53 (27.5)	29.1 [15.0, 29.1]	1.051 [0.718, 1.539]	0.7994	
Number of Organs with Metastatic Sites									
0-2	219	71 (32.4)	26.8 [13.3, NC]	219	71 (32.4)	NC [12.0, NC]	1.022 [0.735, 1.420]	0.8937	0.6740
>=3	64	20 (31.3)	NC [5.1, NC]	63	16 (25.4)	29.1 [8.0, 29.1]	1.202 [0.622, 2.320]	0.5860	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.27.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	142 (50.2%)	147 (52.1%)	
Number of patients censored	141 (49.8%)	135 (47.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.5 [2.9, 5.2]	3.7 [2.6, 4.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.950 [0.752, 1.200]
Log-rank test			
Two-sided stratified log-rank p-value			0.6486

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.27.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	91 (50.3)	3.8 [2.2, 9.0]	181	95 (52.5)	2.8 [2.2, 3.9]	0.877 [0.657, 1.172]	0.3721	0.2577
>65 years	102	51 (50.0)	3.4 [1.6, 4.6]	101	52 (51.5)	4.6 [3.5, 6.7]	1.147 [0.779, 1.689]	0.4872	
Sex									
Male	176	88 (50.0)	3.4 [2.8, 6.5]	175	90 (51.4)	4.0 [2.5, 5.1]	0.983 [0.732, 1.319]	0.9014	0.8004
Female	107	54 (50.5)	3.7 [1.4, 9.0]	107	57 (53.3)	3.3 [2.1, 4.3]	0.915 [0.629, 1.331]	0.6332	
Region									
Asia	88	41 (46.6)	8.0 [3.0, NC]	89	44 (49.4)	5.6 [2.6, NC]	0.889 [0.578, 1.368]	0.5922	0.6023
Non-Asia	195	101 (51.8)	3.0 [1.5, 3.7]	193	103 (53.4)	3.0 [2.3, 4.0]	1.000 [0.759, 1.316]	0.9850	
Number of Organs with Metastatic Sites									
0-2	219	113 (51.6)	3.1 [1.9, 4.6]	219	122 (55.7)	3.3 [2.4, 4.6]	0.944 [0.730, 1.222]	0.6545	0.7331
>=3	64	29 (45.3)	5.2 [2.2, NC]	63	25 (39.7)	4.9 [2.6, NC]	1.055 [0.618, 1.803]	0.8460	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.28.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	164 (58.0%)	169 (59.9%)	
Number of patients censored	119 (42.0%)	113 (40.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.4 [1.9, 3.1]	2.8 [2.3, 3.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.044 [0.840, 1.298]
Log-rank test			
Two-sided stratified log-rank p-value			0.7045

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.28.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	112 (61.9)	2.2 [1.6, 3.1]	181	106 (58.6)	2.8 [2.3, 3.5]	1.169 [0.896, 1.526]	0.2548	0.2220
>65 years	102	52 (51.0)	2.8 [1.6, 5.7]	101	63 (62.4)	3.0 [2.1, 4.4]	0.872 [0.602, 1.261]	0.4655	
Sex									
Male	176	96 (54.5)	2.8 [2.1, 3.7]	175	104 (59.4)	2.8 [2.3, 4.4]	0.979 [0.741, 1.294]	0.8907	0.4266
Female	107	68 (63.6)	1.9 [1.4, 2.8]	107	65 (60.7)	2.6 [2.1, 3.5]	1.191 [0.847, 1.674]	0.3190	
Region									
Asia	88	51 (58.0)	3.5 [1.6, 6.7]	89	54 (60.7)	2.9 [2.1, 5.7]	0.940 [0.640, 1.381]	0.7509	0.4458
Non-Asia	195	113 (57.9)	2.1 [1.6, 3.0]	193	115 (59.6)	2.8 [2.2, 3.5]	1.130 [0.871, 1.467]	0.3605	
Number of Organs with Metastatic Sites									
0-2	219	125 (57.1)	2.6 [1.6, 3.3]	219	139 (63.5)	2.6 [2.2, 3.3]	0.950 [0.745, 1.211]	0.6713	0.0608
>=3	64	39 (60.9)	2.1 [1.6, 3.7]	63	30 (47.6)	4.2 [2.3, 8.0]	1.641 [1.014, 2.654]	0.0417	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.29.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	148 (52.3%)	125 (44.3%)	
Number of patients censored	135 (47.7%)	157 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.1 [2.7, 5.1]	7.2 [3.3, 10.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.283 [1.007, 1.634]
Log-rank test			
Two-sided stratified log-rank p-value			0.0410

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.29.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	102 (56.4)	3.4 [2.2, 4.6]	181	70 (38.7)	9.5 [4.6, NC]	1.610 [1.186, 2.185]	0.0020	0.0146
>65 years	102	46 (45.1)	4.4 [2.2, 8.6]	101	55 (54.5)	3.0 [2.1, 8.1]	0.868 [0.586, 1.286]	0.4861	
Sex									
Male	176	89 (50.6)	4.2 [2.8, 6.2]	175	73 (41.7)	9.4 [5.7, NC]	1.473 [1.080, 2.008]	0.0134	0.2243
Female	107	59 (55.1)	2.8 [2.1, 5.3]	107	52 (48.6)	2.8 [2.3, 8.7]	1.061 [0.730, 1.540]	0.7462	
Region									
Asia	88	53 (60.2)	4.4 [2.5, 8.1]	89	45 (50.6)	8.0 [3.9, 20.7]	1.242 [0.833, 1.854]	0.2758	0.9558
Non-Asia	195	95 (48.7)	3.1 [2.1, 4.8]	193	80 (41.5)	5.2 [2.6, 12.5]	1.273 [0.945, 1.715]	0.1091	
Number of Organs with Metastatic Sites									
0-2	219	114 (52.1)	4.1 [2.5, 5.1]	219	94 (42.9)	8.7 [5.2, 12.7]	1.373 [1.044, 1.806]	0.0225	0.2701
>=3	64	34 (53.1)	3.5 [1.6, 6.8]	63	31 (49.2)	2.6 [1.5, 5.7]	0.980 [0.602, 1.595]	0.9479	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.30.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	108 (38.2%)	86 (30.5%)	
Number of patients censored	175 (61.8%)	196 (69.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	11.8 [6.2, NC]	17.1 [11.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.373 [1.032, 1.828]
Log-rank test			
Two-sided stratified log-rank p-value			0.0285

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.30.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	74 (40.9)	10.4 [5.3, NC]	181	44 (24.3)	NC [12.3, NC]	1.849 [1.272, 2.687]	0.0011	0.0076
>65 years	102	34 (33.3)	14.9 [6.5, NC]	101	42 (41.6)	7.7 [6.2, NC]	0.820 [0.521, 1.289]	0.3949	
Sex									
Male	176	67 (38.1)	10.4 [5.7, NC]	175	59 (33.7)	15.4 [10.6, NC]	1.261 [0.888, 1.789]	0.1937	0.5744
Female	107	41 (38.3)	17.9 [4.4, NC]	107	27 (25.2)	NC [8.3, NC]	1.538 [0.945, 2.503]	0.0805	
Region									
Asia	88	33 (37.5)	17.9 [8.7, NC]	89	26 (29.2)	NC [11.2, NC]	1.200 [0.717, 2.011]	0.4828	0.6673
Non-Asia	195	75 (38.5)	9.4 [4.4, NC]	193	60 (31.1)	15.4 [8.3, NC]	1.407 [1.002, 1.977]	0.0478	
Number of Organs with Metastatic Sites									
0-2	219	84 (38.4)	13.3 [5.9, NC]	219	71 (32.4)	15.4 [11.0, NC]	1.245 [0.907, 1.709]	0.1713	0.3565
>=3	64	24 (37.5)	10.8 [5.5, NC]	63	15 (23.8)	NC [7.8, NC]	1.785 [0.934, 3.415]	0.0761	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.31.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	91 (32.2%)	72 (25.5%)	
Number of patients censored	192 (67.8%)	210 (74.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [12.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.376 [1.008, 1.878]
Log-rank test			
Two-sided stratified log-rank p-value			0.0434

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.31.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	63 (34.8)	16.6 [10.8, NC]	181	37 (20.4)	NC [NC, NC]	1.845 [1.228, 2.770]	0.0028	0.0116
>65 years	102	28 (27.5)	NC [9.4, NC]	101	35 (34.7)	NC [6.7, NC]	0.839 [0.510, 1.379]	0.4887	
Sex									
Male	176	59 (33.5)	NC [9.4, NC]	175	51 (29.1)	NC [11.1, NC]	1.287 [0.885, 1.873]	0.1878	0.5750
Female	107	32 (29.9)	NC [11.5, NC]	107	21 (19.6)	NC [15.0, NC]	1.519 [0.875, 2.637]	0.1352	
Region									
Asia	88	34 (38.6)	NC [6.4, NC]	89	27 (30.3)	NC [12.3, NC]	1.258 [0.757, 2.089]	0.3739	0.7357
Non-Asia	195	57 (29.2)	16.6 [12.2, NC]	193	45 (23.3)	NC [NC, NC]	1.406 [0.951, 2.079]	0.0866	
Number of Organs with Metastatic Sites									
0-2	219	71 (32.4)	NC [12.2, NC]	219	63 (28.8)	NC [15.0, NC]	1.199 [0.854, 1.684]	0.2952	0.0995
>=3	64	20 (31.3)	16.6 [6.5, NC]	63	9 (14.3)	NC [NC, NC]	2.404 [1.092, 5.289]	0.0243	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.32.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	142 (50.2%)	103 (36.5%)	
Number of patients censored	141 (49.8%)	179 (63.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.7, 6.6]	12.3 [7.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.566 [1.211, 2.026]
Log-rank test			
Two-sided stratified log-rank p-value			0.0005

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.32.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	91 (50.3)	5.0 [3.5, 8.6]	181	57 (31.5)	NC [7.6, NC]	1.796 [1.289, 2.503]	0.0005	0.1398
>65 years	102	51 (50.0)	4.7 [3.0, 6.9]	101	46 (45.5)	8.1 [3.5, 20.9]	1.201 [0.804, 1.795]	0.3639	
Sex									
Male	176	92 (52.3)	4.6 [3.1, 6.6]	175	71 (40.6)	8.8 [5.6, NC]	1.492 [1.094, 2.034]	0.0110	0.6948
Female	107	50 (46.7)	5.3 [3.5, 12.9]	107	32 (29.9)	20.9 [20.9, NC]	1.632 [1.046, 2.547]	0.0285	
Region									
Asia	88	41 (46.6)	9.7 [5.0, NC]	89	26 (29.2)	NC [12.3, NC]	1.641 [1.002, 2.689]	0.0469	0.7798
Non-Asia	195	101 (51.8)	3.8 [2.7, 5.6]	193	77 (39.9)	7.6 [4.7, 20.9]	1.505 [1.117, 2.026]	0.0066	
Number of Organs with Metastatic Sites									
0-2	219	109 (49.8)	4.9 [3.7, 7.3]	219	76 (34.7)	NC [8.1, NC]	1.672 [1.247, 2.242]	0.0005	0.2550
>=3	64	33 (51.6)	5.5 [2.6, 12.9]	63	27 (42.9)	6.7 [2.2, 20.9]	1.170 [0.703, 1.947]	0.5372	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.33.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	105 (37.1%)	84 (29.8%)	
Number of patients censored	178 (62.9%)	198 (70.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.3 [8.3, NC]	NC [12.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.373 [1.029, 1.832]
Log-rank test			
Two-sided stratified log-rank p-value			0.0300

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.33.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	74 (40.9)	12.5 [5.1, NC]	181	47 (26.0)	NC [12.9, NC]	1.787 [1.239, 2.577]	0.0016	0.0090
>65 years	102	31 (30.4)	19.1 [9.6, NC]	101	37 (36.6)	NC [4.2, NC]	0.799 [0.496, 1.289]	0.3564	
Sex									
Male	176	66 (37.5)	13.3 [5.5, NC]	175	55 (31.4)	NC [12.3, NC]	1.309 [0.915, 1.873]	0.1404	0.8368
Female	107	39 (36.4)	17.9 [6.6, NC]	107	29 (27.1)	NC [14.1, NC]	1.368 [0.846, 2.213]	0.1990	
Region									
Asia	88	32 (36.4)	NC [9.6, NC]	89	23 (25.8)	NC [12.3, NC]	1.364 [0.797, 2.335]	0.2541	0.9481
Non-Asia	195	73 (37.4)	13.2 [5.1, 19.4]	193	61 (31.6)	NC [9.5, NC]	1.335 [0.950, 1.876]	0.0960	
Number of Organs with Metastatic Sites									
0-2	219	77 (35.2)	19.1 [8.3, NC]	219	67 (30.6)	NC [12.9, NC]	1.235 [0.890, 1.714]	0.2057	0.3630
>=3	64	28 (43.8)	13.2 [3.7, NC]	63	17 (27.0)	NC [6.5, NC]	1.699 [0.928, 3.111]	0.0819	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.34.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	132 (46.6%)	101 (35.8%)	
Number of patients censored	151 (53.4%)	181 (64.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.8, 5.1]	13.2 [7.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.442 [1.109, 1.875]
Log-rank test			
Two-sided stratified log-rank p-value			0.0058

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.34.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	83 (45.9)	4.2 [2.7, 6.5]	181	57 (31.5)	16.3 [12.3, NC]	1.570 [1.120, 2.201]	0.0082	0.4575
>65 years	102	49 (48.0)	3.3 [2.1, 5.8]	101	44 (43.6)	6.6 [2.4, NC]	1.341 [0.890, 2.019]	0.1552	
Sex									
Male	176	77 (43.8)	4.4 [2.8, 6.5]	175	58 (33.1)	15.1 [9.7, NC]	1.627 [1.155, 2.290]	0.0048	0.3407
Female	107	55 (51.4)	2.9 [1.8, 6.0]	107	43 (40.2)	4.7 [2.3, NC]	1.232 [0.827, 1.837]	0.3024	
Region									
Asia	88	50 (56.8)	5.1 [2.8, 6.6]	89	36 (40.4)	15.1 [6.6, NC]	1.485 [0.966, 2.283]	0.0678	0.9629
Non-Asia	195	82 (42.1)	3.0 [2.1, 5.1]	193	65 (33.7)	13.2 [4.5, NC]	1.422 [1.026, 1.971]	0.0332	
Number of Organs with Metastatic Sites									
0-2	219	105 (47.9)	3.9 [2.8, 5.8]	219	74 (33.8)	15.7 [12.3, NC]	1.599 [1.187, 2.155]	0.0018	0.1838
>=3	64	27 (42.2)	3.3 [1.6, NC]	63	27 (42.9)	4.7 [2.3, NC]	1.062 [0.622, 1.814]	0.8255	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 09SEP22

Table 301.1.3004.35.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	29 (10.2%)	33 (11.7%)	
Number of patients censored	254 (89.8%)	249 (88.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.4 [3.5, 15.5]	4.5 [2.8, 7.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.635 [0.369, 1.094]
Log-rank test			
Two-sided stratified log-rank p-value			0.1029

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 09SEP22

Table 301.1.3004.35.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	21 (11.6)	4.1 [2.3, 10.8]	181	25 (13.8)	3.0 [1.4, 4.7]	0.753 [0.419, 1.352]	0.3523	0.6307
>65 years	102	8 (7.8)	15.5 [3.4, 25.5]	101	8 (7.9)	12.3 [4.5, NC]	0.615 [0.210, 1.800]	0.3730	
Sex									
Male	176	13 (7.4)	15.5 [4.1, 25.5]	175	18 (10.3)	4.7 [2.8, 12.5]	0.484 [0.228, 1.029]	0.0548	0.1384
Female	107	16 (15.0)	2.3 [1.4, 4.4]	107	15 (14.0)	3.1 [0.8, 4.8]	1.075 [0.520, 2.221]	0.8241	
Region									
Asia	88	15 (17.0)	4.4 [3.5, 15.5]	89	13 (14.6)	4.0 [1.4, 10.2]	0.651 [0.303, 1.396]	0.2742	0.8130
Non-Asia	195	14 (7.2)	4.7 [2.3, 25.5]	193	20 (10.4)	4.5 [2.5, 12.3]	0.746 [0.370, 1.506]	0.4180	
Number of Organs with Metastatic Sites									
0-2	219	26 (11.9)	4.4 [3.5, 15.5]	219	28 (12.8)	3.1 [1.4, 7.5]	0.576 [0.331, 1.004]	0.0506	0.3152
>=3	64	3 (4.7)	10.8 [0.9, 10.8]	63	5 (7.9)	NC [2.3, NC]	1.145 [0.269, 4.873]	0.8543	

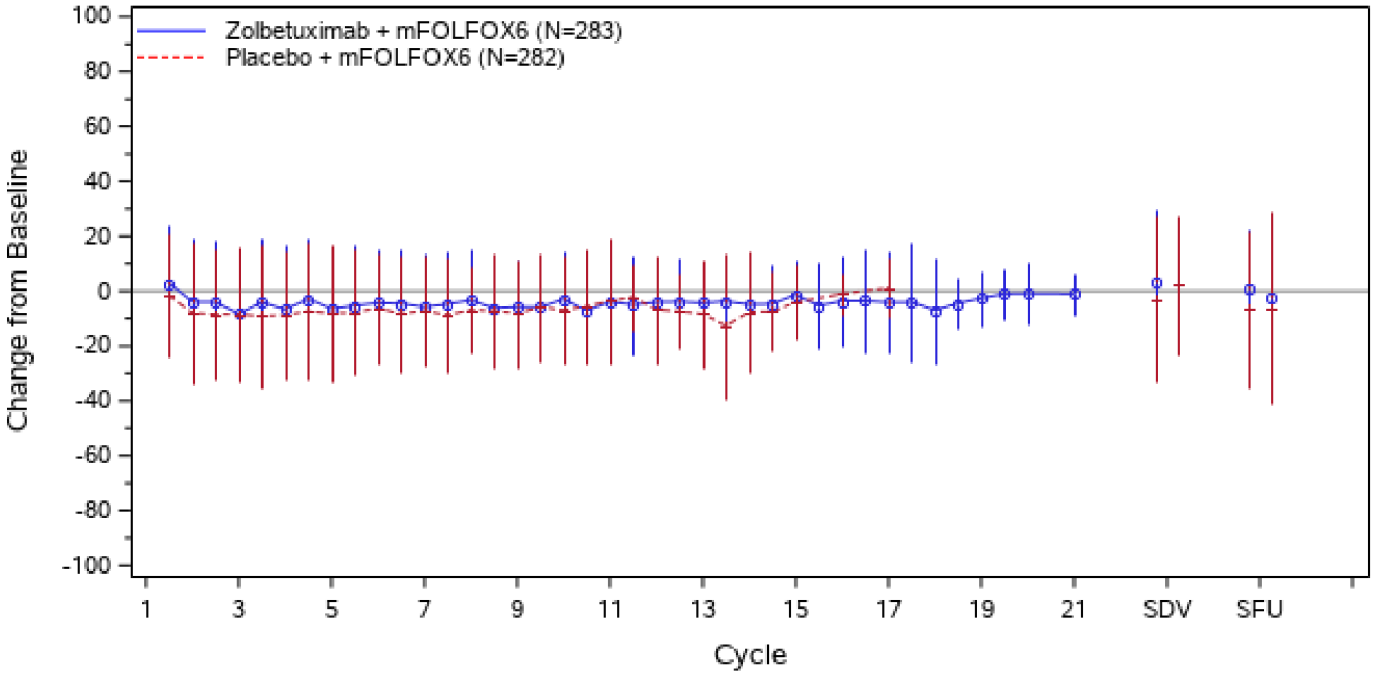
Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; 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 [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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

The SAS System

Figure 301.1.3002.20: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia - Full Analysis Set

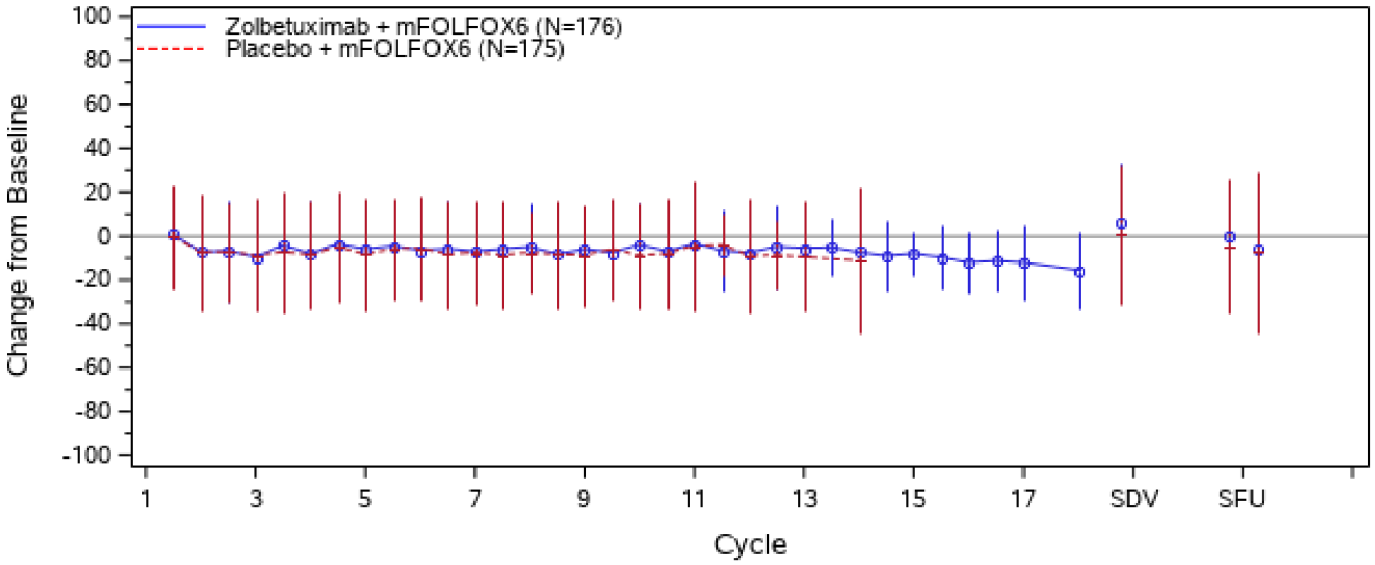


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.20.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia by Sex - Full Analysis Set

Sex: Male

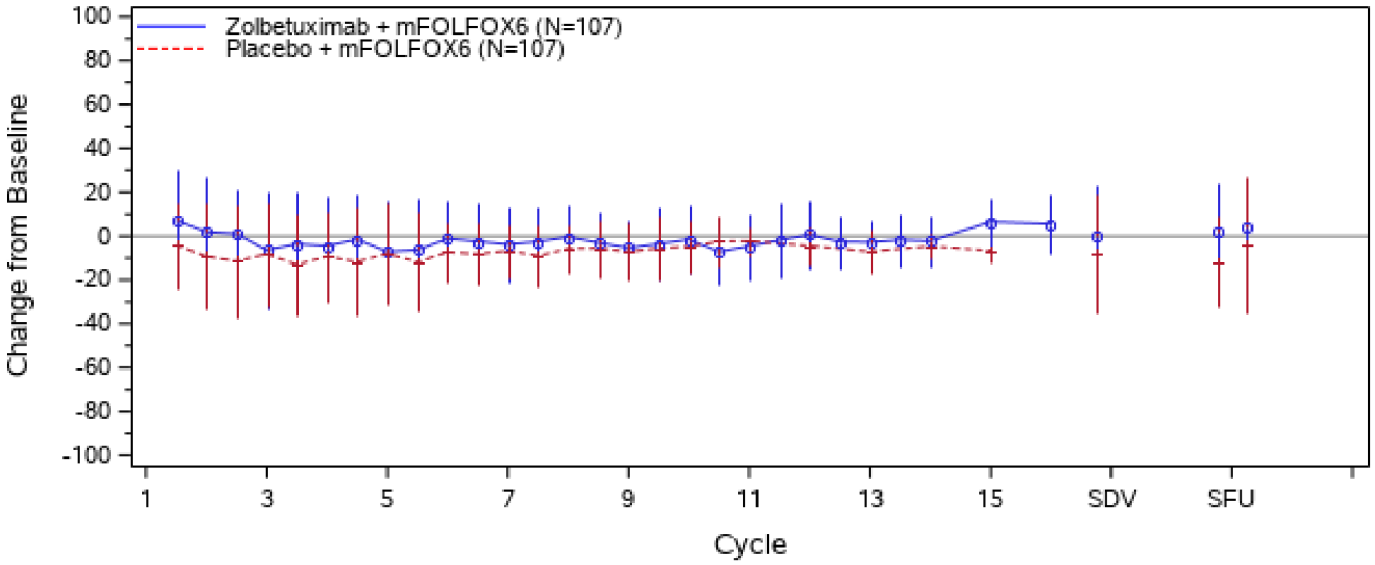


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.20.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia by Sex - Full Analysis Set

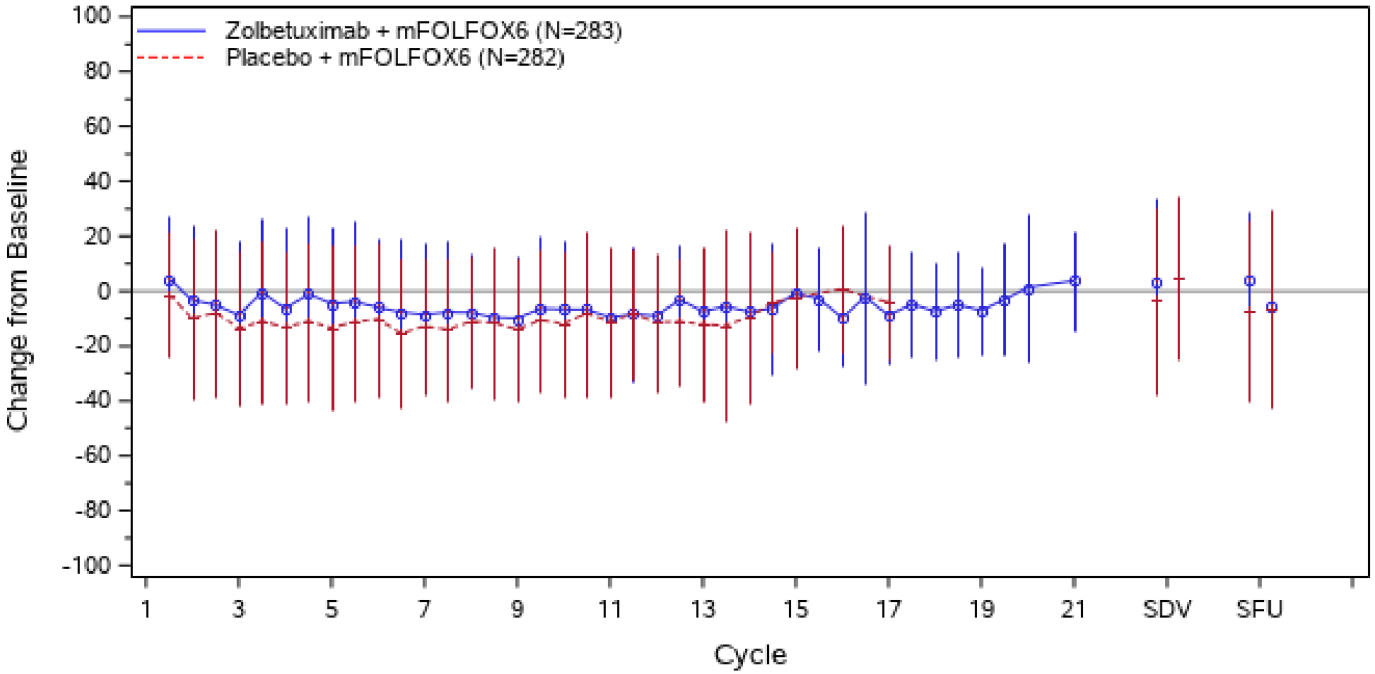
Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

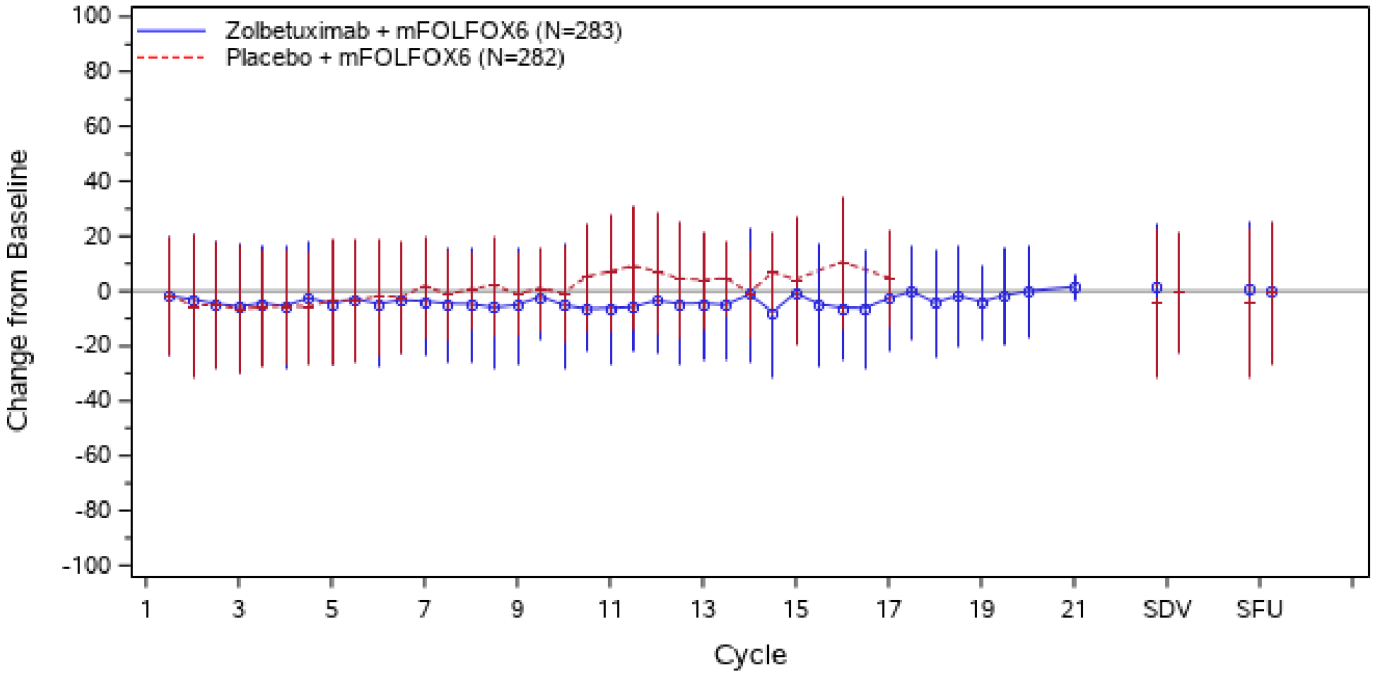
Figure 301.1.3002.21: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating Restrictions - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.22: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux - Full Analysis Set

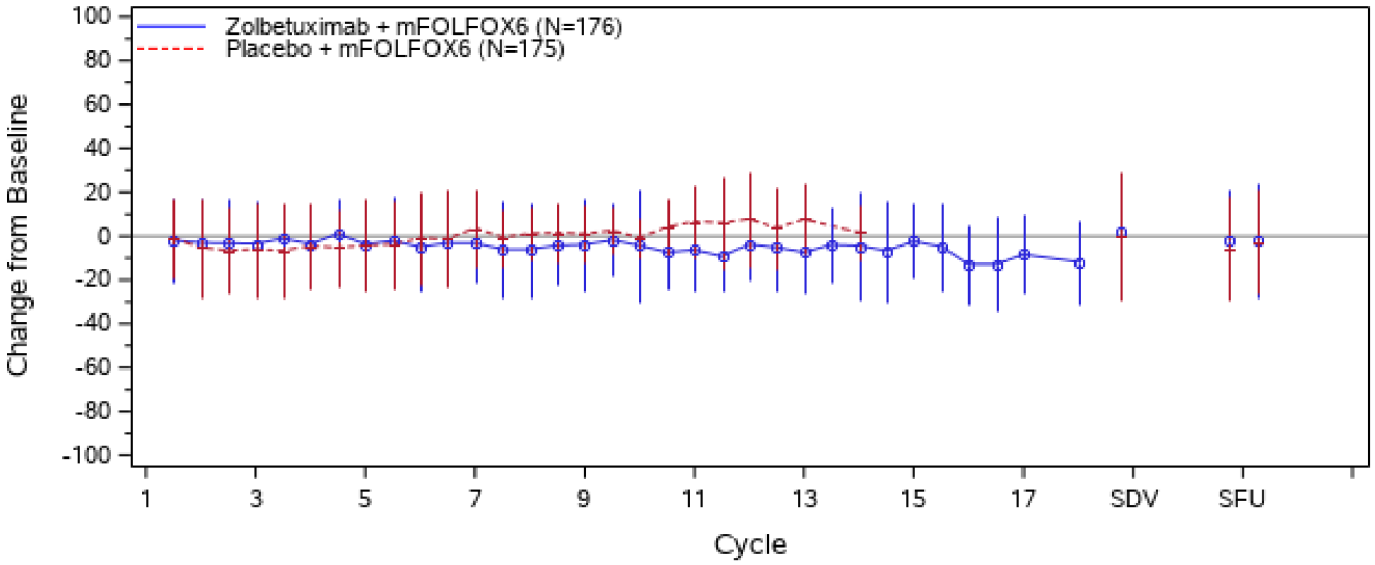


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.22.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux by Sex - Full Analysis Set

Sex: Male

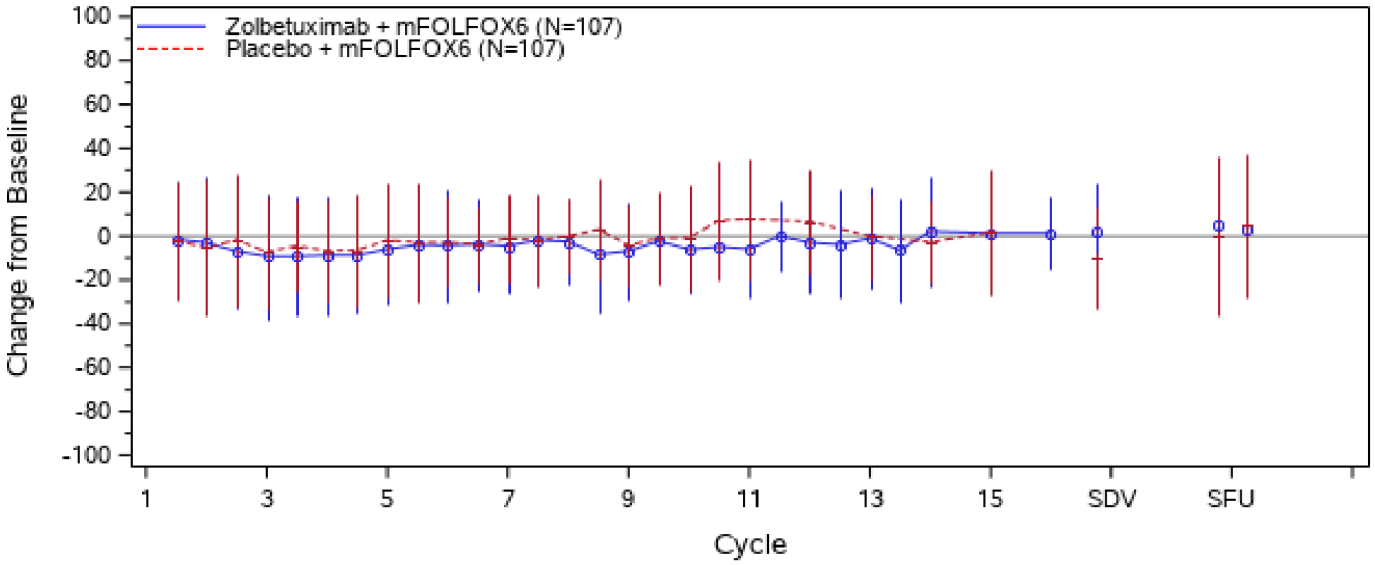


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.22.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux by Sex - Full Analysis Set

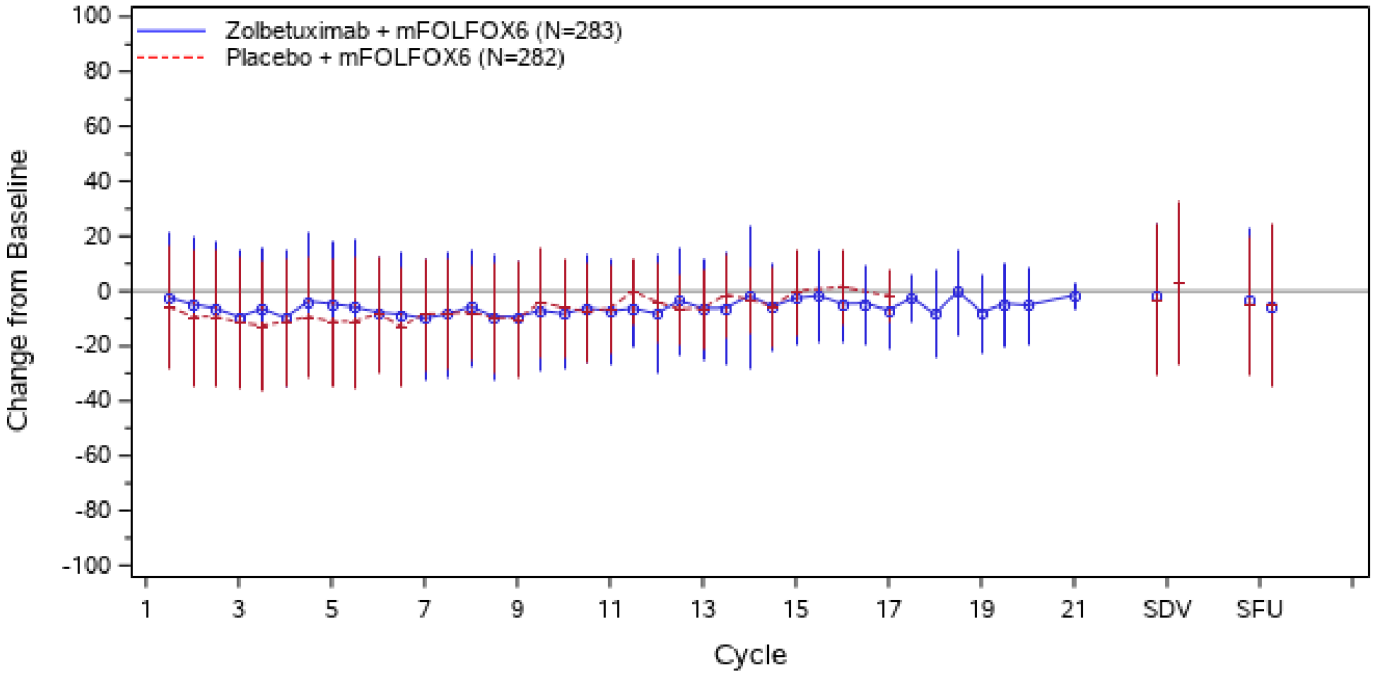
Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

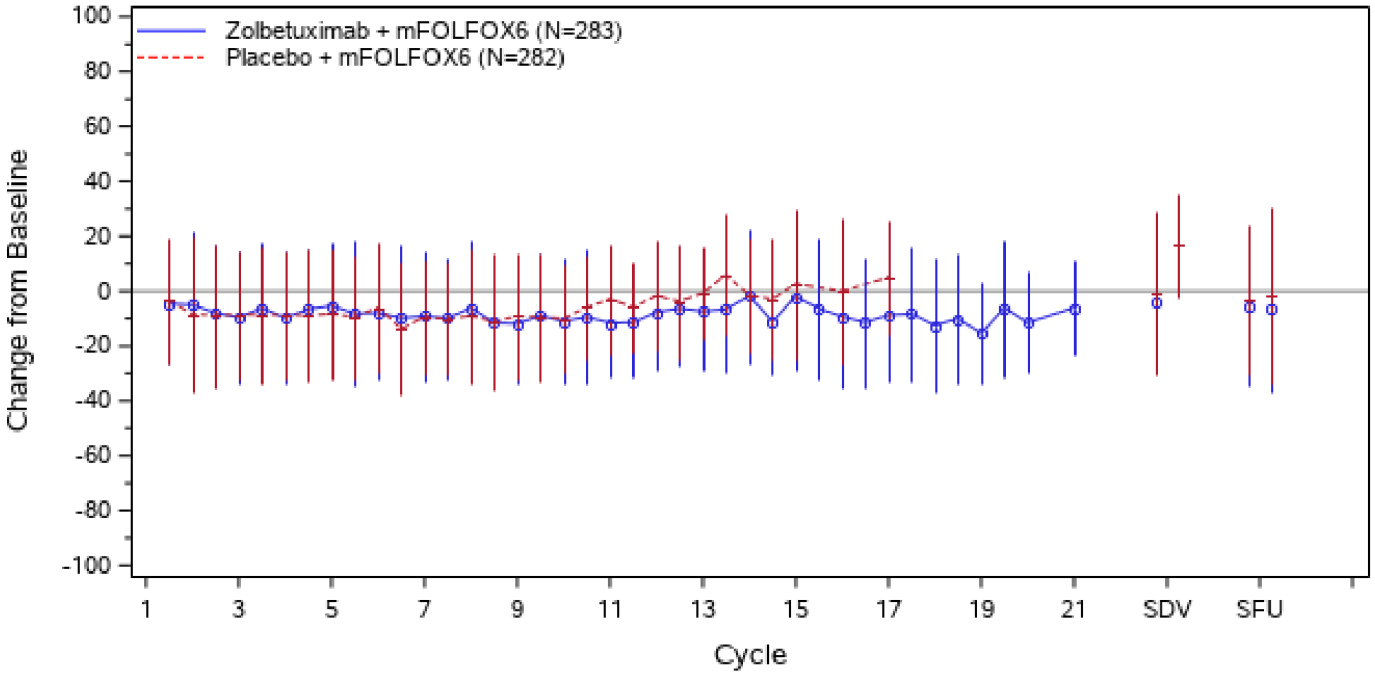
Figure 301.1.3002.23: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Odynophagia - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

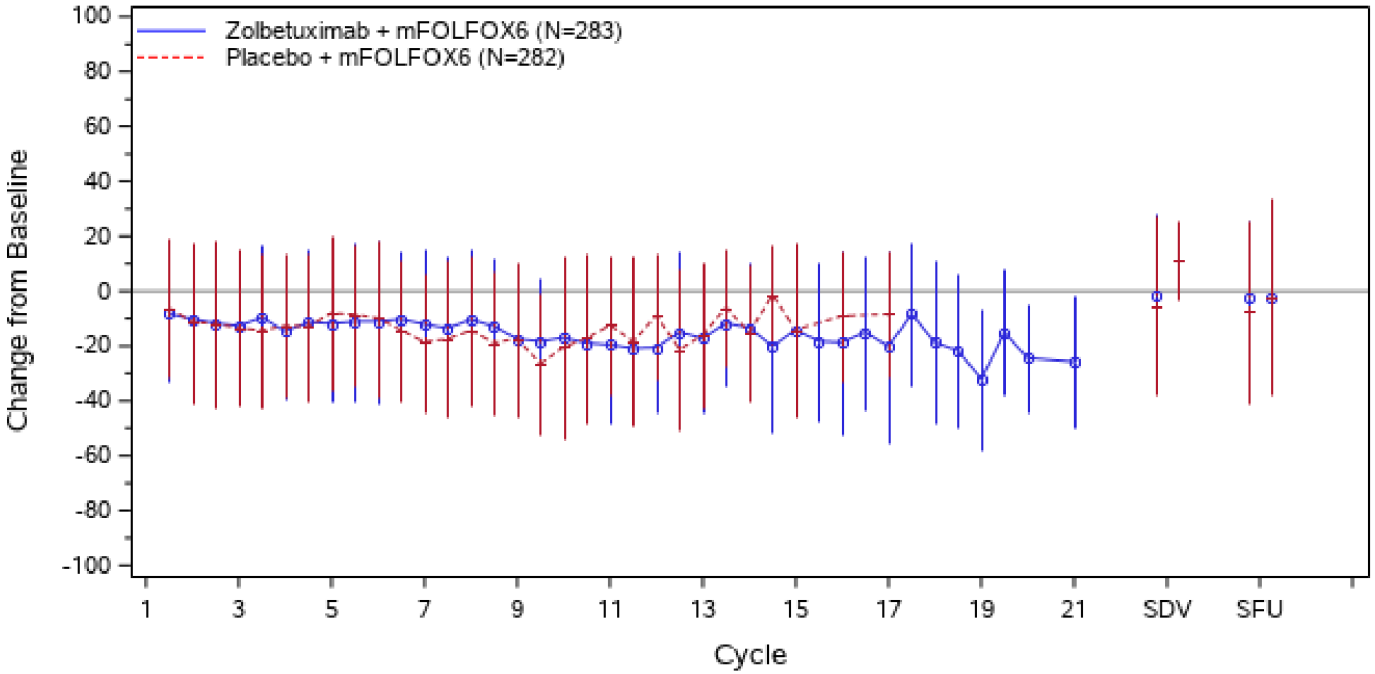
Figure 301.1.3002.24: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Pain and Discomfort - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.25: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety - Full Analysis Set

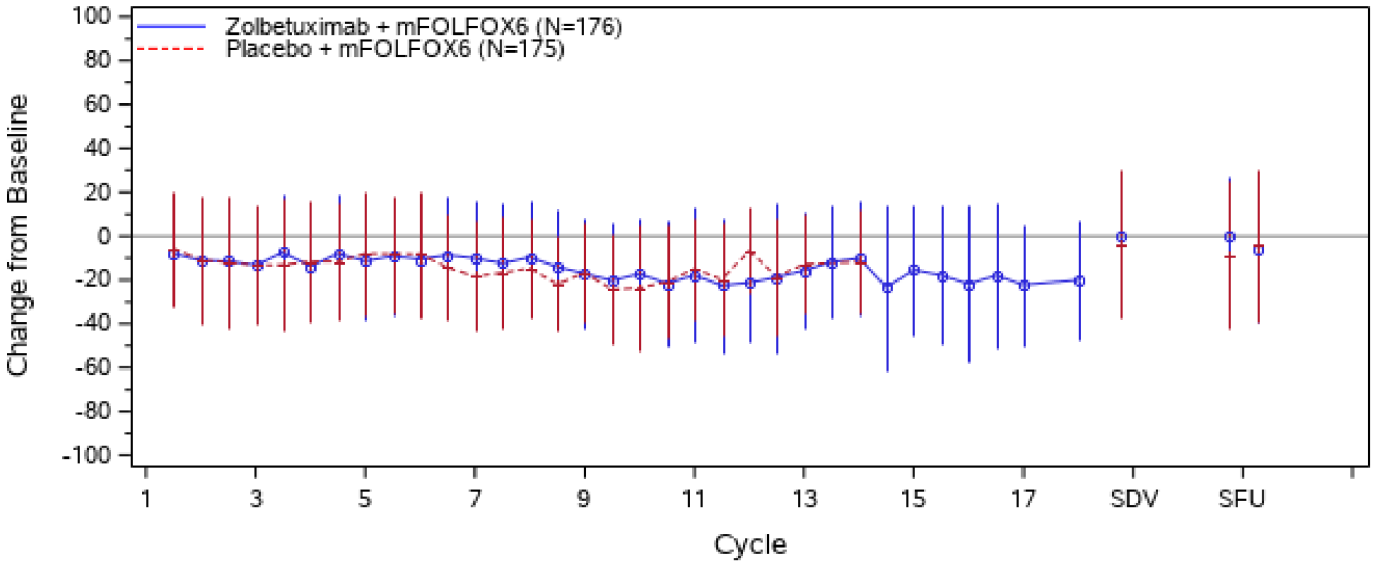


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.25.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety by Sex - Full Analysis Set

Sex: Male

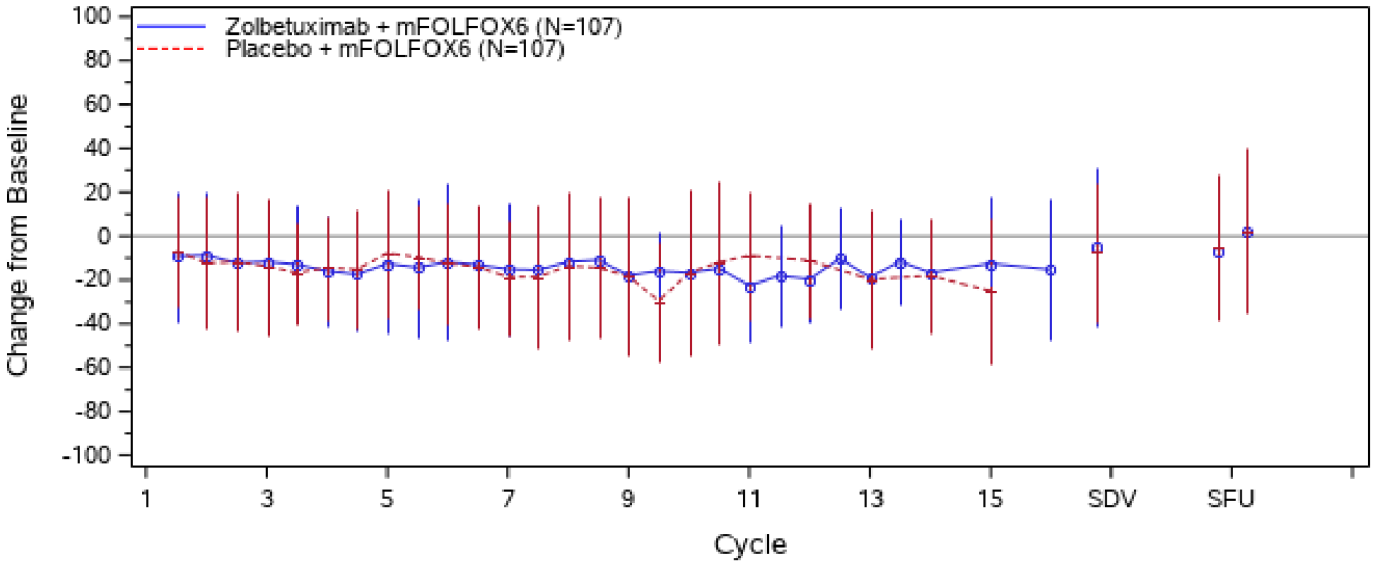


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.25.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety by Sex - Full Analysis Set

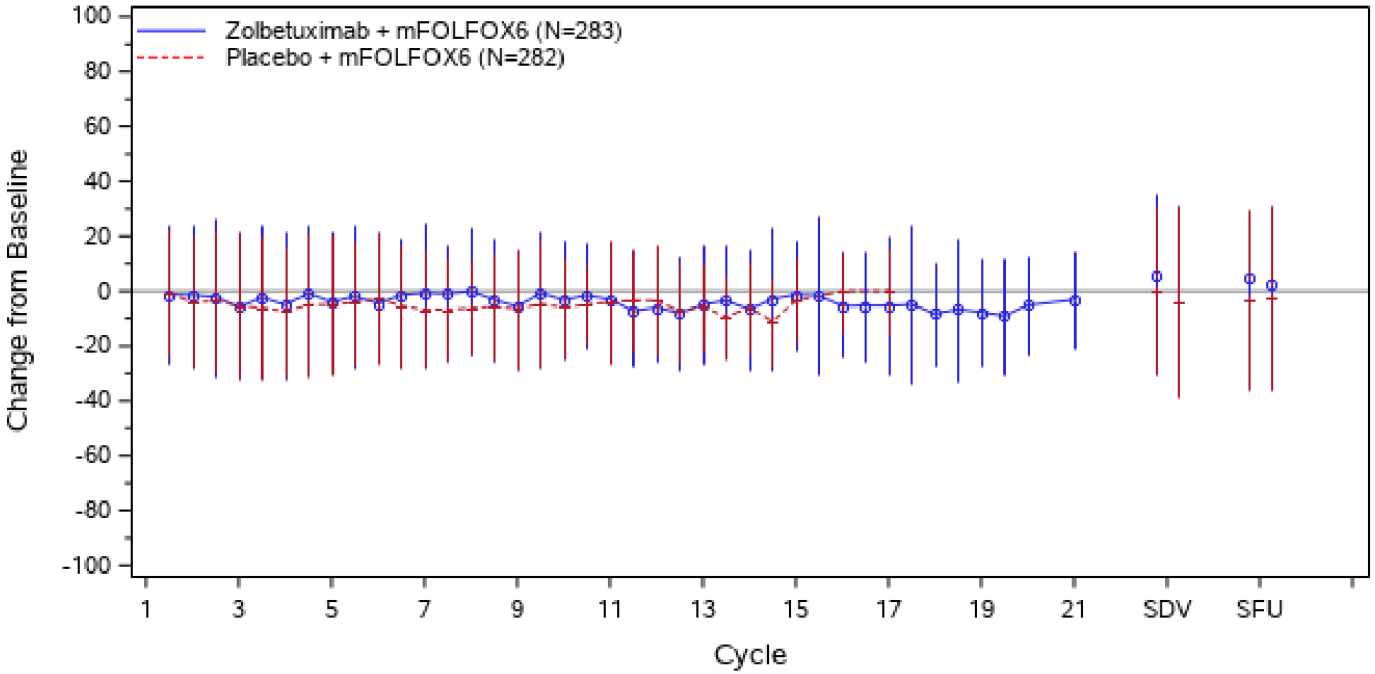
Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

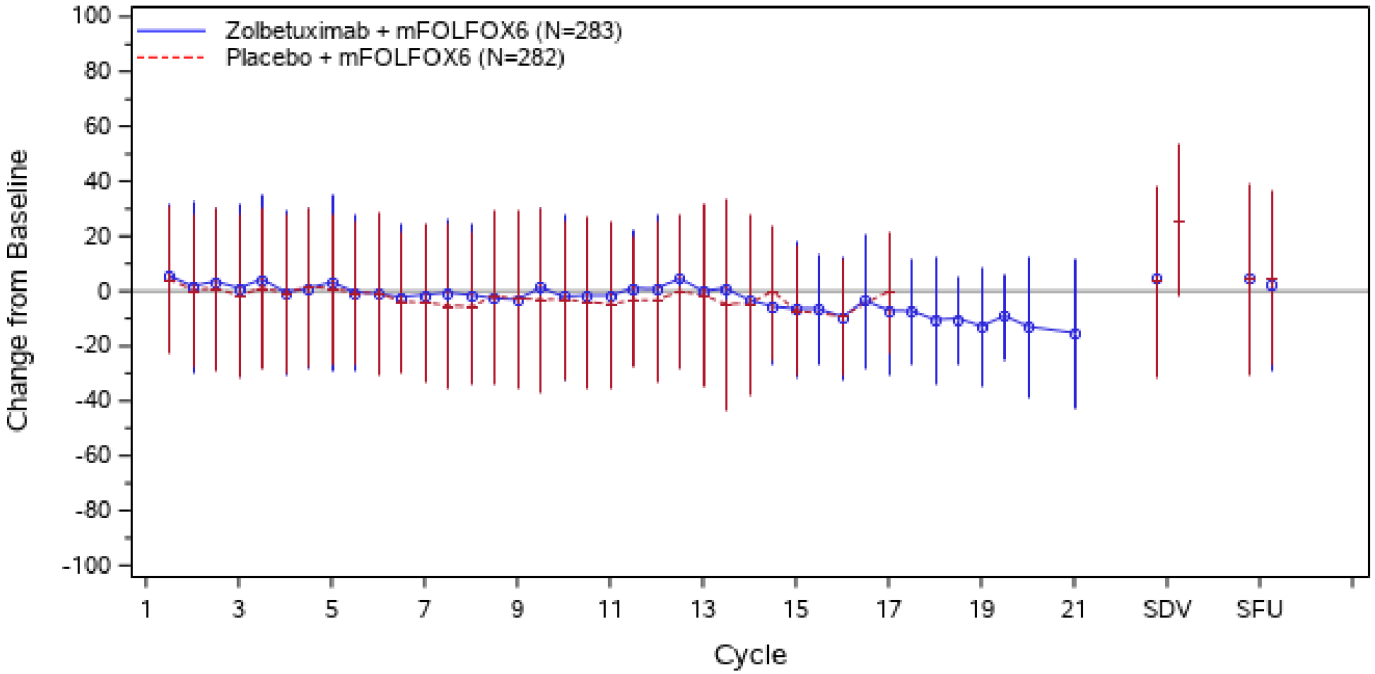
Figure 301.1.3002.26: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating in Front of Others - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

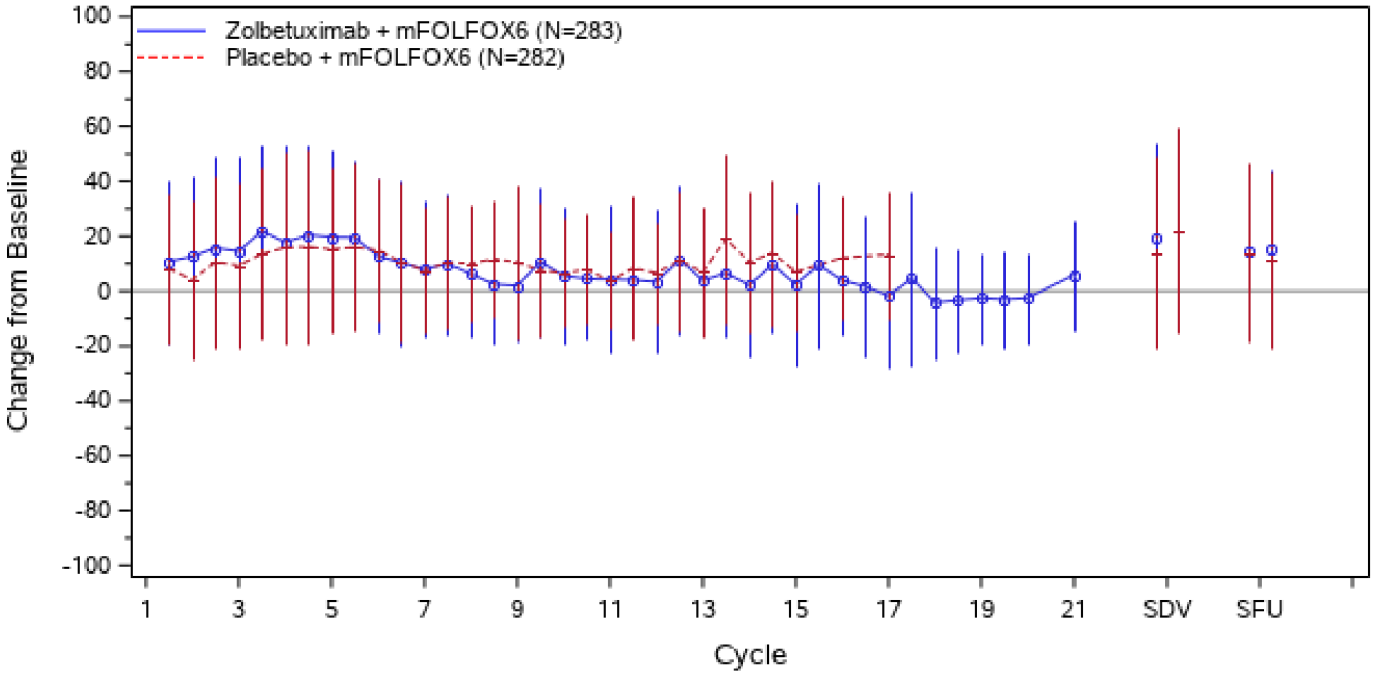
Figure 301.1.3002.27: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dry Mouth - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

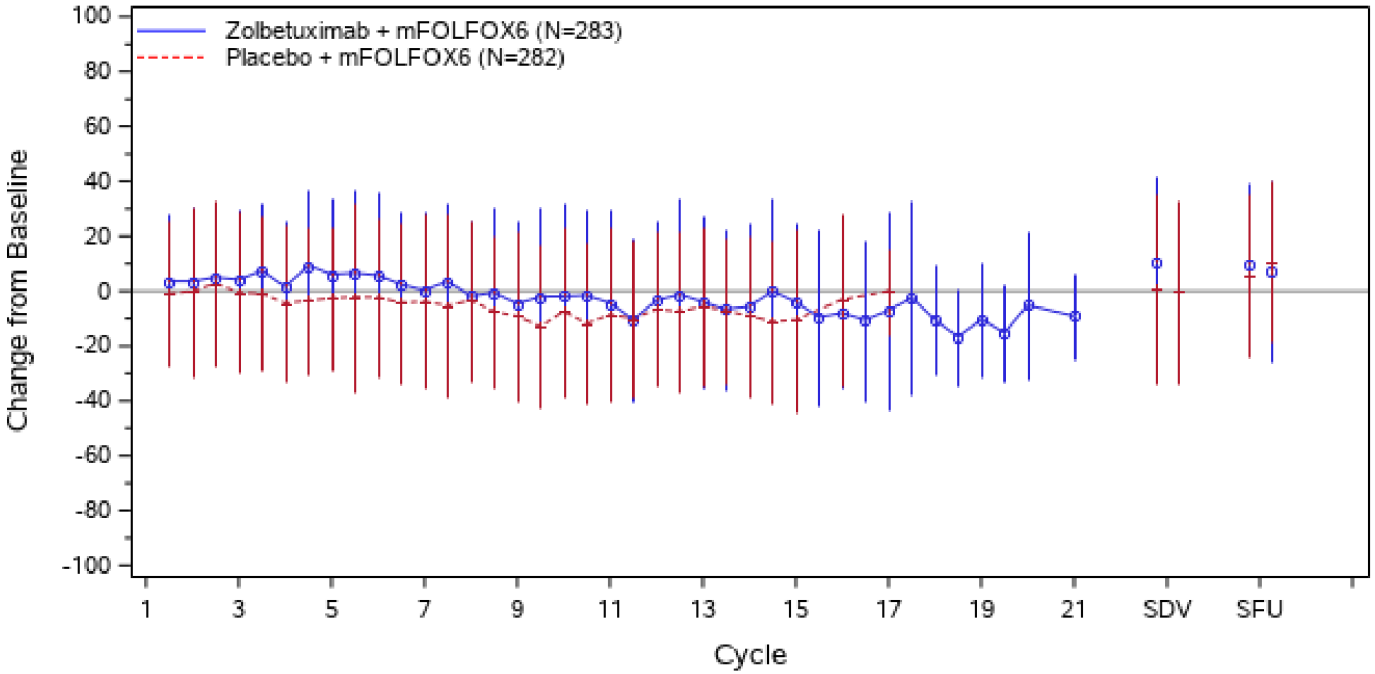
Figure 301.1.3002.28: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Taste - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.29: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image - Full Analysis Set

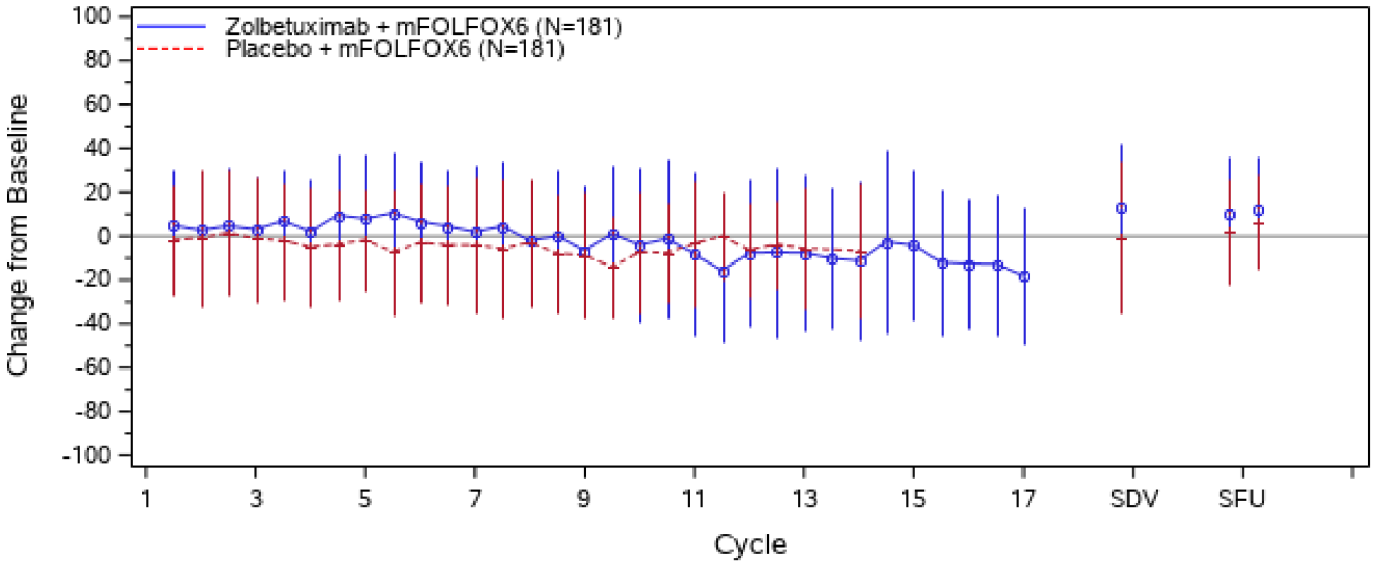


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.29.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

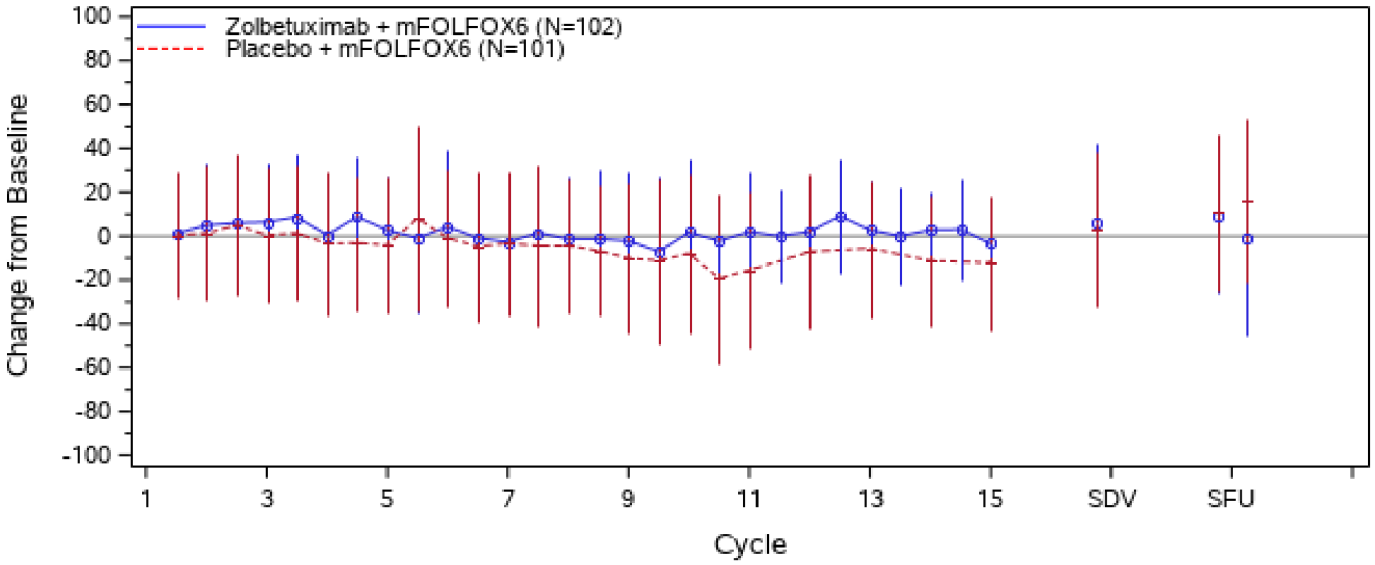


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.29.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

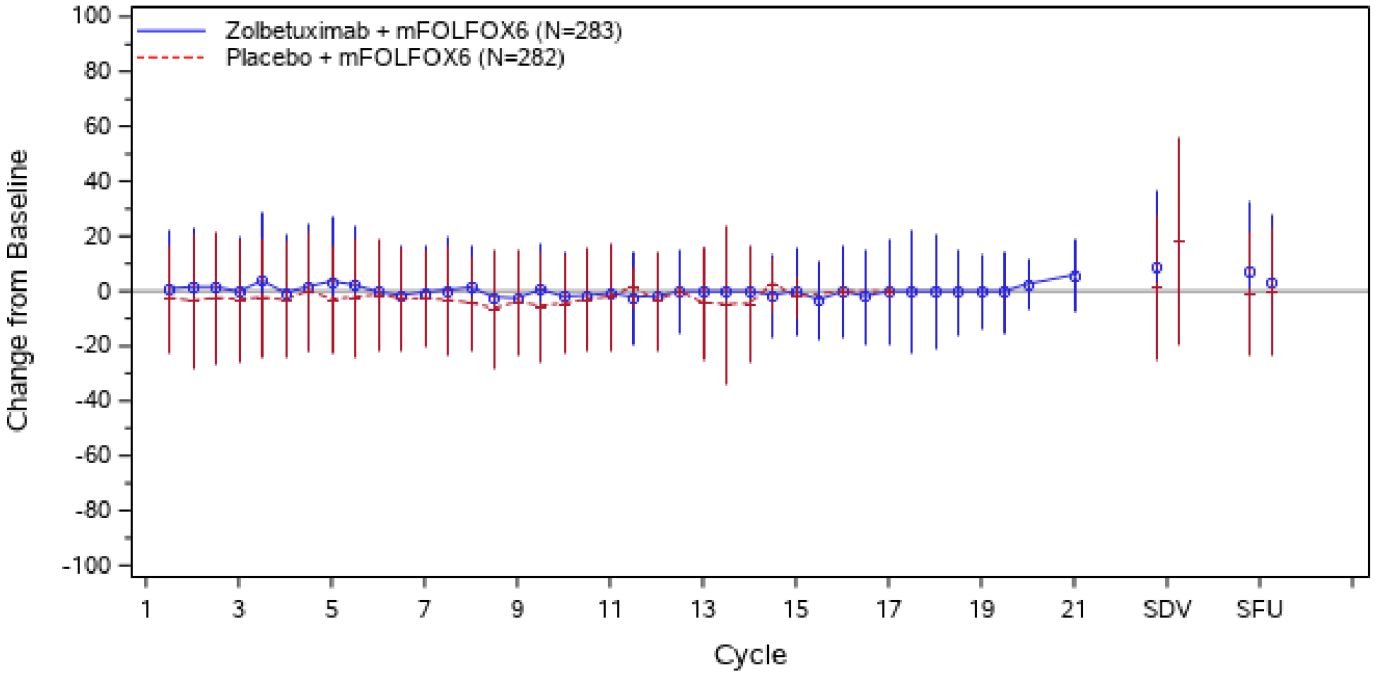
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.30: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

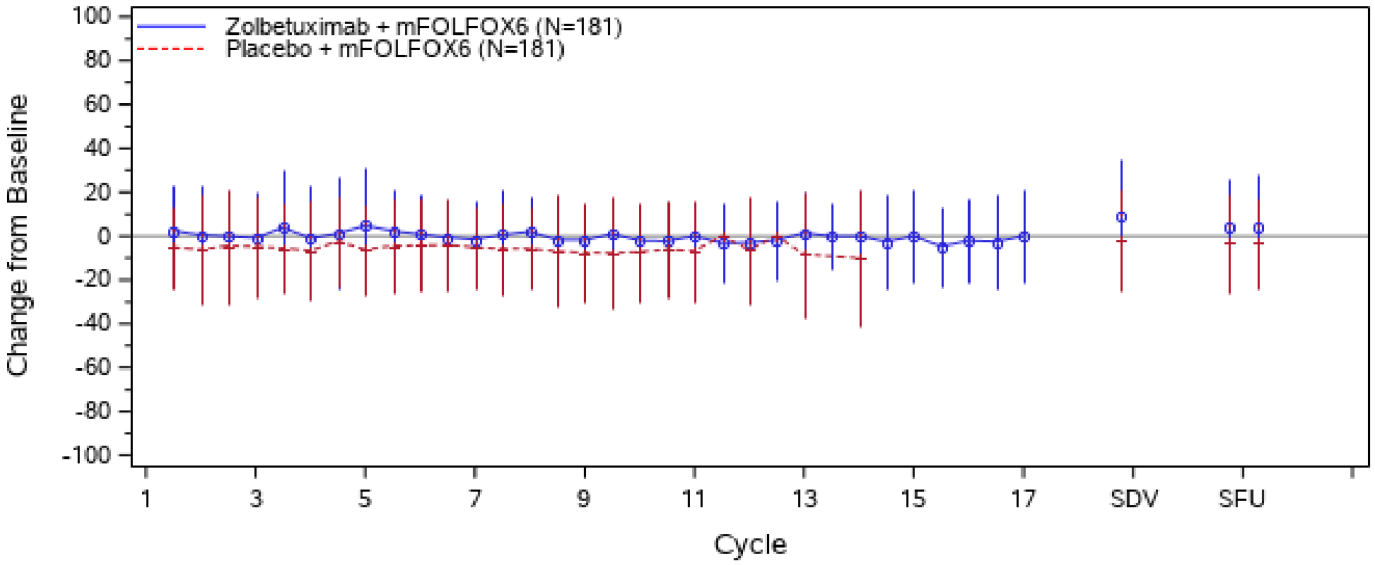


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.30.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

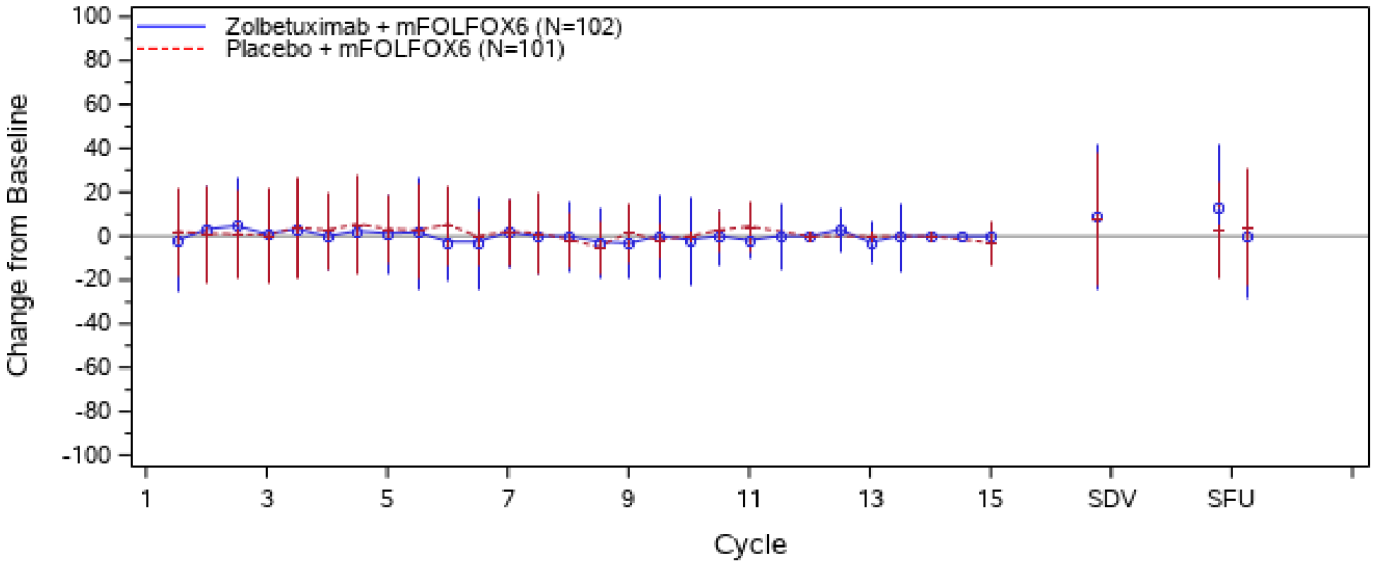


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.30.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

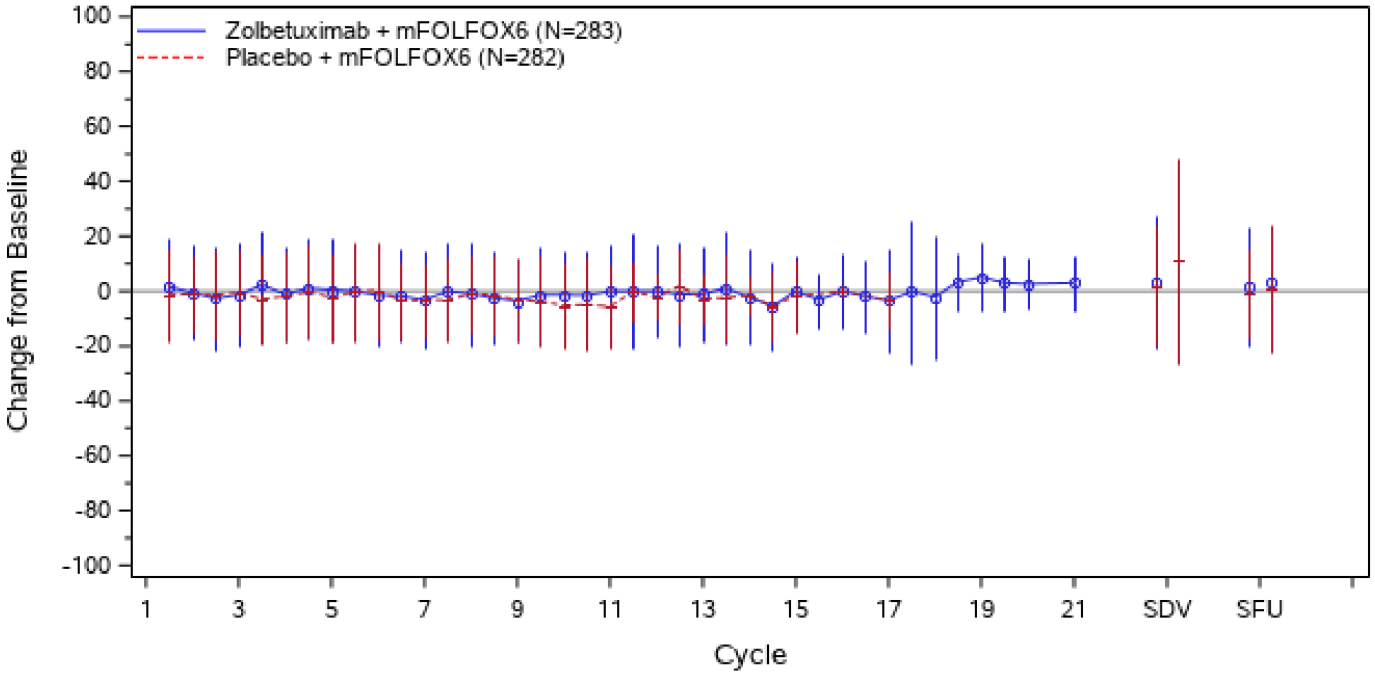
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.31: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score - Full Analysis Set

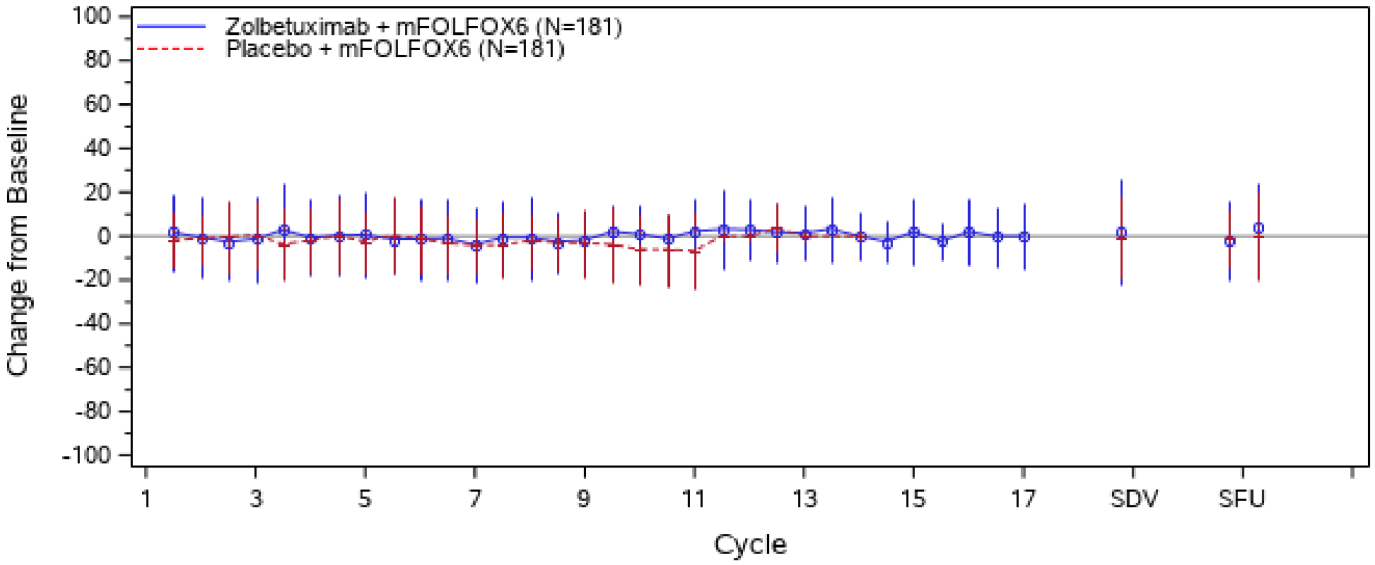


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.31.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

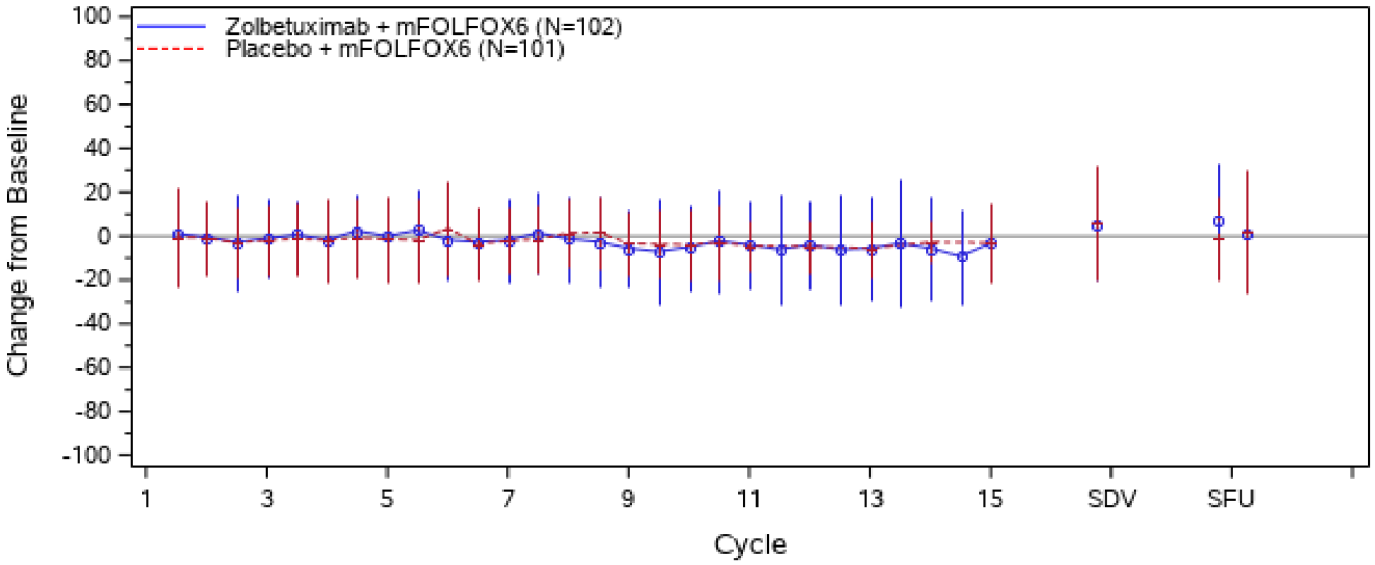


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.31.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

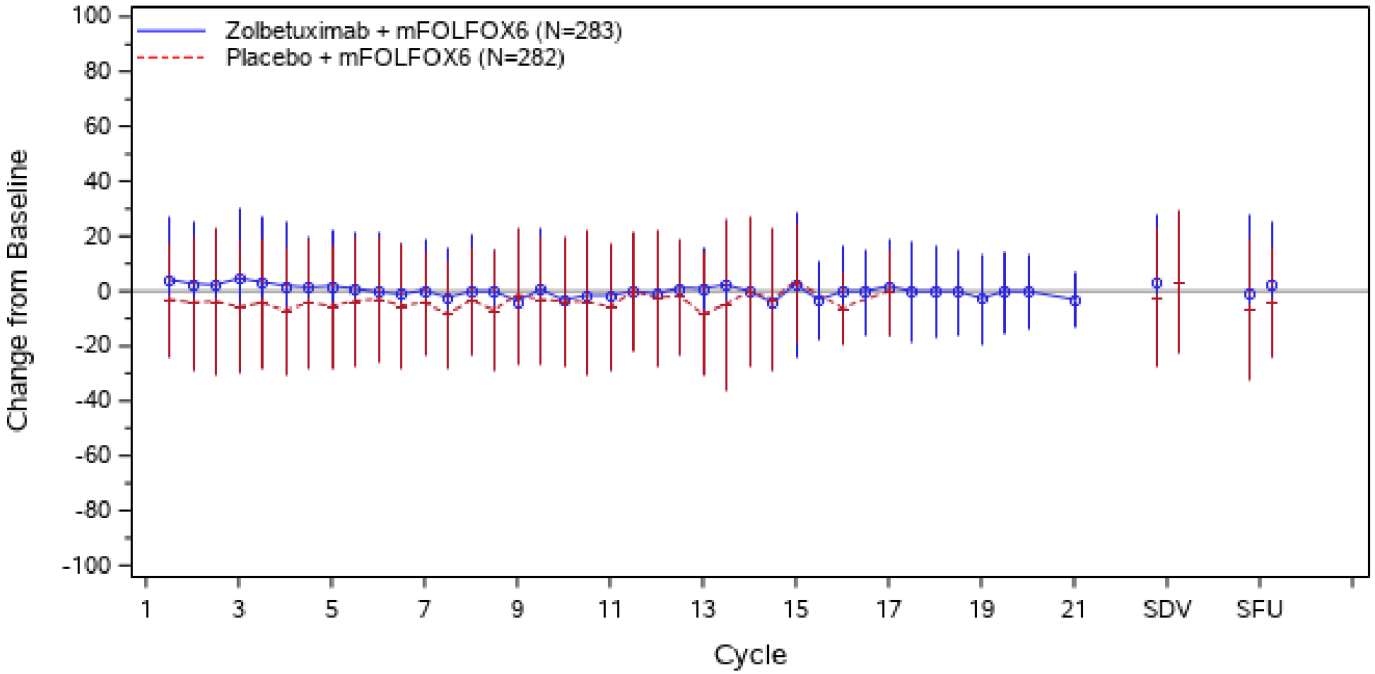
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

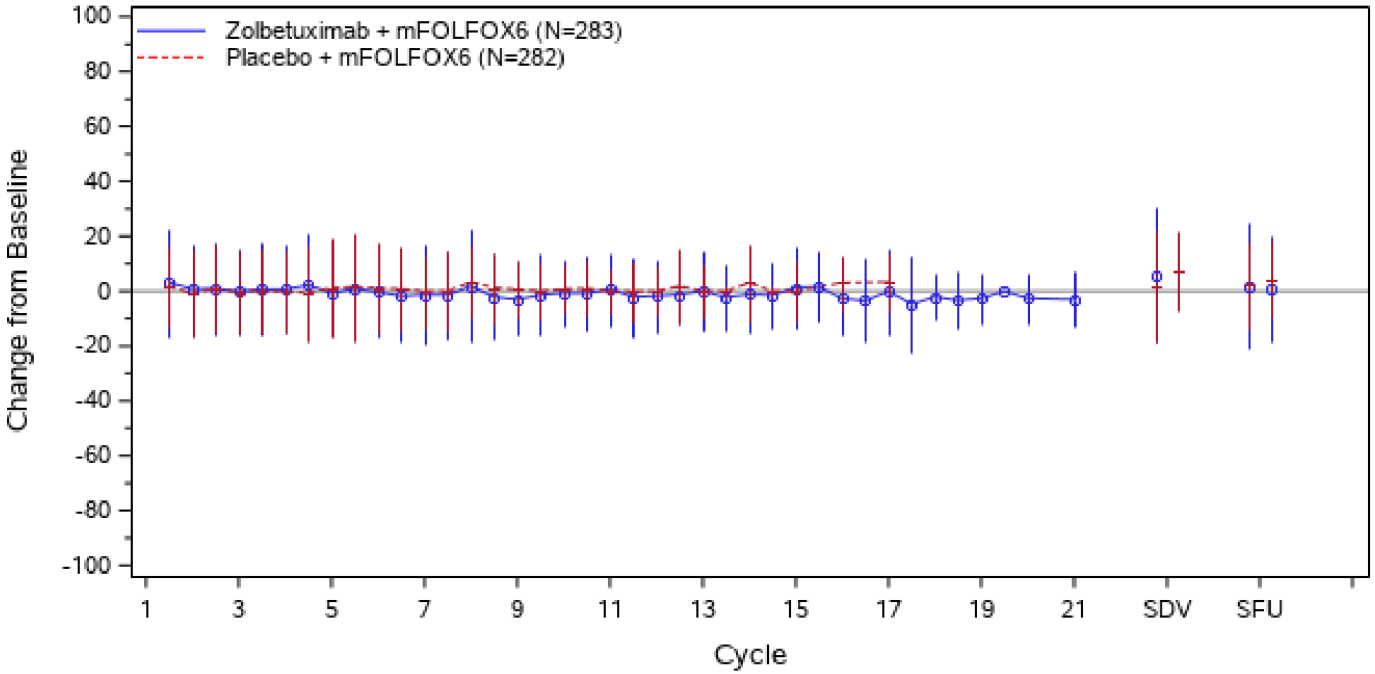
Figure 301.1.3002.32: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.33: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking - Full Analysis Set

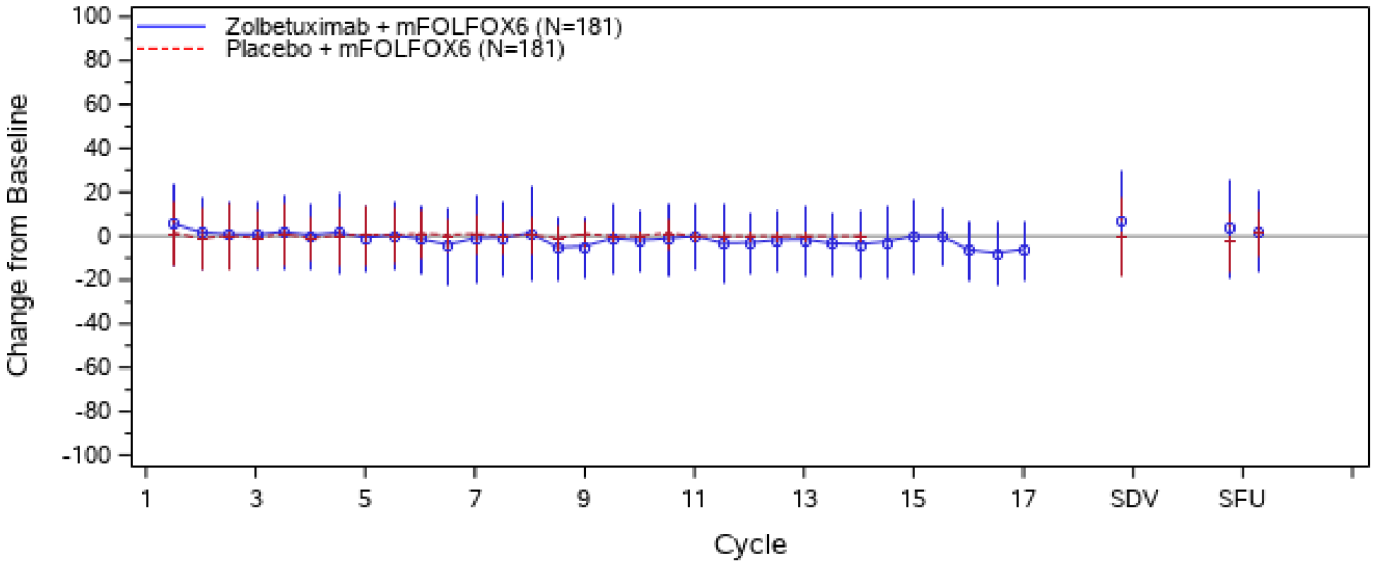


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.33.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

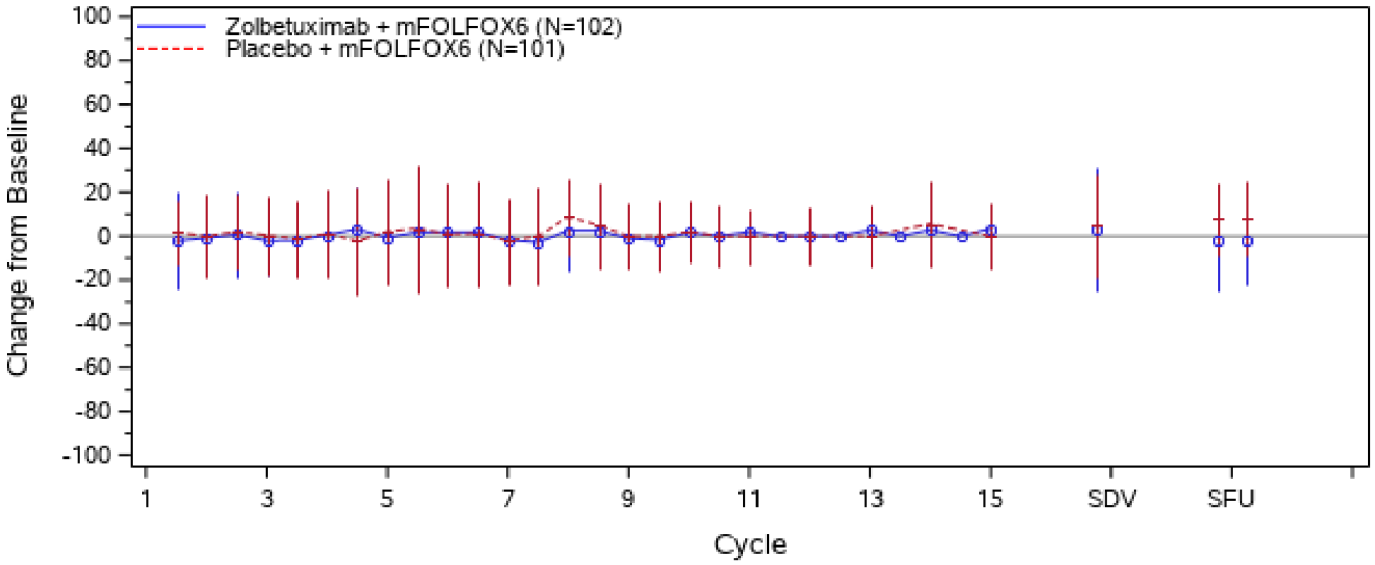


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

Figure 301.1.3002.33.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

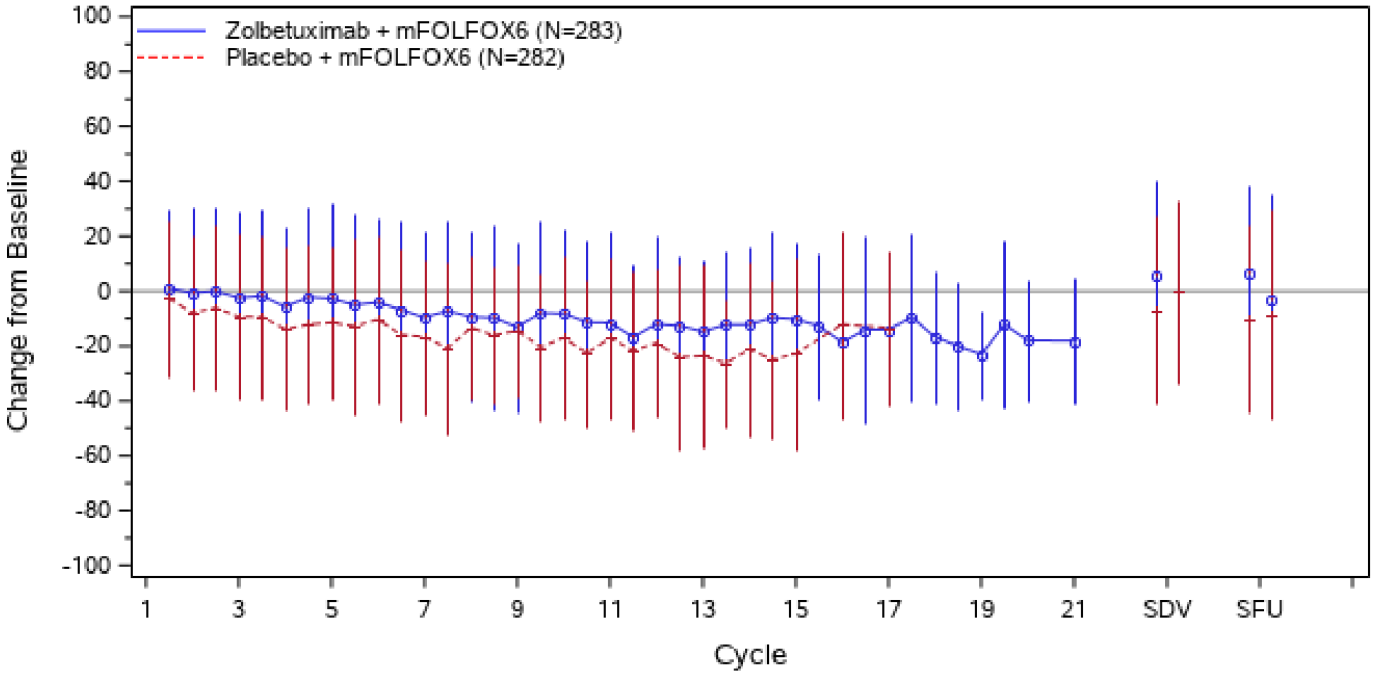
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 09SEP22

The SAS System

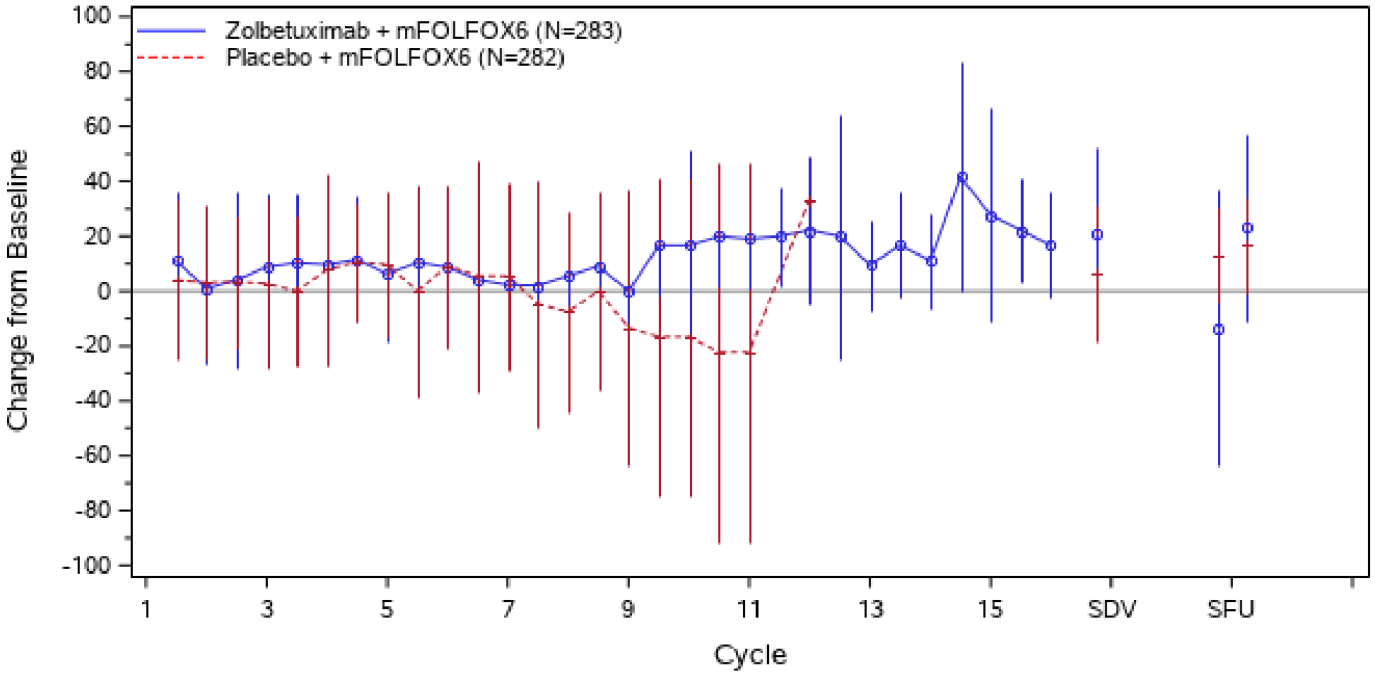
Figure 301.1.3002.34: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Weight Loss - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3002.35: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Hair Loss - Full Analysis Set



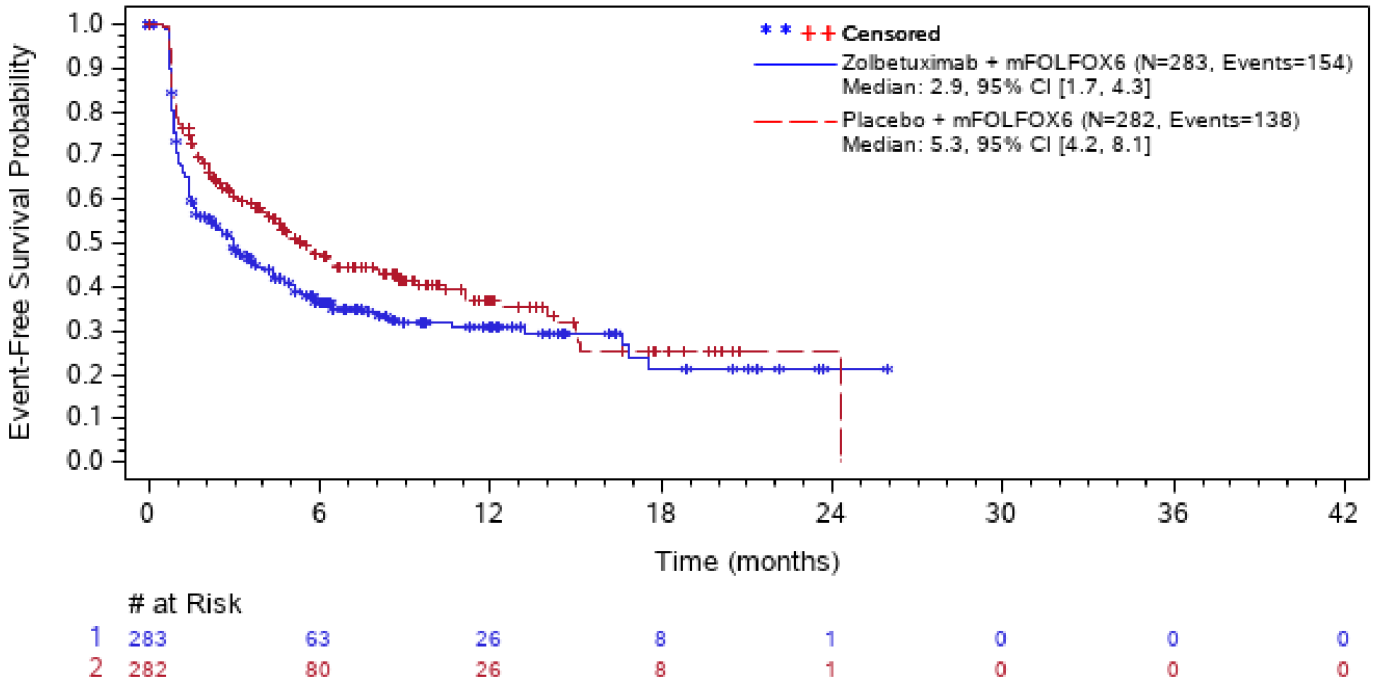
Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

5. Kaplan-Meier-Plots

The SAS System

Figure 301.1.3004.20: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set



	# at Risk							
1	283	63	26	8	1	0	0	0
2	282	80	26	8	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

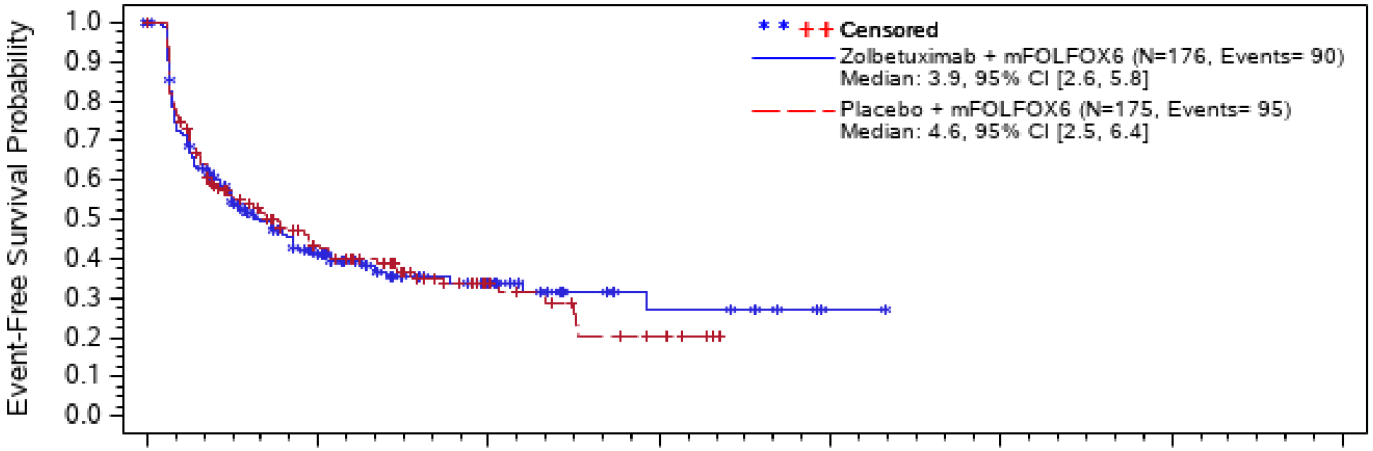
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.20.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - Full Analysis Set

Sex: Male



	# at Risk							
1	176	46	19	6	1	0	0	0
2	175	47	16	5	0	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

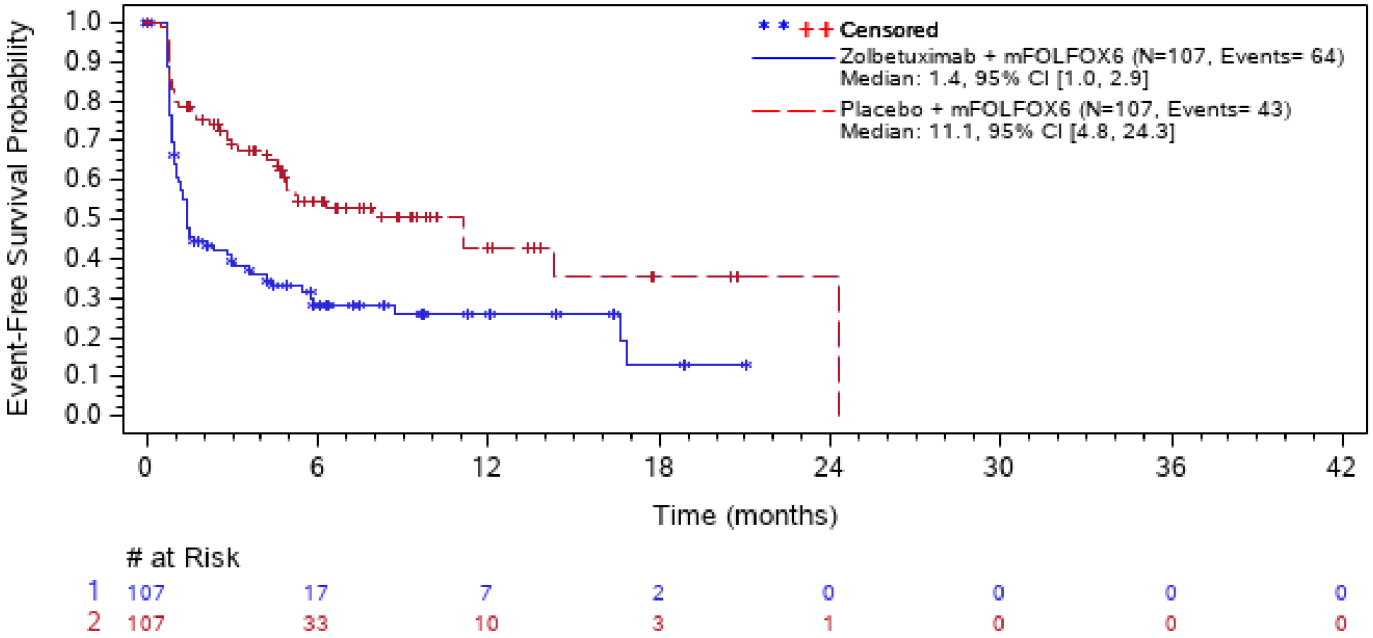
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.20.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - Full Analysis Set

Sex: Female



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

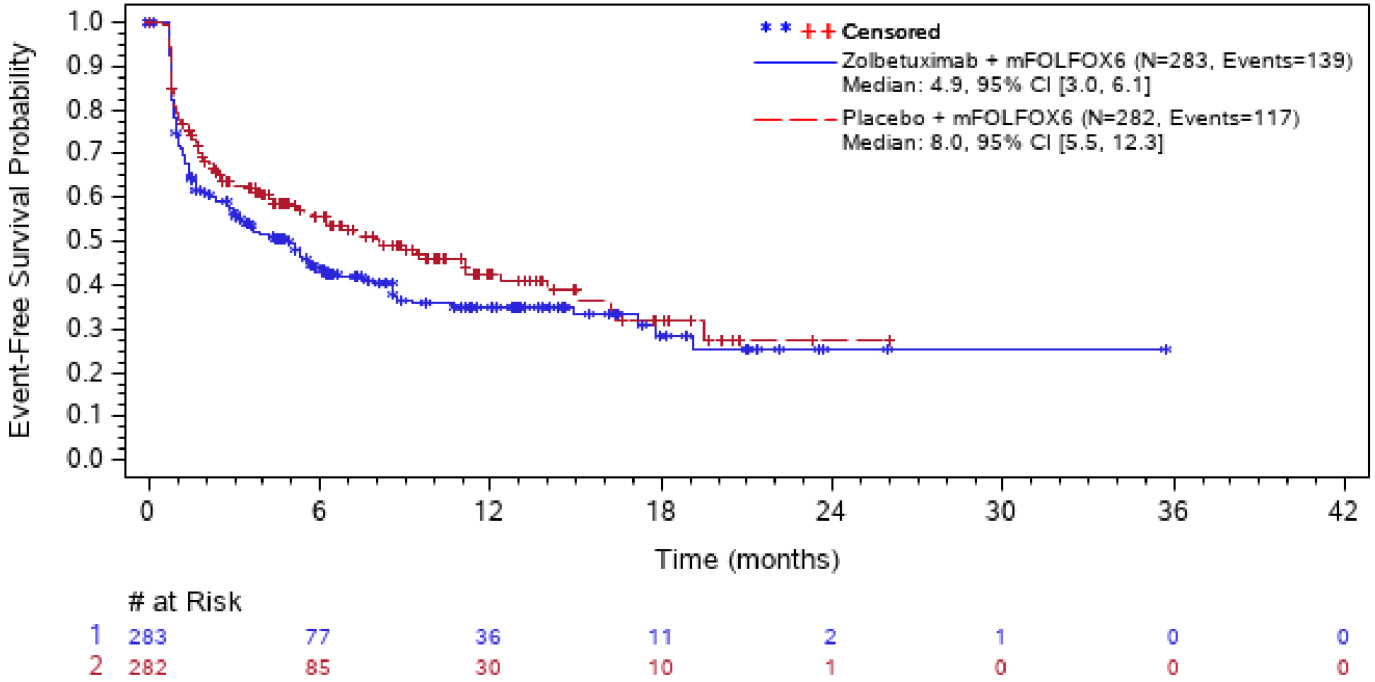
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.21: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set



	# at Risk							
1	283	77	36	11	2	1	0	0
2	282	85	30	10	1	0	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

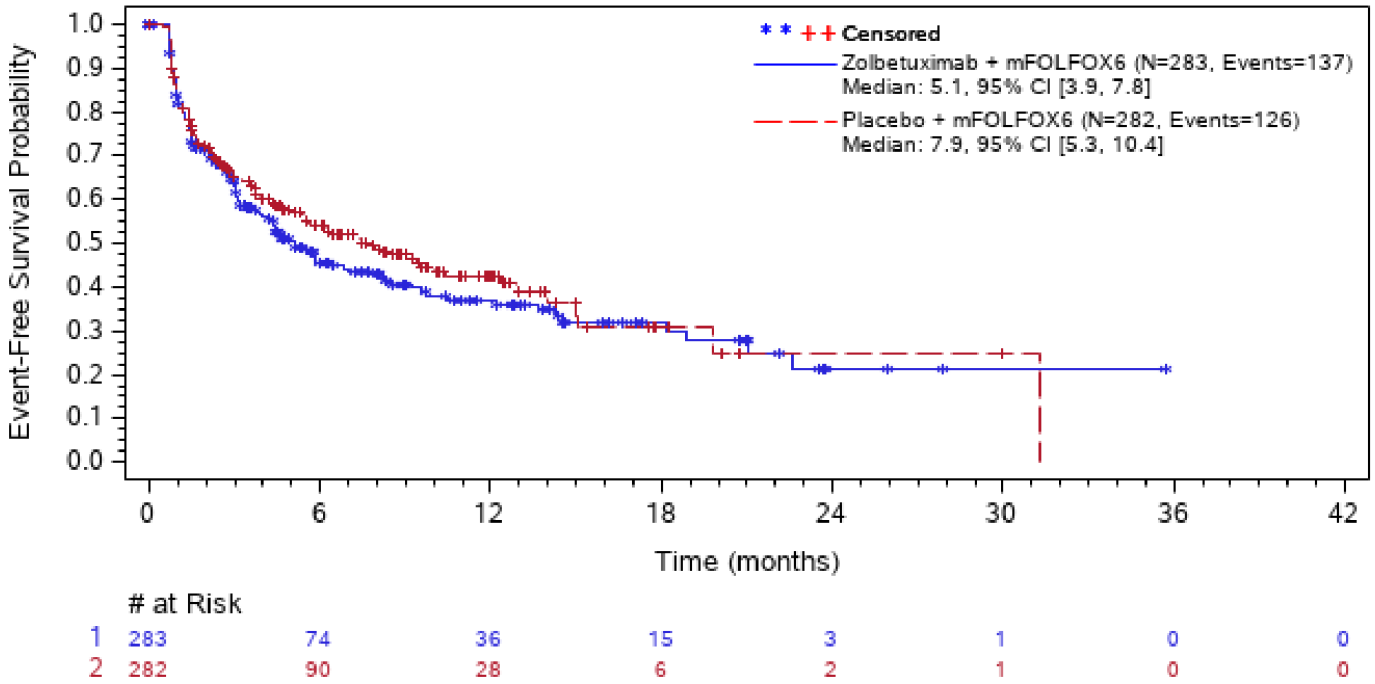
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.22: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set



	# at Risk							
1	283	74	36	15	3	1	0	0
2	282	90	28	6	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

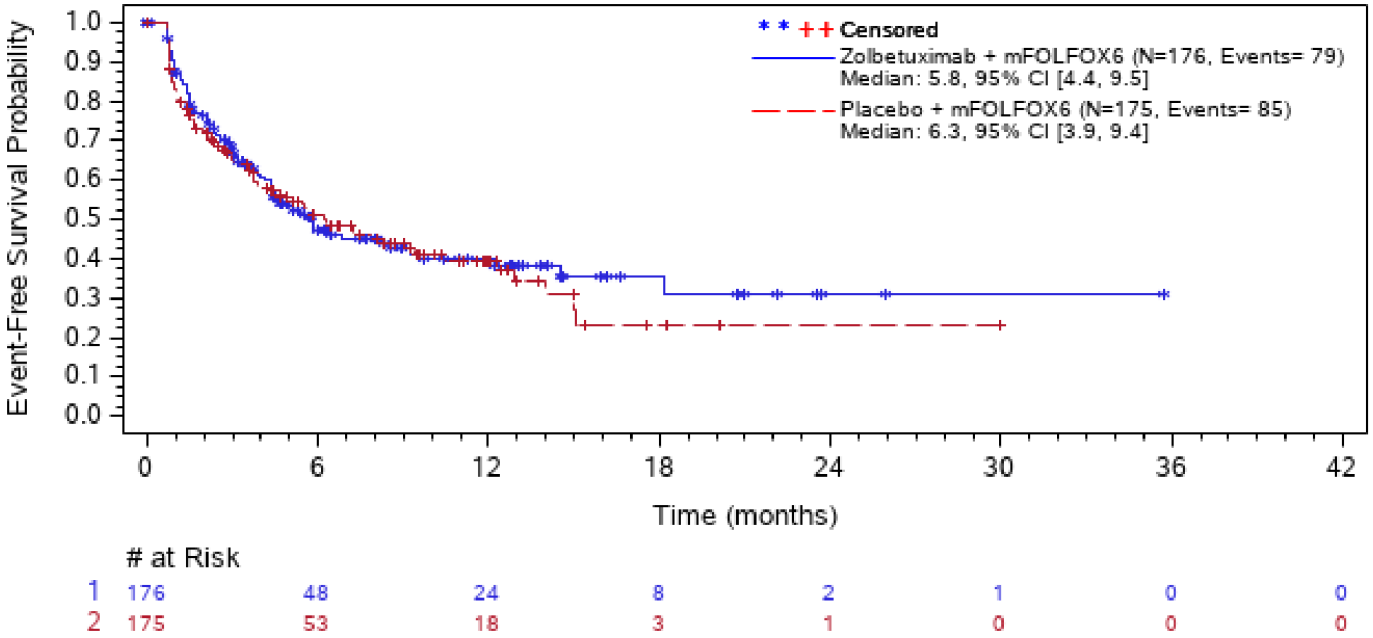
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.22.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux by Sex (MID=10) - Full Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

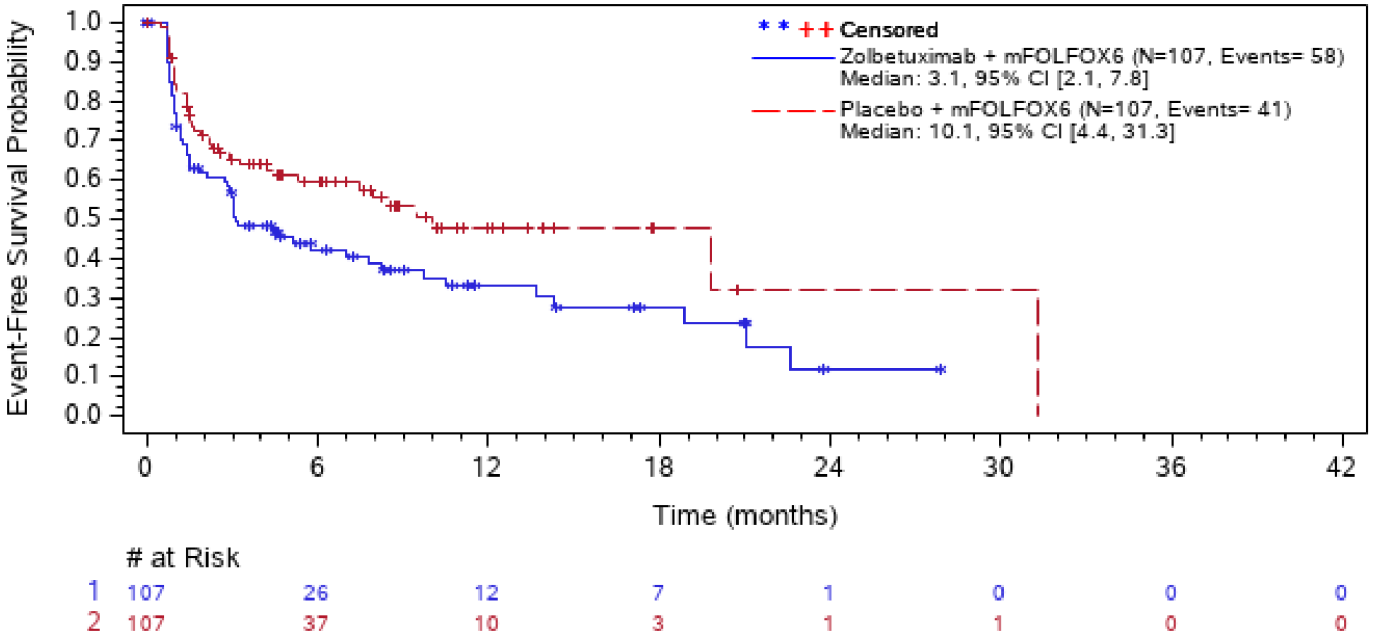
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.22.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux by Sex (MID=10) - Full Analysis Set

Sex: Female



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

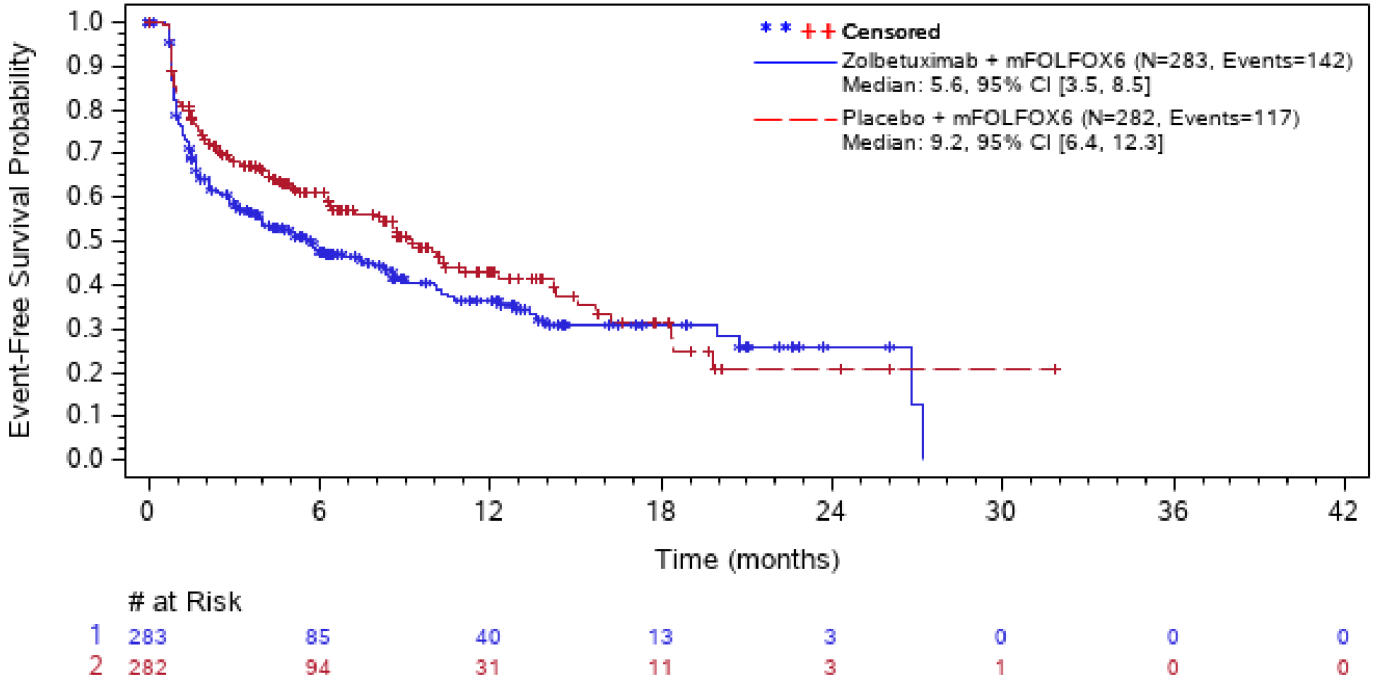
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.23: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set



	# at Risk							
1	283	85	40	13	3	0	0	0
2	282	94	31	11	3	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

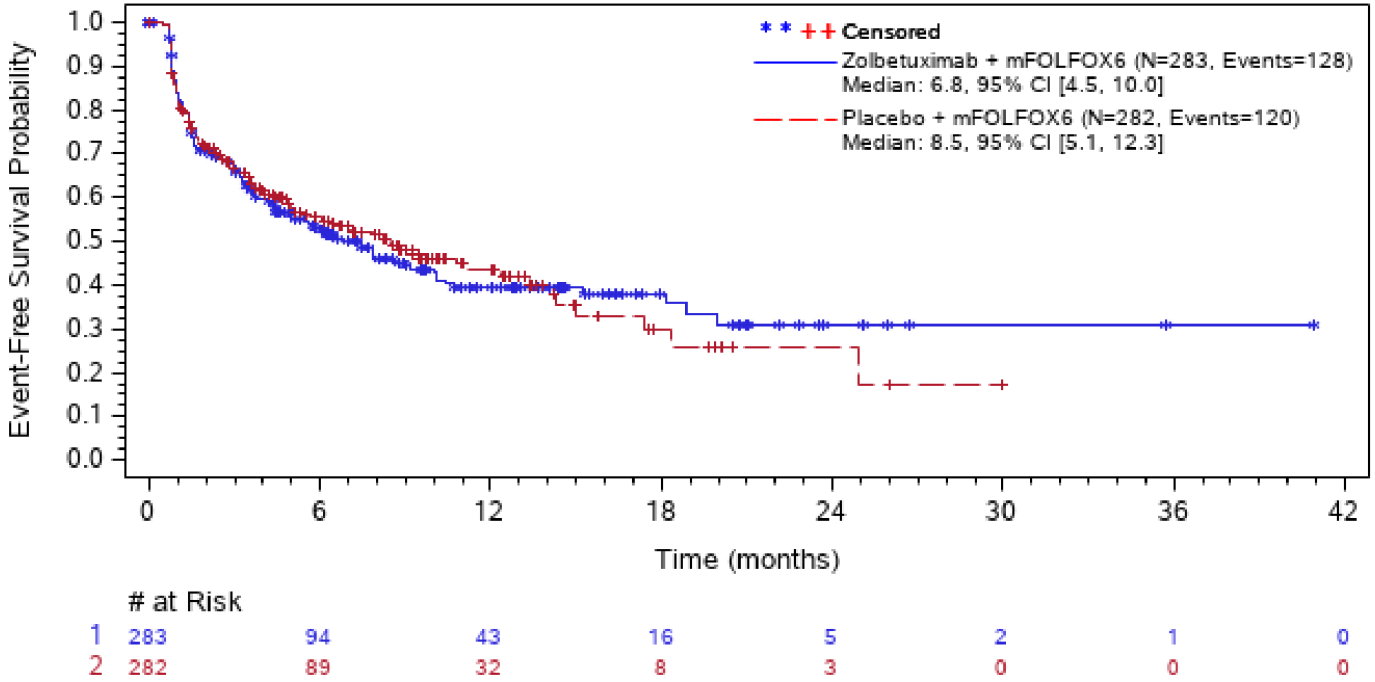
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.24: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

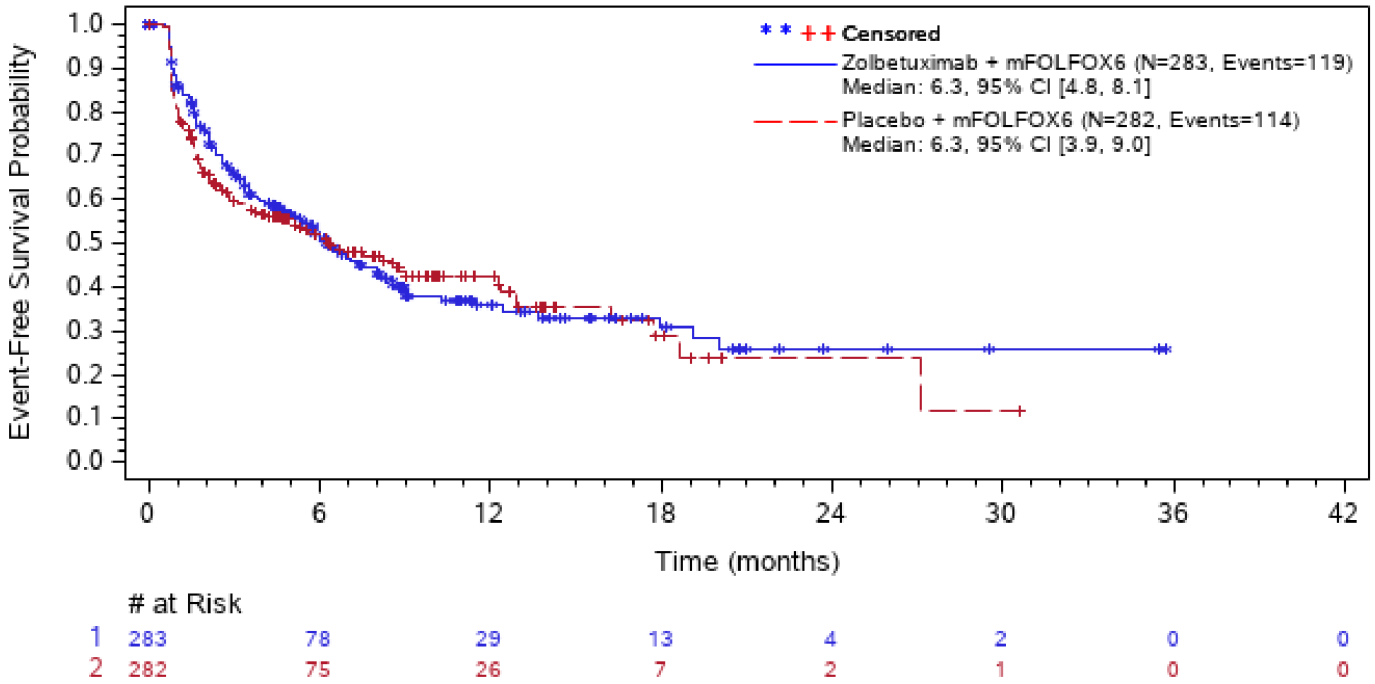
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.25: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set



	# at Risk							
1	283	78	29	13	4	2	0	0
2	282	75	26	7	2	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

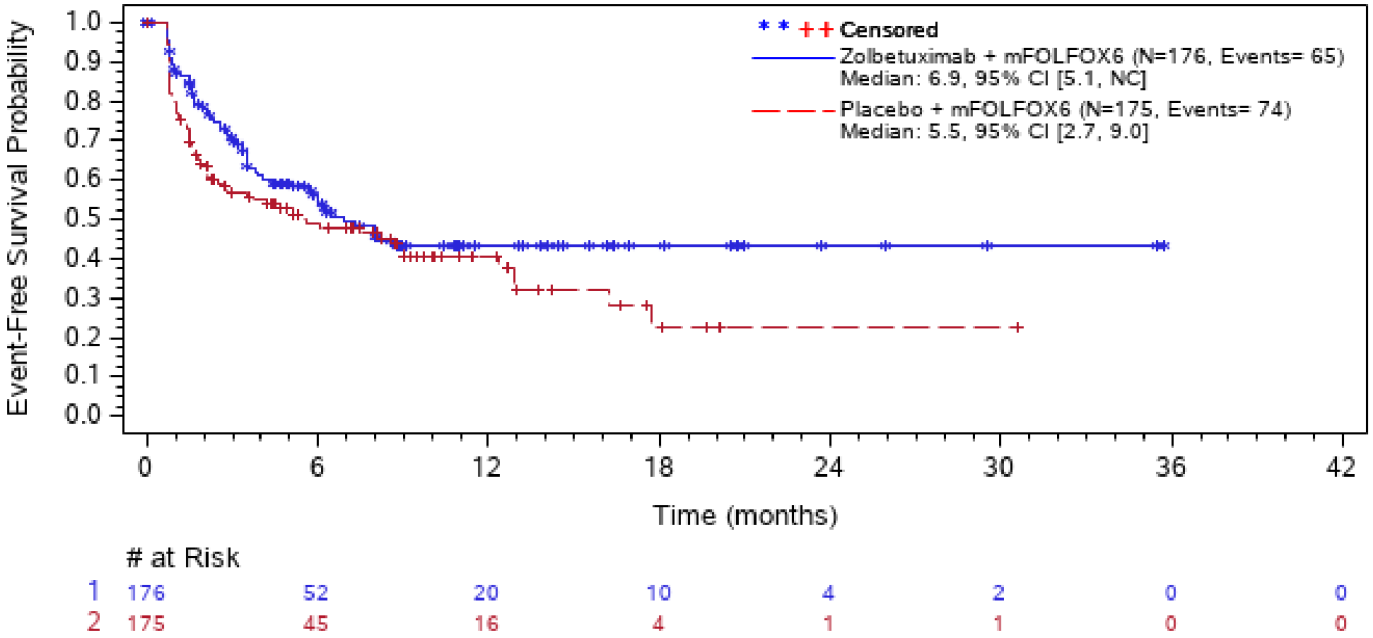
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.25.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety by Sex (MID=10) - Full Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

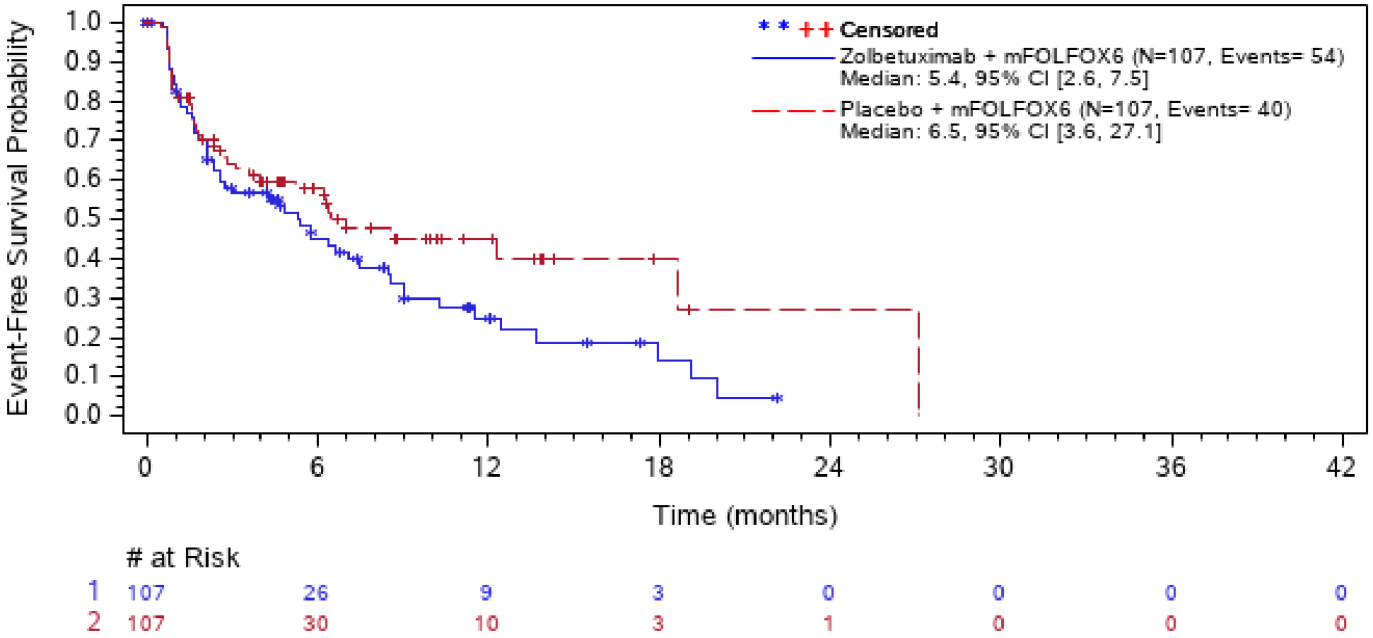
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.25.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety by Sex (MID=10) - Full Analysis Set

Sex: Female



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

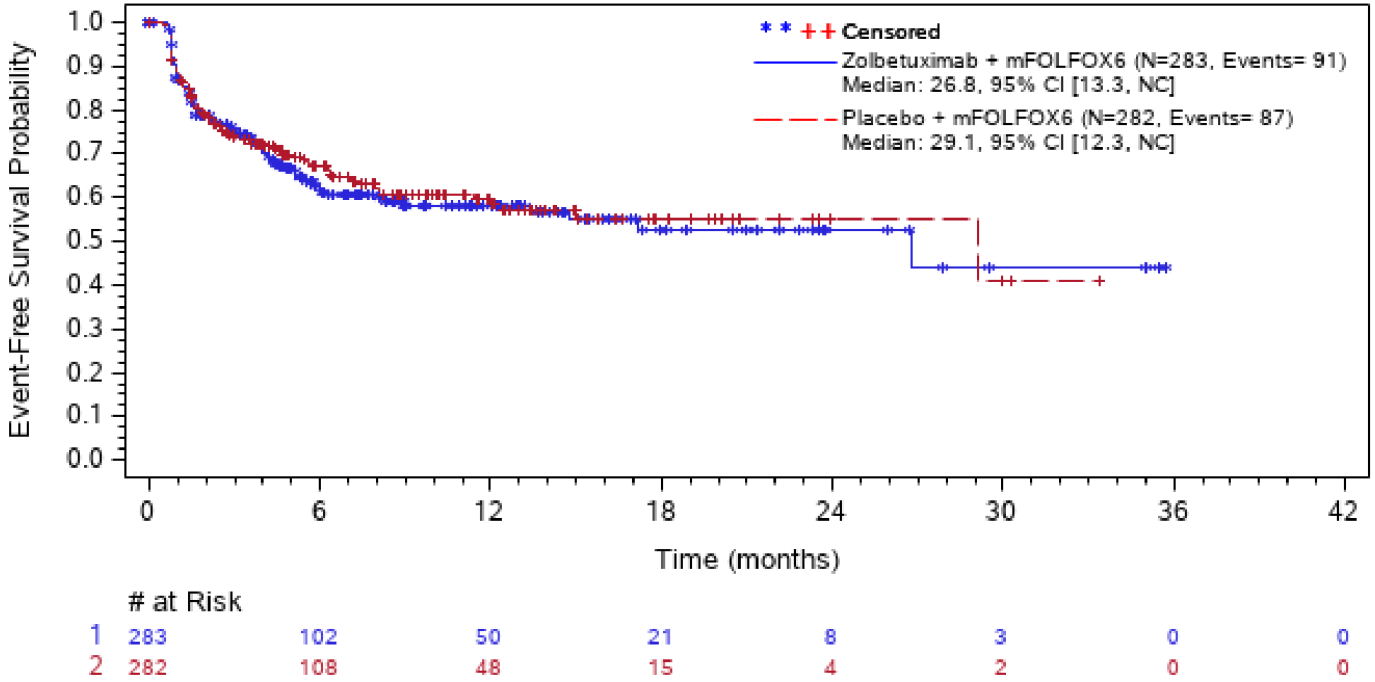
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.26: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set



	# at Risk							
1	283	102	50	21	8	3	0	0
2	282	108	48	15	4	2	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

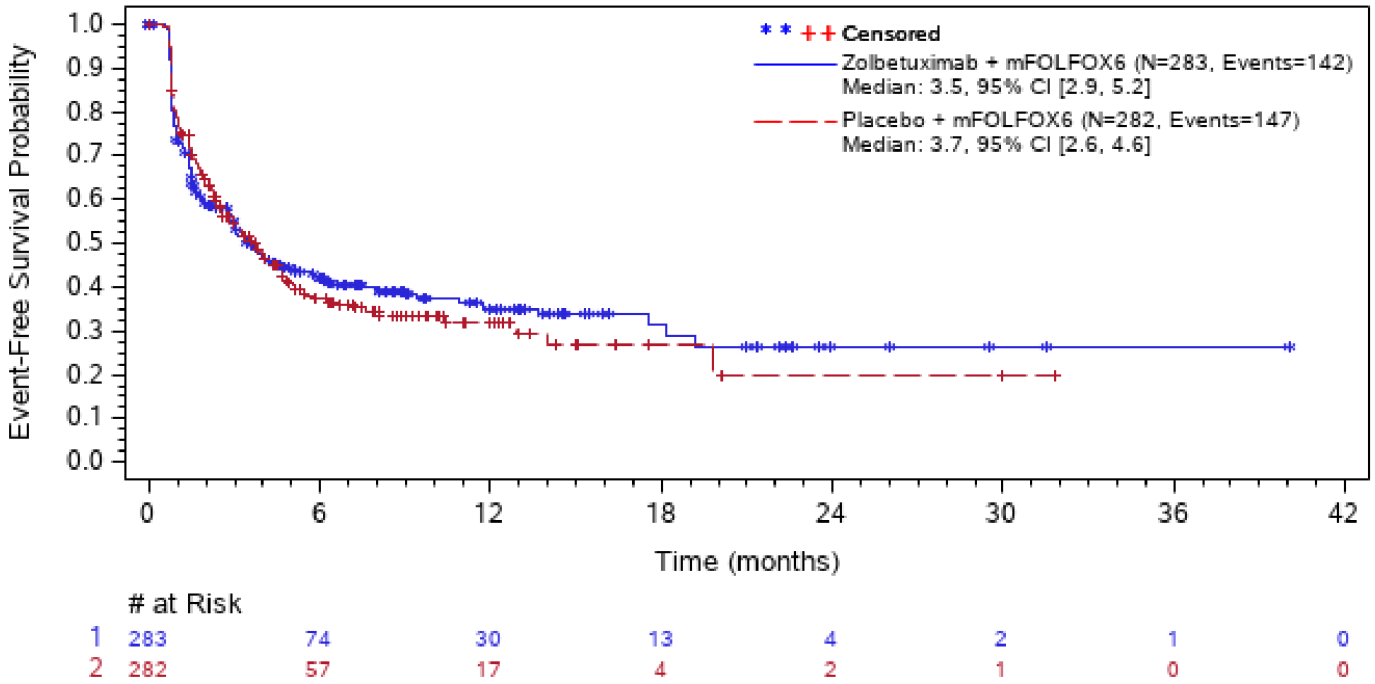
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.27: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

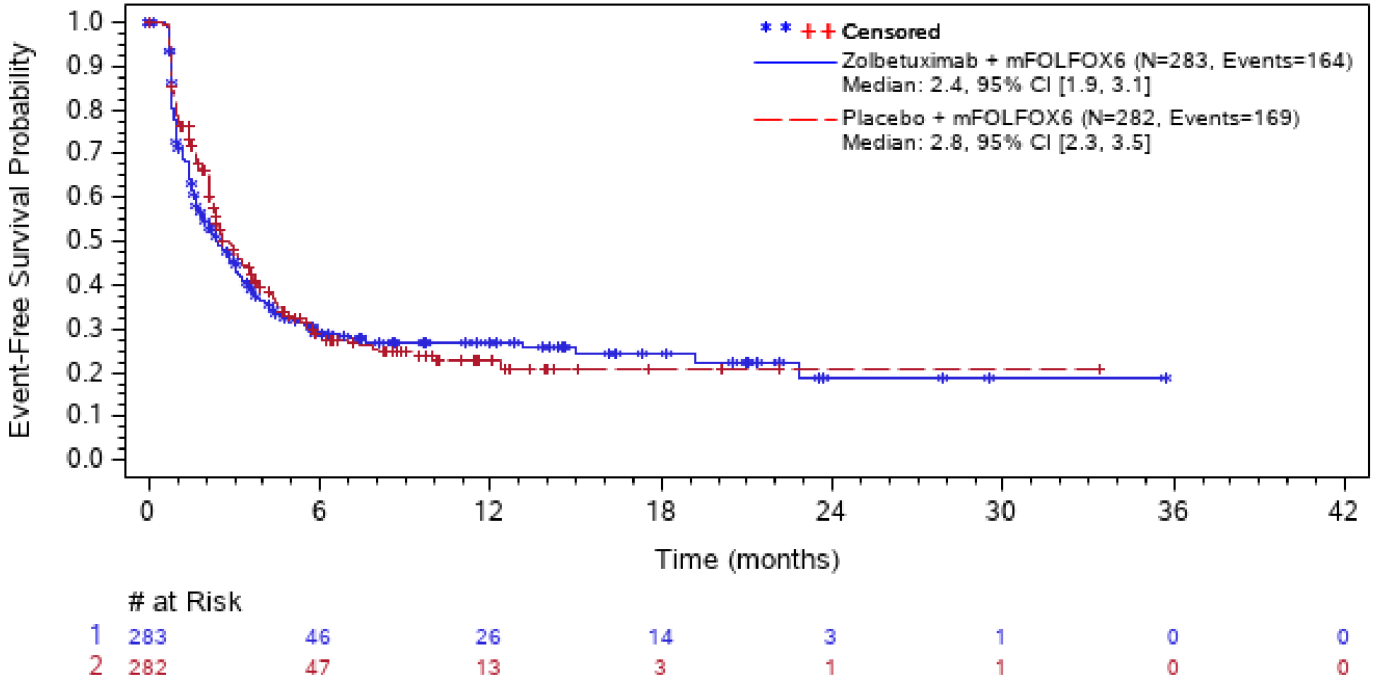
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.28: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set



	# at Risk							
1	283	46	26	14	3	1	0	0
2	282	47	13	3	1	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

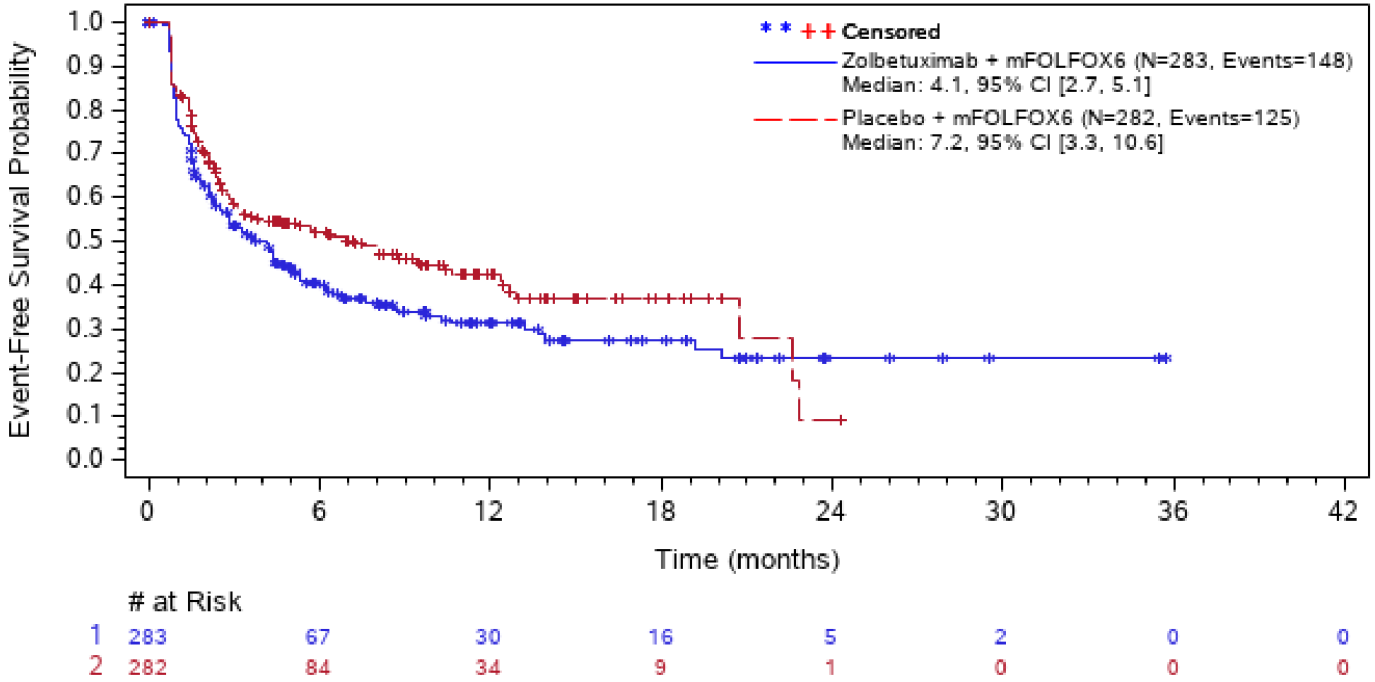
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.29: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

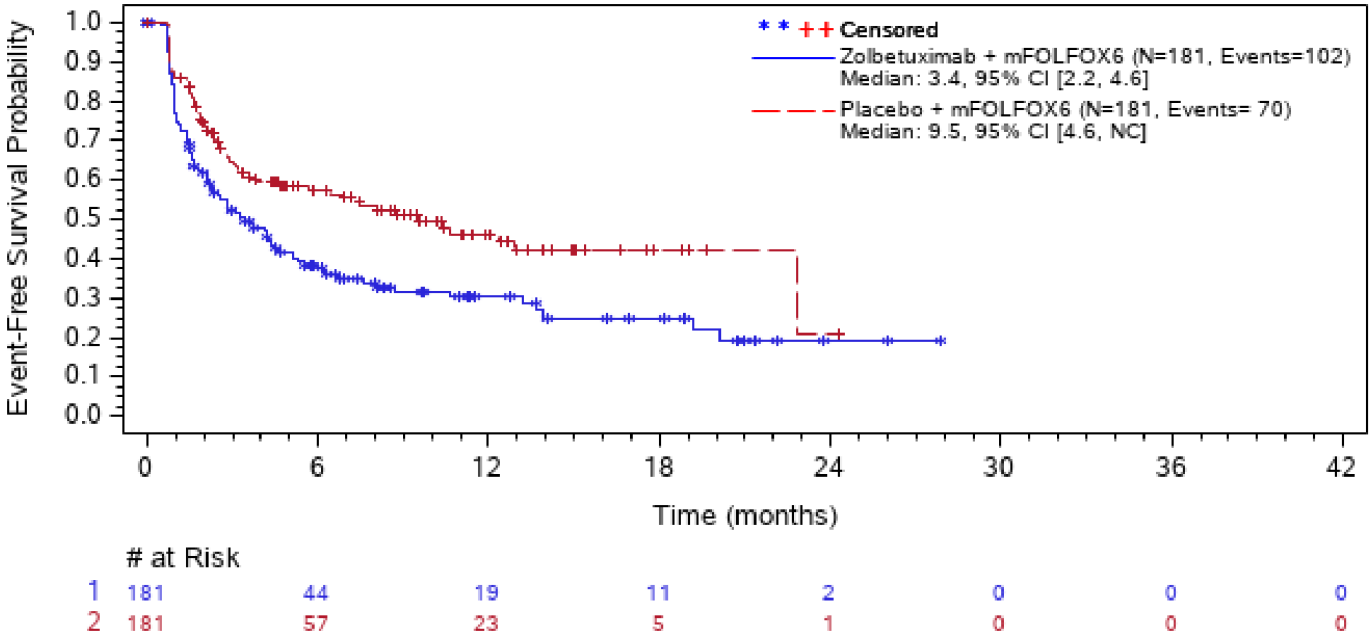
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.29.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

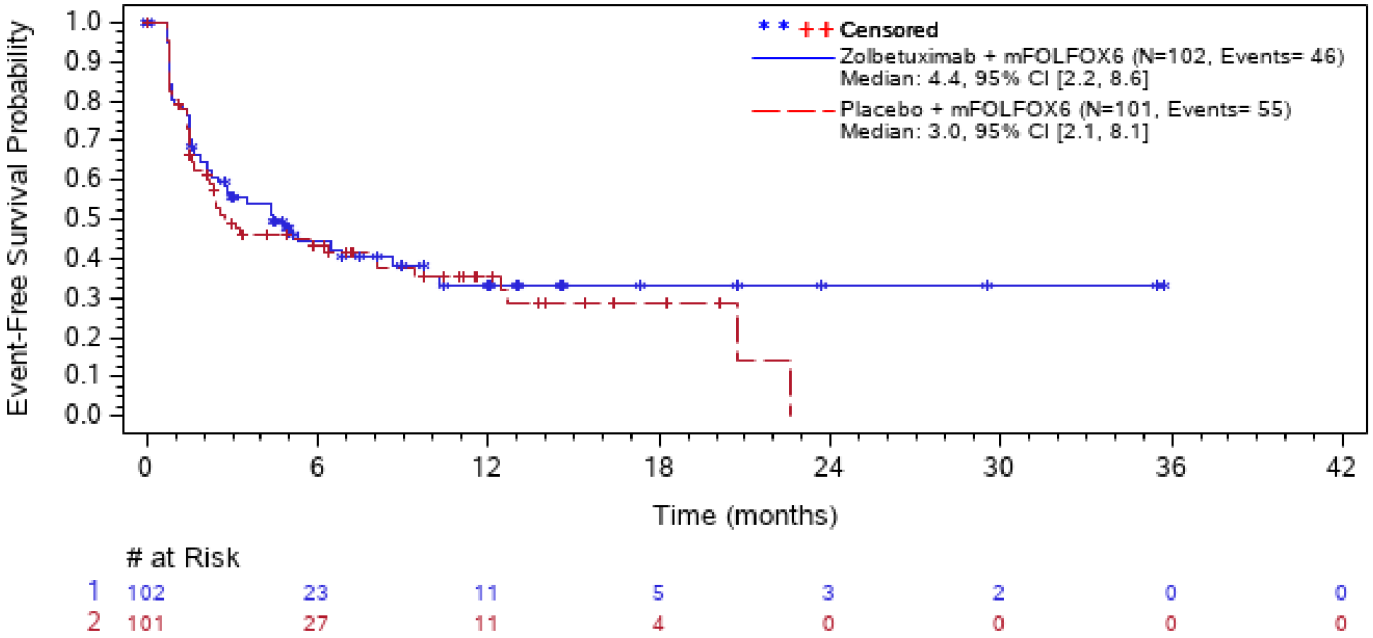
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.29.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

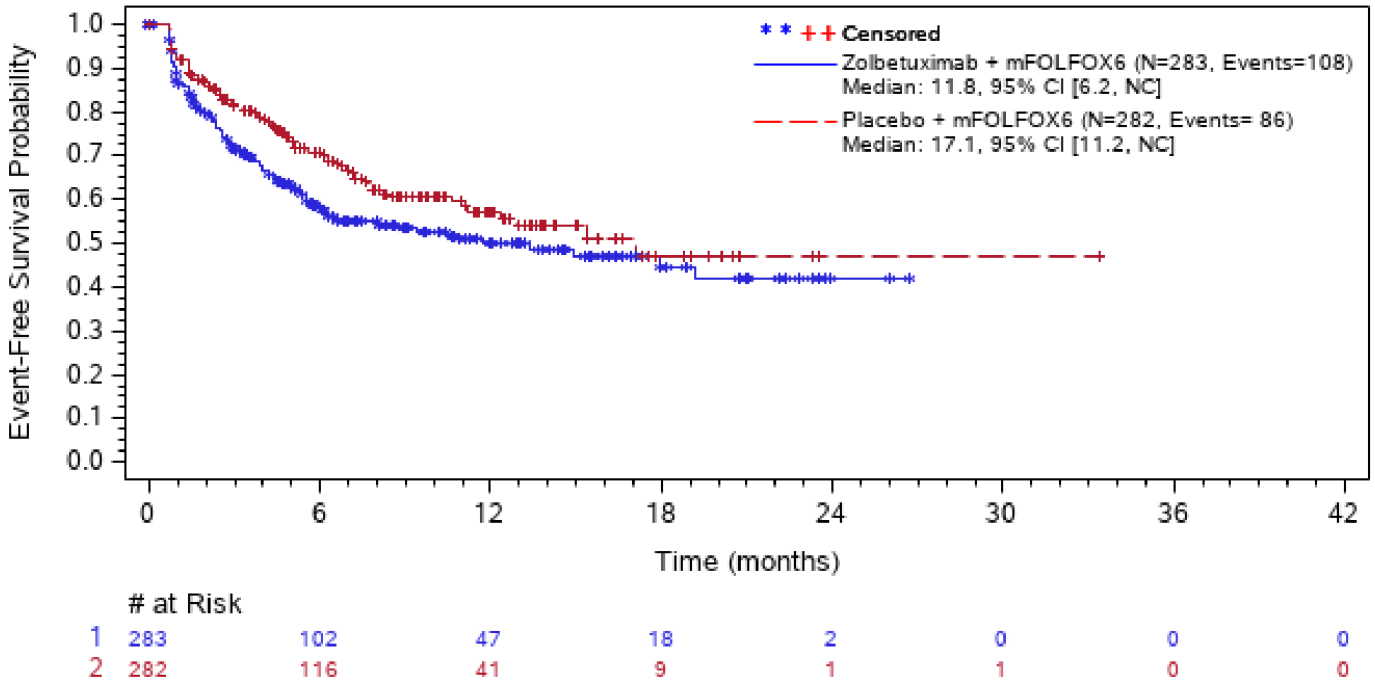
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.30: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

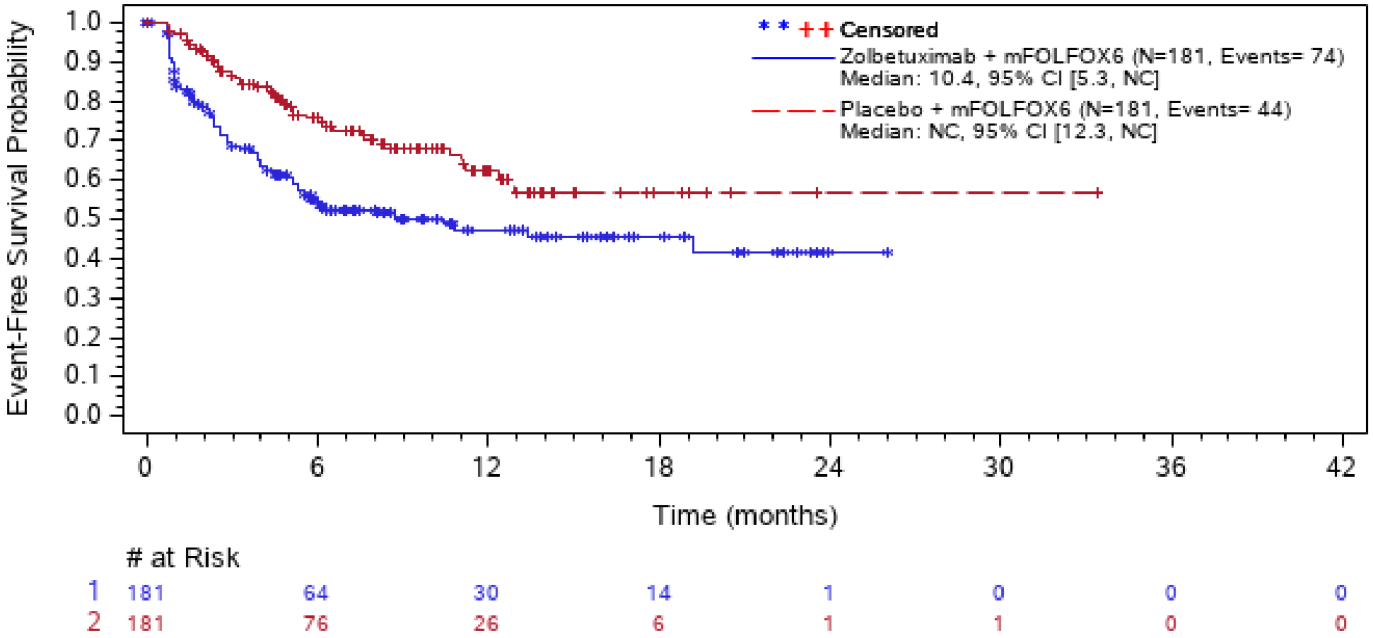
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.30.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

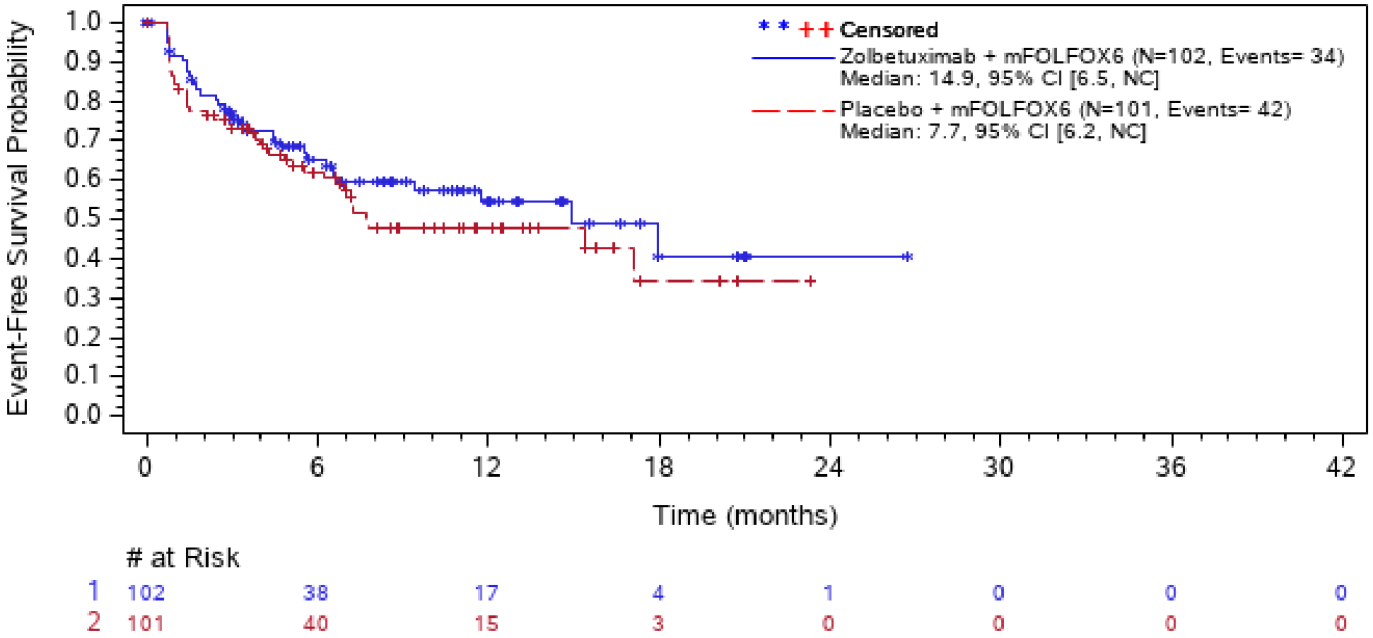
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.30.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

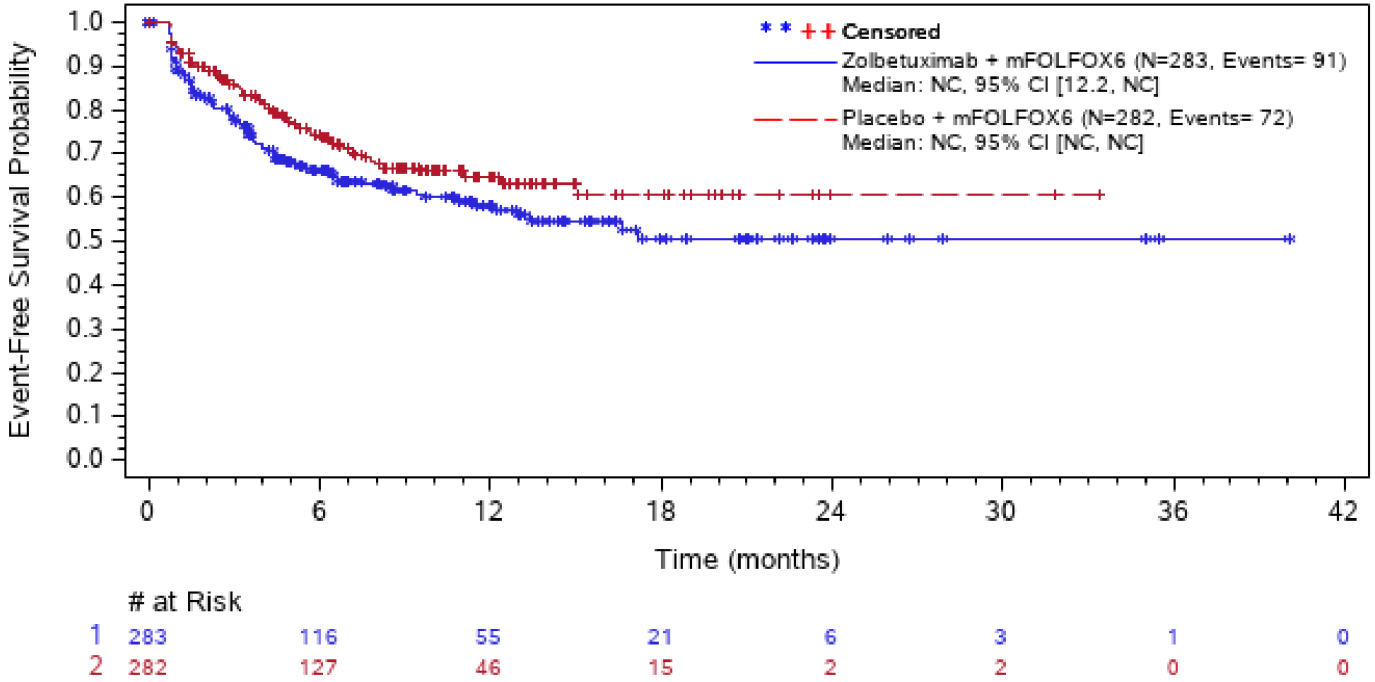
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.31: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

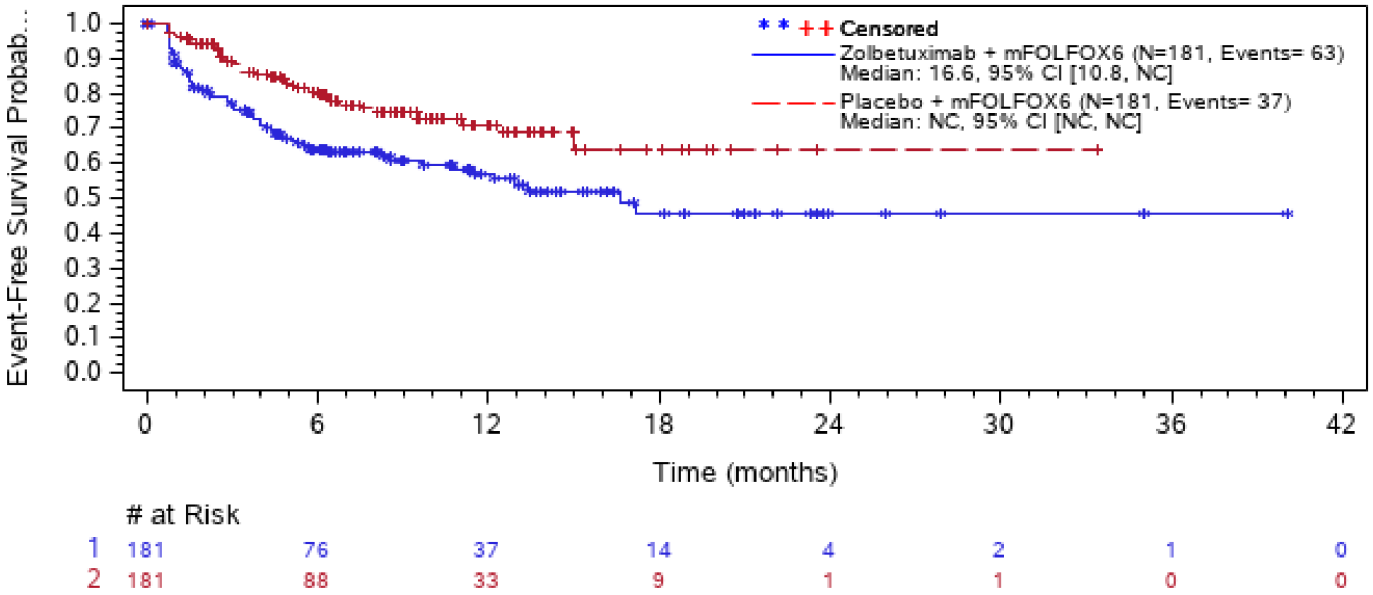
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.31.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

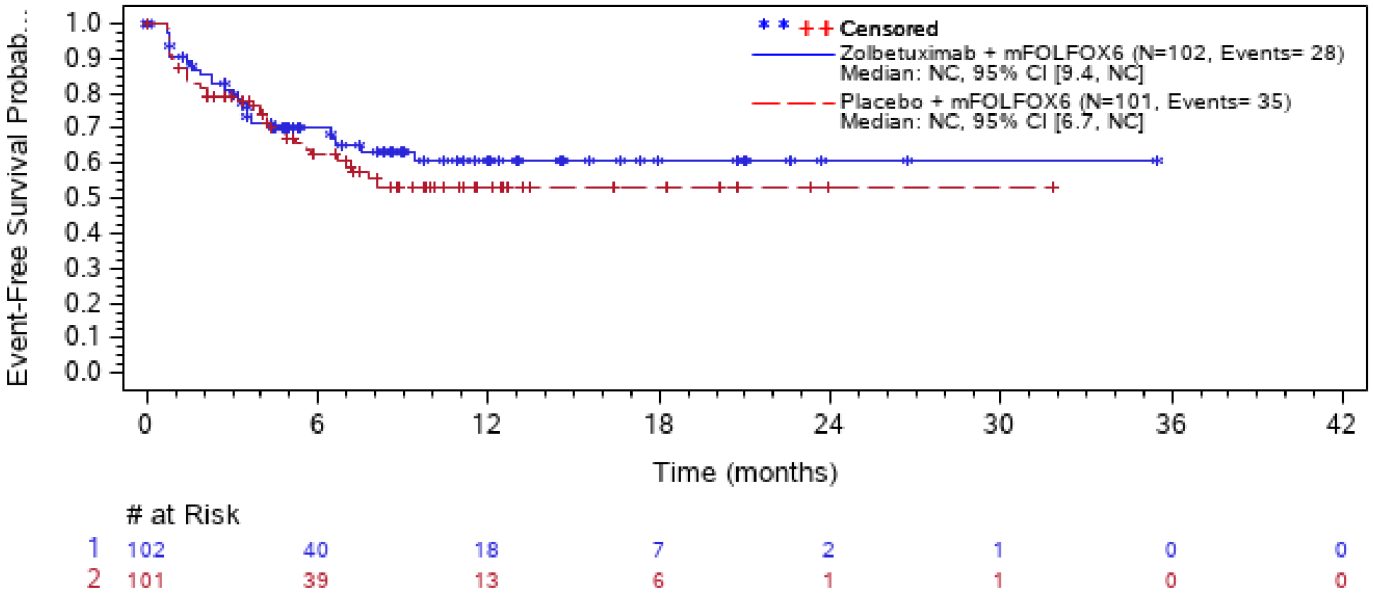
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.31.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

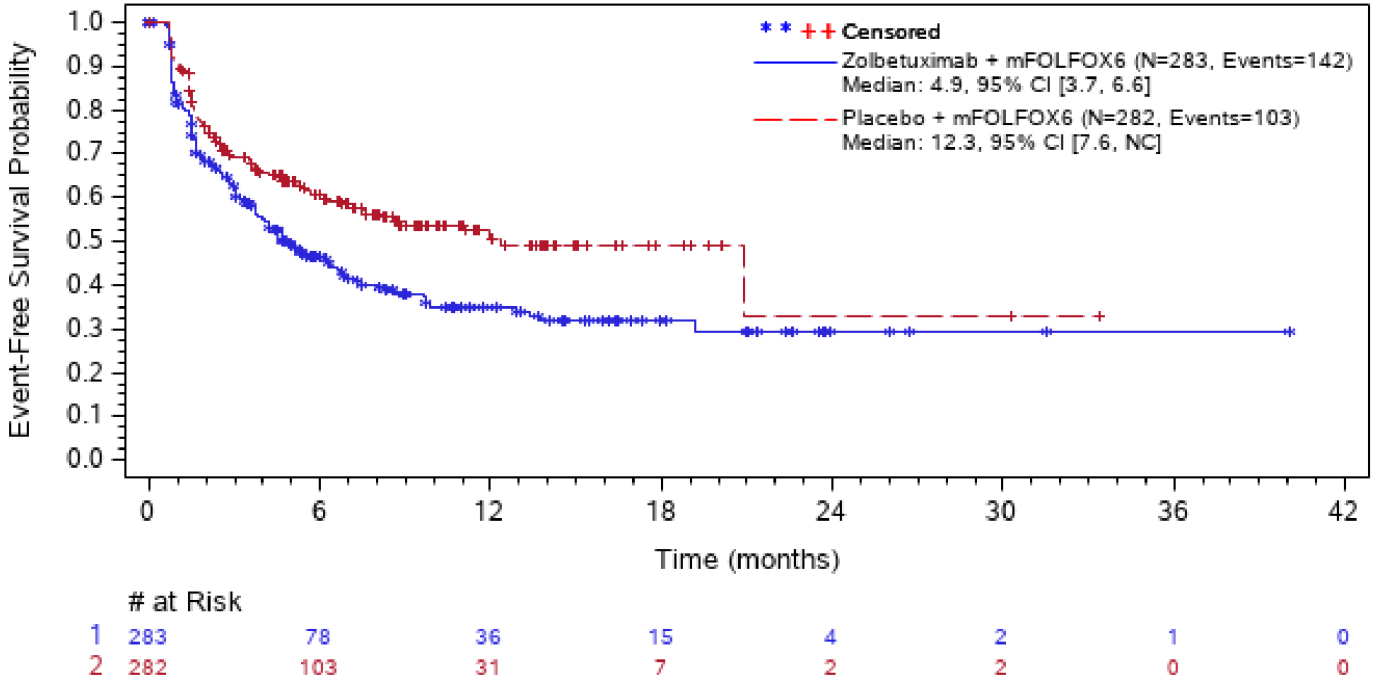
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.32: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

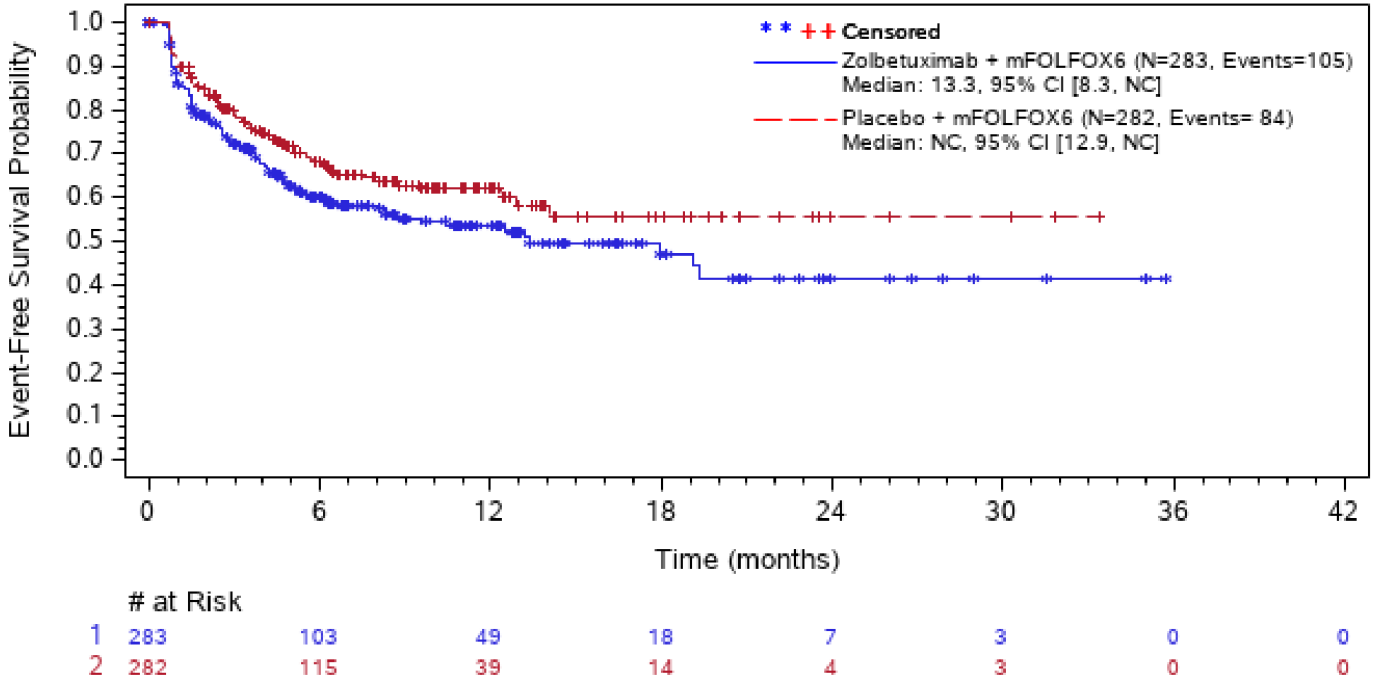
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.33: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

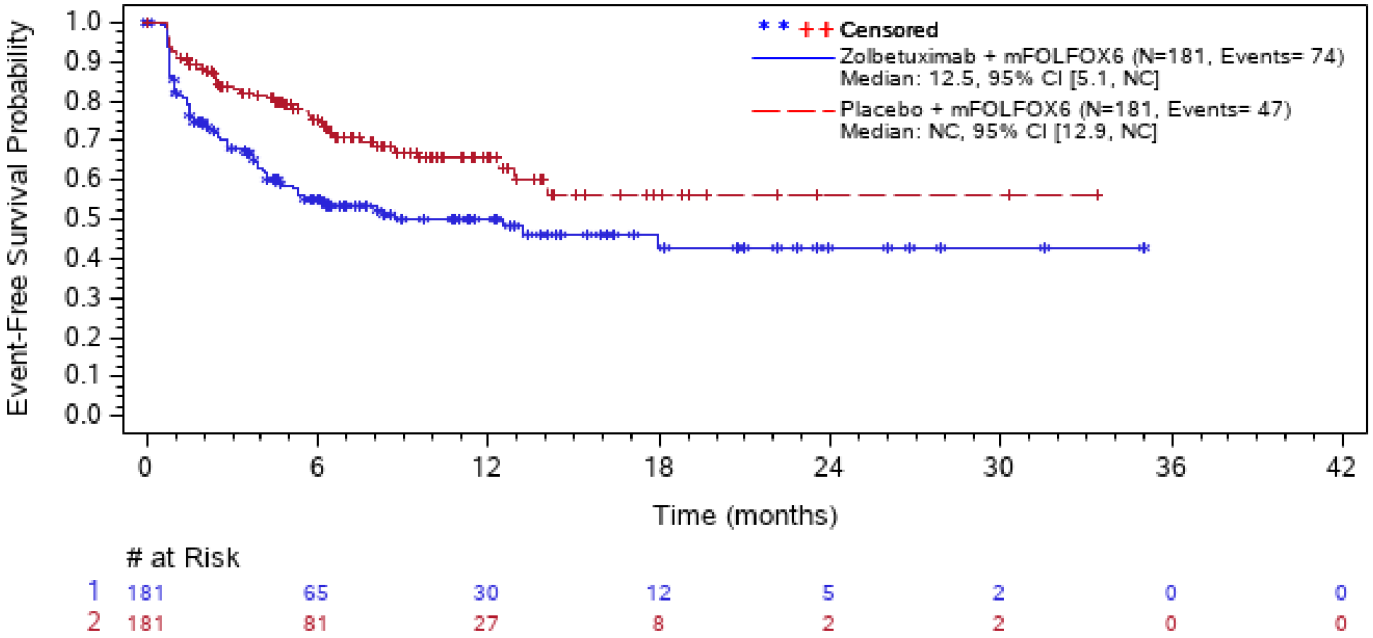
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.33.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

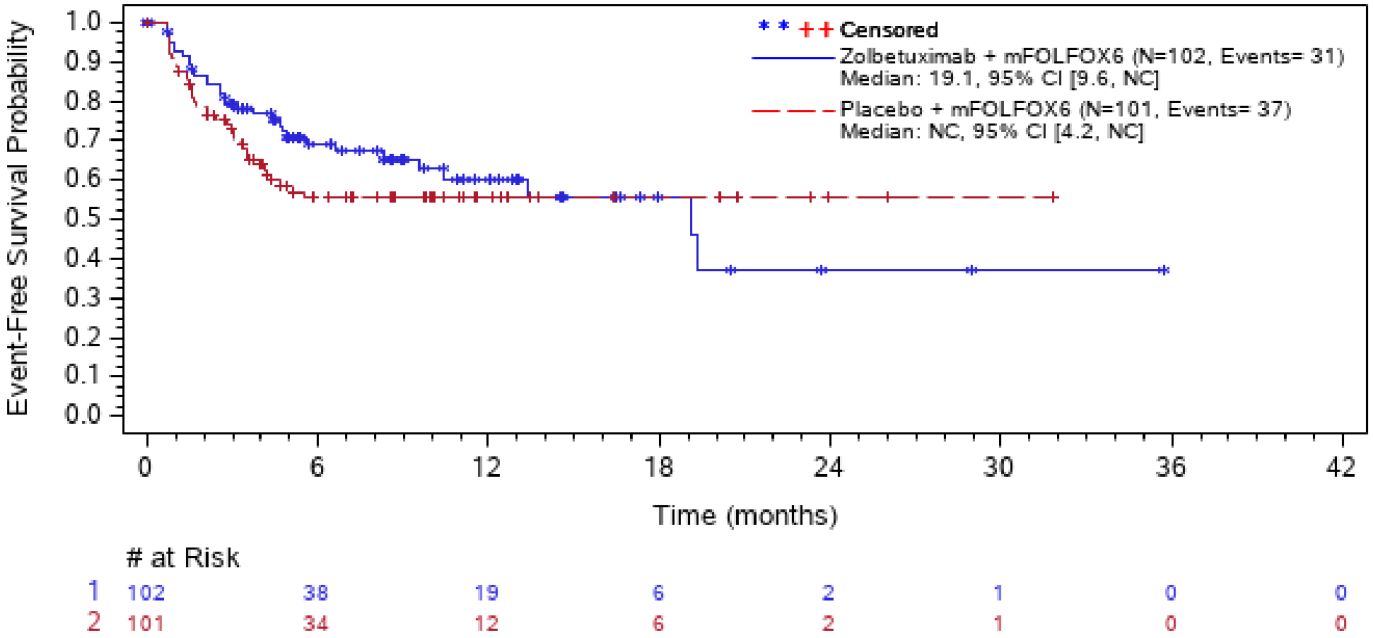
Number of patients at risk is defined as all patients who did not have a (censoring) event immediately before that timepoint.

ASTELLAS Data Cutoff Date: 09SEP22

The SAS System

Figure 301.1.3004.33.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

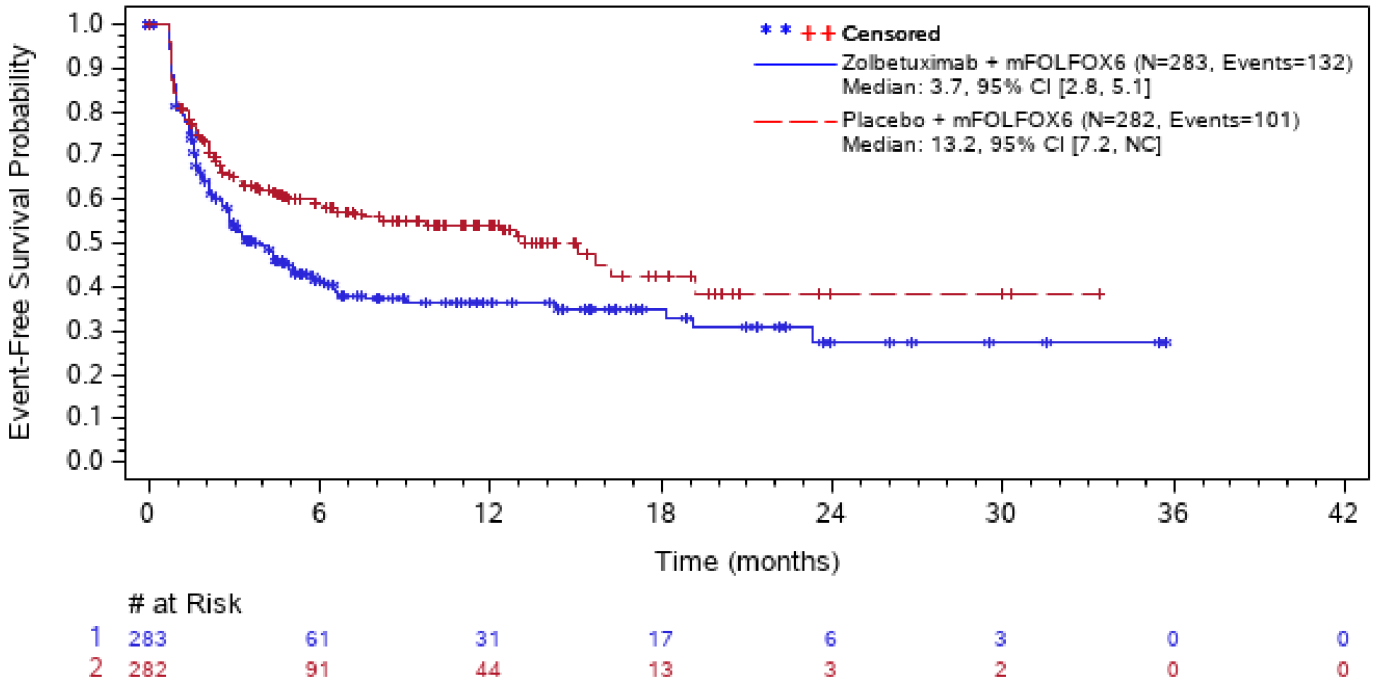
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.34: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

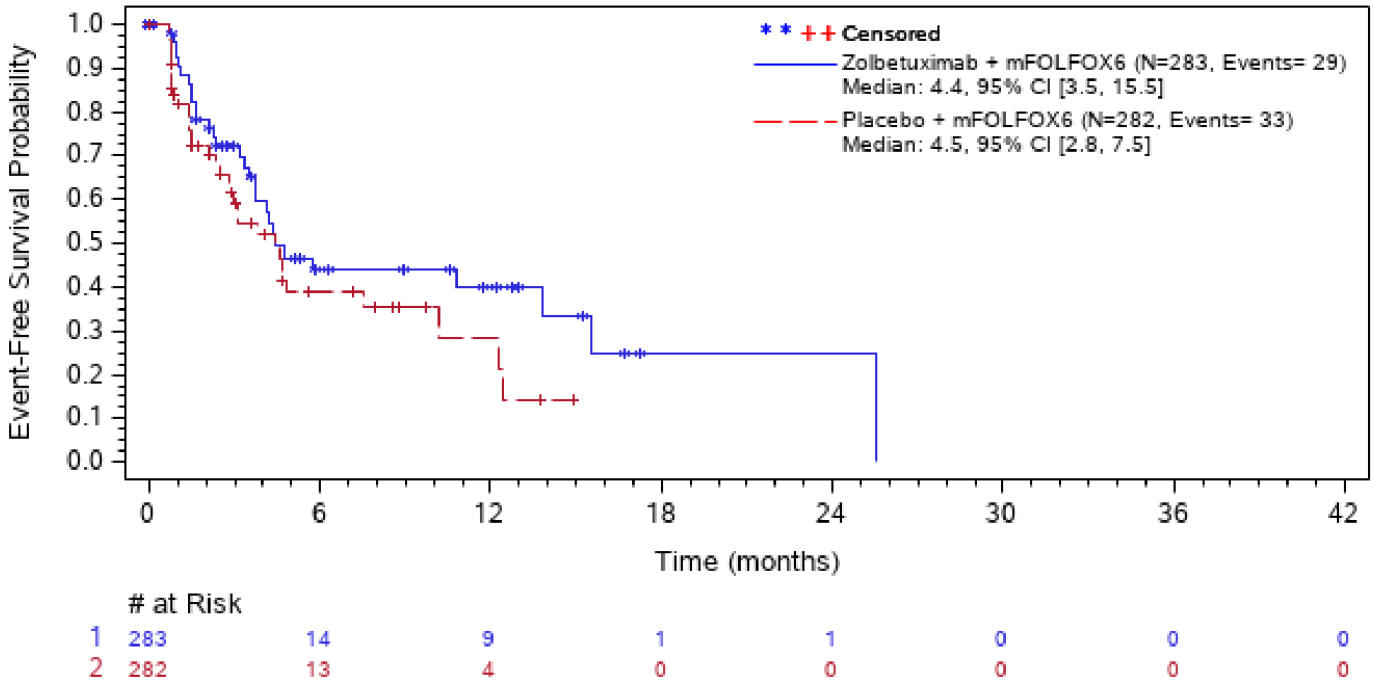
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 09SEP22

The SAS System

Figure 301.1.3004.35: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Schmerzintensität anhand der NRS

1. Rücklaufquoten

Table 301.1.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	184/257 (71.6%)	185/273 (67.8%)	185/283 (65.4%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	212/244 (86.9%)	212/263 (80.6%)	215/283 (76.0%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/257 (61.1%)	157/283 (55.5%)	182/243 (74.9%)	183/264 (69.3%)	183/282 (64.9%)
Cycle 3 Day 1	190/215 (88.4%)	196/254 (77.2%)	199/283 (70.3%)	202/228 (88.6%)	202/259 (78.0%)	202/282 (71.6%)
Cycle 3 Day 22	159/204 (77.9%)	160/250 (64.0%)	160/283 (56.5%)	155/219 (70.8%)	155/257 (60.3%)	155/282 (55.0%)
Cycle 4 Day 1	168/192 (87.5%)	173/244 (70.9%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	126/179 (70.4%)	126/241 (52.3%)	126/283 (44.5%)	131/184 (71.2%)	131/251 (52.2%)	131/282 (46.5%)
Cycle 5 Day 1	148/171 (86.5%)	154/239 (64.4%)	155/283 (54.8%)	147/170 (86.5%)	147/251 (58.6%)	147/282 (52.1%)
Cycle 5 Day 22	112/151 (74.2%)	113/236 (47.9%)	113/283 (39.9%)	118/150 (78.7%)	119/248 (48.0%)	119/282 (42.2%)
Cycle 6 Day 1	120/135 (88.9%)	124/236 (52.5%)	124/283 (43.8%)	118/139 (84.9%)	120/244 (49.2%)	120/282 (42.6%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	92/120 (76.7%)	92/242 (38.0%)	92/282 (32.6%)
Cycle 7 Day 1	106/118 (89.8%)	110/234 (47.0%)	110/283 (38.9%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	80/ 96 (83.3%)	81/231 (35.1%)	81/283 (28.6%)	71/ 85 (83.5%)	71/239 (29.7%)	71/282 (25.2%)
Cycle 8 Day 22	69/ 86 (80.2%)	70/231 (30.3%)	70/283 (24.7%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	71/ 82 (86.6%)	72/229 (31.4%)	72/283 (25.4%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	54/ 69 (78.3%)	54/229 (23.6%)	54/283 (19.1%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	54/ 63 (85.7%)	57/229 (24.9%)	57/283 (20.1%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	46/ 59 (78.0%)	46/229 (20.1%)	46/283 (16.3%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	34/ 51 (66.7%)	35/229 (15.3%)	35/283 (12.4%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	30/ 45 (66.7%)	30/229 (13.1%)	30/283 (10.6%)	19/ 30 (63.3%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 13 Day 1	36/ 43 (83.7%)	36/229 (15.7%)	36/283 (12.7%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	32/ 37 (86.5%)	32/228 (14.0%)	33/283 (11.7%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	21/ 29 (72.4%)	21/228 (9.2%)	21/283 (7.4%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	9/ 10 (90.0%)	9/235 (3.8%)	9/282 (3.2%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	15/ 17 (88.2%)	15/227 (6.6%)	15/283 (5.3%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	4/ 9 (44.4%)	4/227 (1.8%)	4/283 (1.4%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	8/ 9 (88.9%)	8/227 (3.5%)	8/283 (2.8%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	134/223 (60.1%)	135/270 (50.0%)	135/283 (47.7%)	147/222 (66.2%)	147/264 (55.7%)	147/282 (52.1%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	81/199 (40.7%)	81/241 (33.6%)	81/282 (28.7%)
90 D SFU Z/P	82/179 (45.8%)	82/230 (35.7%)	82/283 (29.0%)	69/160 (43.1%)	69/209 (33.0%)	70/282 (24.8%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

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

Table 301.1.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	2.87	2.67	0.0	2.00	10.0						
Cycle 1 Day 22	185	2.50	2.47	0.0	2.00	10.0	175	-0.55	2.85	-10.0	0.00	8.0
Cycle 2 Day 1	215	2.21	2.53	0.0	1.00	10.0	205	-0.75	2.94	-10.0	0.00	9.0
Cycle 2 Day 22	157	2.15	2.42	0.0	1.00	9.0	150	-0.67	3.11	-10.0	0.00	8.0
Cycle 3 Day 1	199	1.82	2.30	0.0	1.00	10.0	189	-0.87	2.88	-10.0	0.00	7.0
Cycle 3 Day 22	160	2.12	2.51	0.0	1.00	9.0	151	-0.62	3.16	-10.0	0.00	8.0
Cycle 4 Day 1	177	1.85	2.20	0.0	1.00	10.0	169	-0.86	2.61	-8.0	0.00	6.0
Cycle 4 Day 22	126	1.98	2.38	0.0	1.00	8.0	122	-0.51	3.02	-8.0	0.00	7.0
Cycle 5 Day 1	155	2.06	2.38	0.0	1.00	10.0	147	-0.54	2.91	-8.0	0.00	8.0
Cycle 5 Day 22	113	1.90	2.35	0.0	1.00	9.0	106	-0.61	2.87	-8.0	0.00	9.0
Cycle 6 Day 1	124	1.90	2.27	0.0	1.00	9.0	115	-0.67	3.03	-8.0	-1.00	9.0
Cycle 6 Day 22	102	1.81	2.41	0.0	0.00	9.0	97	-0.72	2.96	-7.0	0.00	8.0
Cycle 7 Day 1	110	1.72	2.07	0.0	1.00	9.0	104	-0.57	2.83	-7.0	0.00	9.0
Cycle 7 Day 22	80	1.85	2.26	0.0	1.00	8.0	74	-0.57	2.89	-7.0	0.00	8.0
Cycle 8 Day 1	81	1.75	2.32	0.0	0.00	7.0	74	-0.66	2.54	-7.0	0.00	6.0
Cycle 8 Day 22	70	1.80	2.39	0.0	0.00	8.0	65	-0.78	3.33	-7.0	0.00	8.0
Cycle 9 Day 1	72	1.85	2.40	0.0	1.00	9.0	66	-0.71	3.02	-7.0	0.00	8.0
Cycle 9 Day 22	54	1.74	2.15	0.0	1.00	8.0	50	-1.08	2.76	-7.0	0.00	5.0
Cycle 10 Day 1	57	2.16	2.34	0.0	2.00	8.0	52	-0.54	2.95	-6.0	0.00	7.0
Cycle 10 Day 22	46	2.07	2.19	0.0	2.00	9.0	43	-0.44	3.43	-7.0	0.00	6.0
Cycle 11 Day 1	50	2.12	2.55	0.0	1.00	9.0	46	-0.30	3.69	-7.0	0.00	9.0
Cycle 11 Day 22	35	2.09	2.51	0.0	1.00	8.0	32	-0.22	3.50	-7.0	0.00	7.0
Cycle 12 Day 1	43	2.23	2.42	0.0	2.00	8.0	39	0.00	3.74	-7.0	0.00	8.0
Cycle 12 Day 22	30	2.00	1.97	0.0	2.00	7.0	28	0.04	2.94	-4.0	0.00	6.0
Cycle 13 Day 1	36	1.97	2.17	0.0	1.00	7.0	33	-0.42	3.54	-7.0	0.00	6.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	33	1.67	1.91	0.0	1.00	6.0	30	-0.40	2.84	-5.0	0.00	5.0
Cycle 14 Day 1	31	2.39	2.63	0.0	1.00	8.0	30	0.20	2.94	-6.0	0.00	5.0
Cycle 14 Day 22	24	2.29	2.60	0.0	1.00	7.0	24	0.25	3.78	-7.0	0.00	7.0
Cycle 15 Day 1	26	2.77	2.49	0.0	3.00	7.0	26	0.81	3.56	-6.0	0.00	6.0
Cycle 15 Day 22	21	2.33	2.56	0.0	1.00	7.0	21	0.38	3.98	-5.0	0.00	7.0
Cycle 16 Day 1	25	2.44	2.80	0.0	2.00	10.0	25	0.00	4.27	-7.0	0.00	10.0
Cycle 16 Day 22	19	2.26	2.42	0.0	2.00	7.0	19	-0.42	3.56	-7.0	0.00	5.0
Cycle 17 Day 1	19	2.74	2.64	0.0	2.00	8.0	19	0.79	3.03	-5.0	0.00	6.0
Cycle 17 Day 22	14	2.00	2.39	0.0	0.50	5.0	14	0.43	2.90	-4.0	0.00	5.0
Cycle 18 Day 1	15	1.80	2.31	0.0	0.00	6.0	15	-0.40	3.36	-6.0	0.00	5.0
Cycle 18 Day 22	11	2.00	2.65	0.0	0.00	6.0	11	0.18	2.93	-5.0	0.00	5.0
Cycle 19 Day 1	13	1.77	2.35	0.0	0.00	6.0	13	0.15	3.53	-6.0	0.00	5.0
Cycle 19 Day 22	11	1.82	2.09	0.0	1.00	6.0	11	0.45	2.34	-4.0	0.00	4.0
Cycle 20 Day 1	13	2.23	2.59	0.0	1.00	7.0	13	0.54	3.64	-6.0	0.00	5.0
Cycle 21 Day 1	11	2.73	2.72	0.0	2.00	7.0	11	1.18	3.71	-4.0	0.00	7.0
Study Disc 1	130	2.88	2.77	0.0	2.00	10.0	123	-0.07	2.77	-7.0	0.00	6.0
30 D SFU Z/P	69	2.99	2.93	0.0	3.00	10.0	64	-0.17	3.07	-8.0	-1.00	9.0
90 D SFU Z/P	82	2.46	2.61	0.0	2.00	10.0	79	-0.28	2.97	-8.0	0.00	7.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	2.96	2.74	0.0	2.00	10.0						
Cycle 1 Day 22	211	2.17	2.28	0.0	1.00	8.0	208	-0.74	2.32	-8.0	0.00	7.0
Cycle 2 Day 1	230	2.09	2.59	0.0	1.00	10.0	223	-0.75	2.98	-9.0	0.00	10.0
Cycle 2 Day 22	183	1.98	2.48	0.0	1.00	10.0	178	-1.01	2.70	-8.0	0.00	9.0
Cycle 3 Day 1	202	1.97	2.46	0.0	1.00	9.0	195	-0.90	2.70	-9.0	0.00	7.0
Cycle 3 Day 22	155	2.08	2.58	0.0	1.00	9.0	148	-0.83	2.60	-8.0	0.00	8.0
Cycle 4 Day 1	170	1.84	2.47	0.0	1.00	9.0	161	-0.66	2.81	-8.0	0.00	9.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	131	1.89	2.33	0.0	1.00	9.0	125	-0.78	2.56	-8.0	0.00	6.0
Cycle 5 Day 1	147	1.80	2.39	0.0	1.00	10.0	142	-0.80	2.92	-8.0	0.00	7.0
Cycle 5 Day 22	119	2.03	2.43	0.0	1.00	9.0	112	-0.84	2.93	-8.0	0.00	9.0
Cycle 6 Day 1	120	2.12	2.66	0.0	1.00	10.0	115	-0.40	3.19	-8.0	0.00	9.0
Cycle 6 Day 22	92	1.49	2.31	0.0	0.00	8.0	88	-0.93	2.50	-8.0	0.00	8.0
Cycle 7 Day 1	91	1.37	2.32	0.0	0.00	9.0	88	-0.90	2.92	-8.0	0.00	9.0
Cycle 7 Day 22	66	1.12	1.89	0.0	0.00	7.0	64	-1.03	2.59	-8.0	0.00	6.0
Cycle 8 Day 1	71	1.58	2.69	0.0	0.00	10.0	70	-0.60	3.21	-8.0	0.00	10.0
Cycle 8 Day 22	56	1.11	2.14	0.0	0.00	10.0	54	-1.15	2.27	-7.0	-0.50	6.0
Cycle 9 Day 1	53	1.26	2.10	0.0	0.00	8.0	51	-1.02	2.03	-7.0	0.00	4.0
Cycle 9 Day 22	46	1.24	2.09	0.0	0.00	9.0	44	-1.02	2.57	-6.0	-0.50	6.0
Cycle 10 Day 1	47	1.49	2.43	0.0	0.00	10.0	45	-0.53	2.97	-6.0	-1.00	10.0
Cycle 10 Day 22	35	1.34	2.33	0.0	0.00	9.0	34	-0.56	3.00	-6.0	0.00	9.0
Cycle 11 Day 1	37	1.03	1.89	0.0	0.00	8.0	35	-0.94	2.22	-7.0	0.00	4.0
Cycle 11 Day 22	22	0.95	2.34	0.0	0.00	10.0	20	-0.65	1.63	-4.0	0.00	3.0
Cycle 12 Day 1	32	1.56	2.54	0.0	0.00	8.0	30	-0.10	2.80	-7.0	0.00	8.0
Cycle 12 Day 22	19	1.37	2.41	0.0	0.00	8.0	17	-1.12	2.47	-7.0	-1.00	3.0
Cycle 13 Day 1	25	1.20	1.73	0.0	0.00	6.0	24	-0.46	2.52	-7.0	0.00	4.0
Cycle 13 Day 22	15	1.40	1.92	0.0	0.00	5.0	14	-0.36	3.03	-7.0	0.00	5.0
Cycle 14 Day 1	23	1.09	1.76	0.0	0.00	6.0	22	-0.55	2.63	-7.0	0.00	5.0
Cycle 14 Day 22	13	2.08	2.60	0.0	1.00	8.0	12	-0.58	3.63	-7.0	0.00	5.0
Cycle 15 Day 1	19	2.11	3.02	0.0	0.00	10.0	19	0.58	3.82	-7.0	0.00	10.0
Cycle 16 Day 1	11	2.00	2.83	0.0	0.00	8.0	11	0.00	4.20	-7.0	0.00	8.0
Study Disc 1	137	3.39	2.84	0.0	3.00	10.0	133	0.53	3.12	-8.0	0.00	8.0
Study Disc 2	10	3.60	2.32	0.0	3.00	7.0	9	0.56	2.65	-5.0	1.00	3.0
30 D SFU Z/P	81	3.04	2.73	0.0	3.00	10.0	78	0.37	3.31	-8.0	0.00	8.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Table 301.1.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
90 D SFU Z/P	70	2.79	2.73	0.0	2.00	9.0	68	0.40	3.28	-7.0	0.00	8.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

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

Table 301.1.3004.4.1: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	127 (44.9%)	125 (44.3%)	
Number of patients censored	156 (55.1%)	157 (55.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.7 [5.1, 11.1]	8.1 [5.4, 9.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.045 [0.814, 1.342]
Log-rank test			
Two-sided stratified log-rank p-value			0.7271

Abbreviations: CI=confidence interval; HR=hazard ratio; MID=minimally important difference; 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 >=2 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3004.4.2: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity by Subgroups (MID=2) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	83 (45.9)	7.5 [3.7, 12.9]	181	76 (42.0)	9.3 [5.4, 12.3]	1.171 [0.857, 1.599]	0.3232	0.2544
>65 years	102	44 (43.1)	6.7 [4.9, 15.2]	101	49 (48.5)	7.1 [4.2, 10.4]	0.854 [0.568, 1.284]	0.4525	
Sex									
Male	176	75 (42.6)	6.7 [5.5, 14.0]	175	76 (43.4)	9.3 [5.5, 12.3]	1.077 [0.782, 1.481]	0.6504	0.7895
Female	107	52 (48.6)	6.4 [3.5, 15.2]	107	49 (45.8)	5.7 [3.7, 9.7]	1.015 [0.686, 1.500]	0.9370	
Region									
Asia	88	46 (52.3)	6.2 [3.5, 14.3]	89	43 (48.3)	9.3 [5.1, 12.3]	1.159 [0.764, 1.757]	0.4884	0.5904
Non-Asia	195	81 (41.5)	7.6 [5.5, 14.0]	193	82 (42.5)	7.9 [4.6, 10.4]	0.995 [0.732, 1.353]	0.9801	
Number of Organs with Metastatic Sites									
0-2	219	100 (45.7)	6.7 [5.0, 12.9]	219	99 (45.2)	8.7 [5.7, 10.4]	1.097 [0.830, 1.448]	0.5156	0.4571
>=3	64	27 (42.2)	8.1 [3.5, 15.8]	63	26 (41.3)	4.2 [3.3, NC]	0.845 [0.491, 1.457]	0.5489	

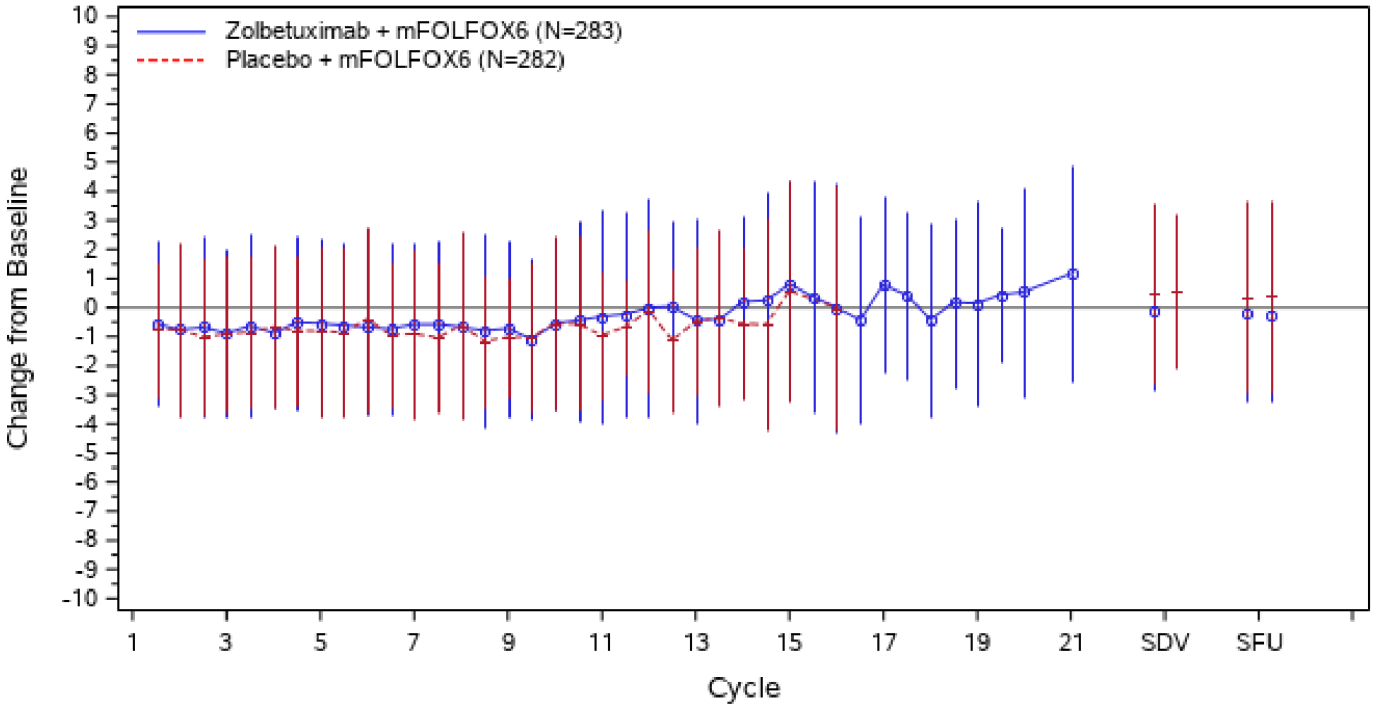
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=2 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 [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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

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

The SAS System

Figure 301.1.3002.4: Global Pain(GP) - Plot of Mean Change from Baseline of PI01 - Pain Intensity - Full Analysis Set



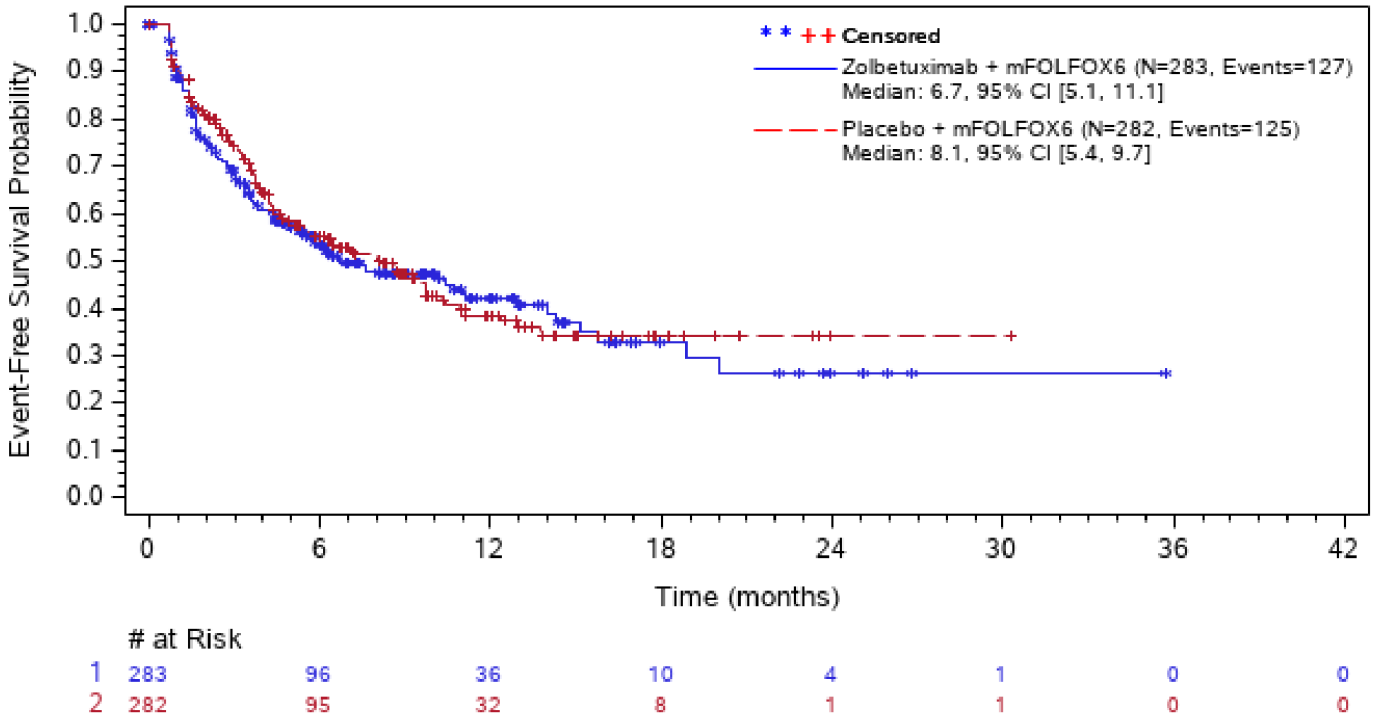
Abbreviations: N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

5. Kaplan-Meier-Plots

The SAS System

Figure 301.1.3004.4: Global Pain - Kaplan-Meier Plot of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; MID=minimally important difference; 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 >=2 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 EQ-5D VAS

1. Rücklaufquoten

Table 301.1.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	258/279 (92.5%)	258/282 (91.5%)	258/283 (91.2%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	187/257 (72.8%)	188/273 (68.9%)	188/283 (66.4%)	214/266 (80.5%)	214/271 (79.0%)	214/282 (75.9%)
Cycle 2 Day 1	214/244 (87.7%)	214/263 (81.4%)	217/283 (76.7%)	232/263 (88.2%)	233/270 (86.3%)	233/282 (82.6%)
Cycle 2 Day 22	158/222 (71.2%)	159/257 (61.9%)	159/283 (56.2%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/254 (77.6%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	162/204 (79.4%)	163/250 (65.2%)	163/283 (57.6%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	171/192 (89.1%)	176/244 (72.1%)	180/283 (63.6%)	171/202 (84.7%)	171/254 (67.3%)	172/282 (61.0%)
Cycle 4 Day 22	130/179 (72.6%)	130/241 (53.9%)	130/283 (45.9%)	132/184 (71.7%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/171 (87.1%)	155/239 (64.9%)	156/283 (55.1%)	148/170 (87.1%)	148/251 (59.0%)	148/282 (52.5%)
Cycle 5 Day 22	116/151 (76.8%)	117/236 (49.6%)	117/283 (41.3%)	119/150 (79.3%)	120/248 (48.4%)	120/282 (42.6%)
Cycle 6 Day 1	121/135 (89.6%)	125/236 (53.0%)	125/283 (44.2%)	120/139 (86.3%)	122/244 (50.0%)	122/282 (43.3%)
Cycle 6 Day 22	100/125 (80.0%)	102/234 (43.6%)	102/283 (36.0%)	94/120 (78.3%)	94/242 (38.8%)	94/282 (33.3%)
Cycle 7 Day 1	107/118 (90.7%)	111/234 (47.4%)	111/283 (39.2%)	91/103 (88.3%)	91/240 (37.9%)	91/282 (32.3%)
Cycle 7 Day 22	80/105 (76.2%)	80/232 (34.5%)	80/283 (28.3%)	66/ 93 (71.0%)	66/239 (27.6%)	66/282 (23.4%)
Cycle 8 Day 1	82/ 96 (85.4%)	83/231 (35.9%)	83/283 (29.3%)	73/ 85 (85.9%)	73/239 (30.5%)	73/282 (25.9%)
Cycle 8 Day 22	70/ 86 (81.4%)	71/231 (30.7%)	71/283 (25.1%)	56/ 75 (74.7%)	56/237 (23.6%)	56/282 (19.9%)
Cycle 9 Day 1	72/ 82 (87.8%)	73/229 (31.9%)	73/283 (25.8%)	53/ 63 (84.1%)	53/237 (22.4%)	53/282 (18.8%)
Cycle 9 Day 22	55/ 69 (79.7%)	55/229 (24.0%)	55/283 (19.4%)	46/ 58 (79.3%)	46/237 (19.4%)	46/282 (16.3%)
Cycle 10 Day 1	55/ 63 (87.3%)	58/229 (25.3%)	58/283 (20.5%)	46/ 49 (93.9%)	47/237 (19.8%)	47/282 (16.7%)
Cycle 10 Day 22	47/ 59 (79.7%)	47/229 (20.5%)	47/283 (16.6%)	35/ 43 (81.4%)	35/237 (14.8%)	35/282 (12.4%)
Cycle 11 Day 1	50/ 56 (89.3%)	50/229 (21.8%)	50/283 (17.7%)	37/ 40 (92.5%)	37/237 (15.6%)	37/282 (13.1%)
Cycle 11 Day 22	35/ 51 (68.6%)	36/229 (15.7%)	36/283 (12.7%)	22/ 35 (62.9%)	22/236 (9.3%)	22/282 (7.8%)
Cycle 12 Day 1	42/ 48 (87.5%)	43/229 (18.8%)	43/283 (15.2%)	32/ 34 (94.1%)	32/236 (13.6%)	32/282 (11.3%)
Cycle 12 Day 22	33/ 45 (73.3%)	33/229 (14.4%)	33/283 (11.7%)	21/ 30 (70.0%)	21/235 (8.9%)	21/282 (7.4%)
Cycle 13 Day 1	37/ 43 (86.0%)	37/229 (16.2%)	37/283 (13.1%)	25/ 27 (92.6%)	25/235 (10.6%)	25/282 (8.9%)
Cycle 13 Day 22	33/ 37 (89.2%)	33/228 (14.5%)	34/283 (12.0%)	15/ 26 (57.7%)	15/235 (6.4%)	15/282 (5.3%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	31/ 32 (96.9%)	31/228 (13.6%)	31/283 (11.0%)	23/ 25 (92.0%)	23/235 (9.8%)	23/282 (8.2%)
Cycle 14 Day 22	24/ 30 (80.0%)	24/228 (10.5%)	24/283 (8.5%)	13/ 22 (59.1%)	13/235 (5.5%)	13/282 (4.6%)
Cycle 15 Day 1	26/ 29 (89.7%)	26/228 (11.4%)	26/283 (9.2%)	19/ 20 (95.0%)	19/235 (8.1%)	19/282 (6.7%)
Cycle 15 Day 22	22/ 29 (75.9%)	22/228 (9.6%)	22/283 (7.8%)	8/ 15 (53.3%)	8/235 (3.4%)	8/282 (2.8%)
Cycle 16 Day 1	24/ 26 (92.3%)	25/228 (11.0%)	25/283 (8.8%)	11/ 13 (84.6%)	11/235 (4.7%)	11/282 (3.9%)
Cycle 16 Day 22	18/ 23 (78.3%)	19/228 (8.3%)	19/283 (6.7%)	6/ 11 (54.5%)	6/235 (2.6%)	6/282 (2.1%)
Cycle 17 Day 1	19/ 20 (95.0%)	19/227 (8.4%)	19/283 (6.7%)	10/ 10 (100.0%)	10/235 (4.3%)	10/282 (3.5%)
Cycle 17 Day 22	14/ 18 (77.8%)	14/227 (6.2%)	14/283 (4.9%)	3/ 8 (37.5%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 18 Day 1	16/ 17 (94.1%)	16/227 (7.0%)	16/283 (5.7%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 18 Day 22	11/ 16 (68.8%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 19 Day 1	13/ 15 (86.7%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 19 Day 22	11/ 15 (73.3%)	11/227 (4.8%)	11/283 (3.9%)	4/ 7 (57.1%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 20 Day 1	13/ 14 (92.9%)	13/227 (5.7%)	13/283 (4.6%)	7/ 7 (100.0%)	7/235 (3.0%)	7/282 (2.5%)
Cycle 20 Day 22	9/ 13 (69.2%)	9/227 (4.0%)	9/283 (3.2%)	4/ 6 (66.7%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 21 Day 1	11/ 12 (91.7%)	11/227 (4.8%)	11/283 (3.9%)	5/ 6 (83.3%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 21 Day 22	9/ 11 (81.8%)	9/227 (4.0%)	9/283 (3.2%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 22 Day 1	8/ 10 (80.0%)	8/227 (3.5%)	8/283 (2.8%)	5/ 5 (100.0%)	5/235 (2.1%)	5/282 (1.8%)
Cycle 22 Day 22	5/ 9 (55.6%)	5/227 (2.2%)	5/283 (1.8%)	3/ 5 (60.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 23 Day 1	9/ 9 (100.0%)	9/227 (4.0%)	9/283 (3.2%)	4/ 4 (100.0%)	4/235 (1.7%)	4/282 (1.4%)
Cycle 23 Day 22	4/ 7 (57.1%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 24 Day 1	7/ 7 (100.0%)	7/227 (3.1%)	7/283 (2.5%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 24 Day 22	4/ 6 (66.7%)	4/227 (1.8%)	4/283 (1.4%)	1/ 3 (33.3%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 25 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	3/ 3 (100.0%)	3/235 (1.3%)	3/282 (1.1%)
Cycle 25 Day 22	4/ 5 (80.0%)	4/227 (1.8%)	4/283 (1.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 26 Day 1	5/ 5 (100.0%)	5/227 (2.2%)	5/283 (1.8%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 26 Day 22	1/ 4 (25.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 2 (0.0%)	0/235 (0.0%)	0/282 (0.0%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	4/ 4 (100.0%)	4/227 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/235 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	3/ 4 (75.0%)	3/227 (1.3%)	3/283 (1.1%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 28 Day 1	3/ 3 (100.0%)	3/227 (1.3%)	3/283 (1.1%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 28 Day 22	2/ 3 (66.7%)	2/227 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 29 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 29 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 30 Day 1	2/ 2 (100.0%)	2/227 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	0/ 1 (0.0%)	0/235 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	1/ 2 (50.0%)	1/227 (0.4%)	1/283 (0.4%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	0	0/227 (0.0%)	0/283 (0.0%)	1/ 1 (100.0%)	1/235 (0.4%)	1/282 (0.4%)
Study Disc	137/223 (61.4%)	138/270 (51.1%)	138/283 (48.8%)	149/222 (67.1%)	149/264 (56.4%)	149/282 (52.8%)
30 D SFU Z/P	67/203 (33.0%)	68/251 (27.1%)	69/283 (24.4%)	82/199 (41.2%)	82/241 (34.0%)	82/282 (29.1%)
90 D SFU Z/P	83/179 (46.4%)	83/230 (36.1%)	83/283 (29.3%)	71/160 (44.4%)	71/209 (34.0%)	72/282 (25.5%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

Table 301.1.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	258	68.91	19.15	0.0	70.00	100.0						
Cycle 1 Day 22	188	67.32	18.91	0.0	70.00	100.0	178	-3.44	18.53	-87.0	-1.00	61.0
Cycle 2 Day 1	217	70.41	17.66	0.0	74.00	100.0	207	0.05	18.05	-72.0	0.00	40.0
Cycle 2 Day 22	159	70.18	14.99	0.0	71.00	95.0	152	0.63	18.37	-100.0	0.00	39.0
Cycle 3 Day 1	200	72.97	16.23	0.0	74.50	100.0	190	1.16	18.61	-61.0	0.00	52.0
Cycle 3 Day 22	163	69.13	17.49	0.0	70.00	100.0	154	-1.69	18.39	-50.0	0.00	48.0
Cycle 4 Day 1	180	71.43	15.82	26.0	73.00	100.0	172	0.35	17.10	-49.0	0.00	45.0
Cycle 4 Day 22	130	70.35	15.97	15.0	70.00	100.0	125	-1.11	19.16	-44.0	0.00	59.0
Cycle 5 Day 1	156	70.57	17.31	0.0	73.00	100.0	149	-0.82	19.12	-58.0	0.00	61.0
Cycle 5 Day 22	117	71.97	18.58	0.0	76.00	100.0	110	0.70	21.50	-81.0	0.00	50.0
Cycle 6 Day 1	125	70.57	18.37	0.0	75.00	100.0	116	0.44	19.64	-60.0	1.50	52.0
Cycle 6 Day 22	102	72.76	17.01	25.0	76.00	96.0	97	3.92	18.56	-55.0	2.00	49.0
Cycle 7 Day 1	111	72.48	16.09	15.0	77.00	98.0	105	1.32	20.70	-72.0	1.00	50.0
Cycle 7 Day 22	80	73.59	14.15	32.0	78.50	98.0	74	3.20	17.57	-29.0	0.50	52.0
Cycle 8 Day 1	83	75.46	16.04	0.0	79.00	100.0	76	3.41	21.58	-80.0	4.50	53.0
Cycle 8 Day 22	71	73.73	14.97	20.0	76.00	97.0	66	2.94	19.41	-60.0	0.50	45.0
Cycle 9 Day 1	73	73.44	17.80	9.0	79.00	97.0	66	4.61	20.05	-60.0	2.50	45.0
Cycle 9 Day 22	55	71.44	18.64	9.0	74.00	98.0	51	2.20	21.98	-62.0	1.00	54.0
Cycle 10 Day 1	58	71.48	17.98	18.0	75.50	98.0	53	2.47	19.51	-62.0	0.00	44.0
Cycle 10 Day 22	47	75.13	15.27	18.0	80.00	94.0	44	3.23	18.81	-62.0	7.50	44.0
Cycle 11 Day 1	50	75.06	15.52	10.0	78.50	98.0	46	5.22	19.02	-70.0	9.00	36.0
Cycle 11 Day 22	36	75.81	13.48	46.0	77.00	94.0	33	3.67	17.36	-20.0	6.00	37.0
Cycle 12 Day 1	43	72.47	15.90	18.0	73.00	98.0	39	-1.03	19.84	-62.0	0.00	48.0
Cycle 12 Day 22	33	71.00	14.75	22.0	70.00	97.0	30	-3.50	17.58	-58.0	-1.50	22.0
Cycle 13 Day 1	37	72.84	15.11	25.0	72.00	97.0	34	0.21	17.80	-55.0	7.00	23.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 09SEP22

Table 301.1.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	34	74.09	13.36	35.0	75.50	97.0	31	-1.35	18.39	-45.0	1.00	27.0
Cycle 14 Day 1	31	70.42	16.05	31.0	70.00	96.0	30	-3.40	16.49	-30.0	-6.00	25.0
Cycle 14 Day 22	24	71.13	12.11	49.0	70.00	97.0	24	-4.08	19.70	-34.0	-9.00	28.0
Cycle 15 Day 1	26	72.42	11.23	50.0	70.00	94.0	26	-2.88	17.03	-30.0	-9.50	28.0
Cycle 15 Day 22	22	65.59	16.60	29.0	68.50	99.0	22	-9.00	24.57	-71.0	-14.00	38.0
Cycle 16 Day 1	25	73.24	14.49	39.0	70.00	97.0	25	0.40	18.00	-35.0	-2.00	23.0
Cycle 16 Day 22	19	70.68	11.12	49.0	70.00	88.0	19	-0.58	16.64	-34.0	-1.00	20.0
Cycle 17 Day 1	19	70.74	13.00	39.0	70.00	90.0	19	-1.47	16.71	-35.0	-1.00	21.0
Cycle 17 Day 22	14	66.36	12.02	41.0	67.50	84.0	14	-7.00	17.16	-35.0	-11.00	30.0
Cycle 18 Day 1	16	69.75	13.80	39.0	69.50	91.0	16	-1.63	19.15	-32.0	-10.00	25.0
Cycle 18 Day 22	11	67.18	10.79	47.0	67.00	81.0	11	-9.45	17.08	-32.0	-13.00	20.0
Cycle 19 Day 1	13	77.85	10.56	64.0	78.00	93.0	13	0.85	17.01	-24.0	-3.00	29.0
Cycle 19 Day 22	11	70.45	10.94	56.0	68.00	90.0	11	-9.00	16.67	-29.0	-14.00	20.0
Cycle 20 Day 1	13	74.38	9.98	64.0	70.00	91.0	13	-4.15	18.28	-27.0	-11.00	22.0
Cycle 21 Day 1	11	76.73	10.56	65.0	72.00	94.0	11	-2.36	16.58	-19.0	-8.00	25.0
Study Disc 1	133	62.02	21.80	0.0	67.00	96.0	126	-7.24	20.25	-64.0	-7.00	48.0
30 D SFU Z/P	69	64.04	18.91	22.0	65.00	100.0	64	-2.00	19.35	-48.0	0.50	39.0
90 D SFU Z/P	83	66.12	19.59	0.0	70.00	95.0	80	-4.10	20.84	-52.0	-1.50	49.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	67.95	19.78	0.0	70.00	100.0						
Cycle 1 Day 22	214	68.17	18.71	10.0	70.00	100.0	212	-0.21	15.63	-60.0	0.00	61.0
Cycle 2 Day 1	233	72.18	17.92	11.0	73.00	100.0	226	4.10	17.43	-59.0	1.00	79.0
Cycle 2 Day 22	185	70.40	19.39	2.0	71.00	100.0	181	2.25	19.26	-81.0	2.00	50.0
Cycle 3 Day 1	204	73.88	17.10	3.0	79.00	100.0	198	5.57	18.23	-67.0	3.50	58.0
Cycle 3 Day 22	156	72.12	19.03	0.0	78.00	100.0	149	2.73	19.27	-88.0	1.00	52.0
Cycle 4 Day 1	172	73.81	16.83	11.0	78.00	100.0	164	5.89	17.65	-41.0	5.00	54.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 09SEP22

Table 301.1.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 4 Day 22	132	70.45	18.22	10.0	71.00	100.0	127	3.46	17.46	-43.0	4.00	49.0
Cycle 5 Day 1	148	73.34	16.84	11.0	75.00	100.0	144	5.18	17.35	-40.0	4.00	53.0
Cycle 5 Day 22	120	70.99	18.64	10.0	72.00	100.0	113	2.31	18.20	-60.0	2.00	53.0
Cycle 6 Day 1	122	71.68	20.12	10.0	75.00	100.0	117	2.37	20.82	-69.0	2.00	58.0
Cycle 6 Day 22	94	75.69	18.43	9.0	80.00	100.0	90	5.36	17.03	-29.0	3.50	54.0
Cycle 7 Day 1	91	76.64	15.82	27.0	79.00	100.0	88	5.39	15.32	-33.0	4.00	48.0
Cycle 7 Day 22	66	76.11	14.76	29.0	79.50	100.0	64	4.05	14.62	-26.0	1.00	48.0
Cycle 8 Day 1	73	78.08	14.35	33.0	80.00	100.0	72	6.15	14.99	-28.0	4.50	48.0
Cycle 8 Day 22	56	78.04	15.23	31.0	80.00	100.0	54	7.81	14.62	-29.0	6.50	48.0
Cycle 9 Day 1	53	77.75	14.84	29.0	80.00	100.0	51	4.47	13.74	-24.0	3.00	48.0
Cycle 9 Day 22	46	77.17	17.32	28.0	78.00	100.0	44	6.50	15.29	-25.0	3.50	48.0
Cycle 10 Day 1	47	77.19	17.39	29.0	80.00	100.0	45	4.38	18.16	-51.0	4.00	48.0
Cycle 10 Day 22	35	77.60	16.98	38.0	81.00	100.0	34	4.88	15.76	-23.0	2.50	48.0
Cycle 11 Day 1	37	79.92	15.60	40.0	84.00	100.0	35	5.71	15.94	-20.0	2.00	48.0
Cycle 11 Day 22	22	77.77	17.19	40.0	80.00	100.0	20	2.85	15.84	-20.0	0.00	48.0
Cycle 12 Day 1	32	75.69	18.94	16.0	80.50	100.0	30	0.57	16.94	-40.0	0.00	36.0
Cycle 12 Day 22	21	73.33	21.17	10.0	80.00	100.0	19	0.37	14.39	-40.0	1.00	20.0
Cycle 13 Day 1	25	77.16	15.72	49.0	80.00	100.0	24	0.96	16.45	-24.0	-1.00	48.0
Cycle 13 Day 22	15	76.73	15.82	39.0	80.00	96.0	14	0.86	13.68	-21.0	-2.50	20.0
Cycle 14 Day 1	23	77.83	13.91	50.0	80.00	98.0	22	3.41	14.43	-19.0	4.50	26.0
Cycle 14 Day 22	13	72.77	17.13	35.0	73.00	96.0	12	-1.92	11.24	-25.0	-0.50	11.0
Cycle 15 Day 1	19	77.42	14.08	47.0	80.00	98.0	19	3.74	12.14	-20.0	5.00	25.0
Cycle 16 Day 1	11	71.00	17.46	39.0	73.00	94.0	11	0.18	15.13	-21.0	1.00	25.0
Cycle 17 Day 1	10	74.30	17.13	40.0	80.00	91.0	10	4.20	16.98	-20.0	0.00	28.0
Study Disc 1	139	64.06	21.42	0.0	70.00	99.0	133	-3.34	21.35	-78.0	-3.00	51.0
Study Disc 2	10	54.50	14.74	34.0	55.00	81.0	10	-12.60	23.80	-42.0	-17.00	29.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 09SEP22

Table 301.1.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
30 D SFU Z/P	82	63.49	18.83	15.0	66.50	98.0	80	-3.21	17.68	-45.0	-3.00	41.0
90 D SFU Z/P	72	62.75	20.90	10.0	69.00	100.0	70	-6.26	20.39	-68.0	-6.50	59.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

Table 301.1.3004.3.1: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	126 (44.5%)	118 (41.8%)	
Number of patients censored	157 (55.5%)	164 (58.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.4 [4.6, 9.5]	9.3 [6.7, 12.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.191 [0.924, 1.536]
Log-rank test			
Two-sided stratified log-rank p-value			0.1798

Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; MID=minimally important difference; 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 >=15 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3004.3.2: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale by Subgroups (MID=15) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	81 (44.8)	6.4 [4.2, 21.3]	181	75 (41.4)	9.3 [6.7, 15.1]	1.176 [0.858, 1.611]	0.3133	0.9725
>65 years	102	45 (44.1)	6.9 [3.7, 17.9]	101	43 (42.6)	9.4 [5.2, NC]	1.177 [0.775, 1.790]	0.4477	
Sex									
Male	176	72 (40.9)	7.6 [4.7, NC]	175	71 (40.6)	9.7 [7.2, 15.7]	1.160 [0.836, 1.611]	0.3758	0.9065
Female	107	54 (50.5)	5.3 [2.4, 12.9]	107	47 (43.9)	6.8 [4.7, 13.9]	1.185 [0.801, 1.755]	0.3968	
Region									
Asia	88	53 (60.2)	4.4 [2.2, 6.9]	89	46 (51.7)	6.7 [4.9, 13.9]	1.265 [0.850, 1.882]	0.2474	0.6235
Non-Asia	195	73 (37.4)	8.9 [4.7, NC]	193	72 (37.3)	10.4 [7.2, NC]	1.113 [0.803, 1.542]	0.5235	
Number of Organs with Metastatic Sites									
0-2	219	100 (45.7)	6.3 [3.7, 8.6]	219	91 (41.6)	9.3 [6.7, 15.1]	1.243 [0.936, 1.653]	0.1338	0.4272
>=3	64	26 (40.6)	8.9 [4.4, NC]	63	27 (42.9)	9.2 [4.4, NC]	0.960 [0.560, 1.649]	0.8840	

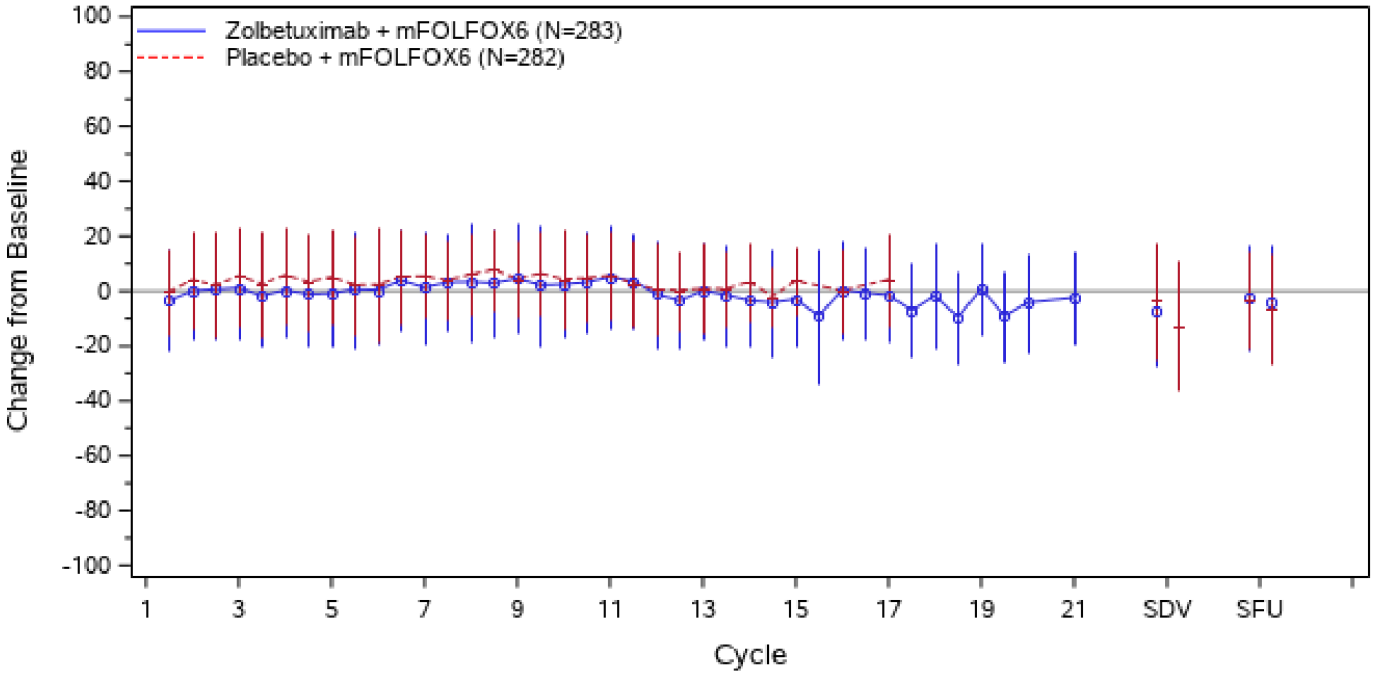
Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=15 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 [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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

The SAS System

Figure 301.1.3002.3: EQ-5D-5L - Plot of Mean Change from Baseline of Visual Analog Scale - Full Analysis Set



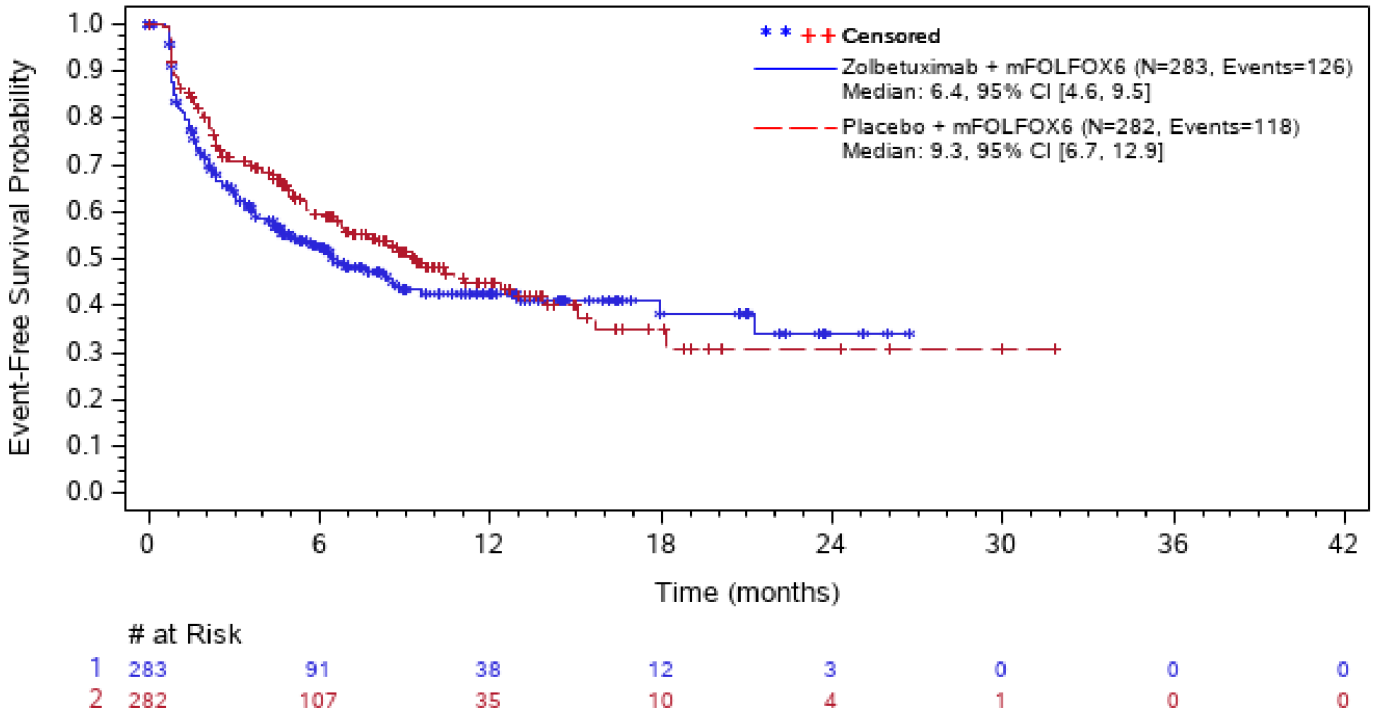
Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

5. Kaplan-Meier-Plots

The SAS System

Figure 301.1.3004.3: EQ-5D-5L - Kaplan-Meier Plot of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set



	# at Risk							
1	283	91	38	12	3	0	0	0
2	282	107	35	10	4	1	0	0

Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; MID=minimally important difference; 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 >=15 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Sicherheit

Anhang 4-G4 Unerwünschte Ereignisse

1. Time-to Event-Analysen

Table 301.1.2001.1.1: Summary and Results of TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	278 (99.6%)	277 (99.6%)	
Number of patients censored	1 (0.4%)	1 (0.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.1 [0.1, 0.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.650 [1.385, 1.967]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 09SEP22

Table 301.1.2001.1.2: Summary and Results of TEAEs by Subgroups - Safety Analysis Set

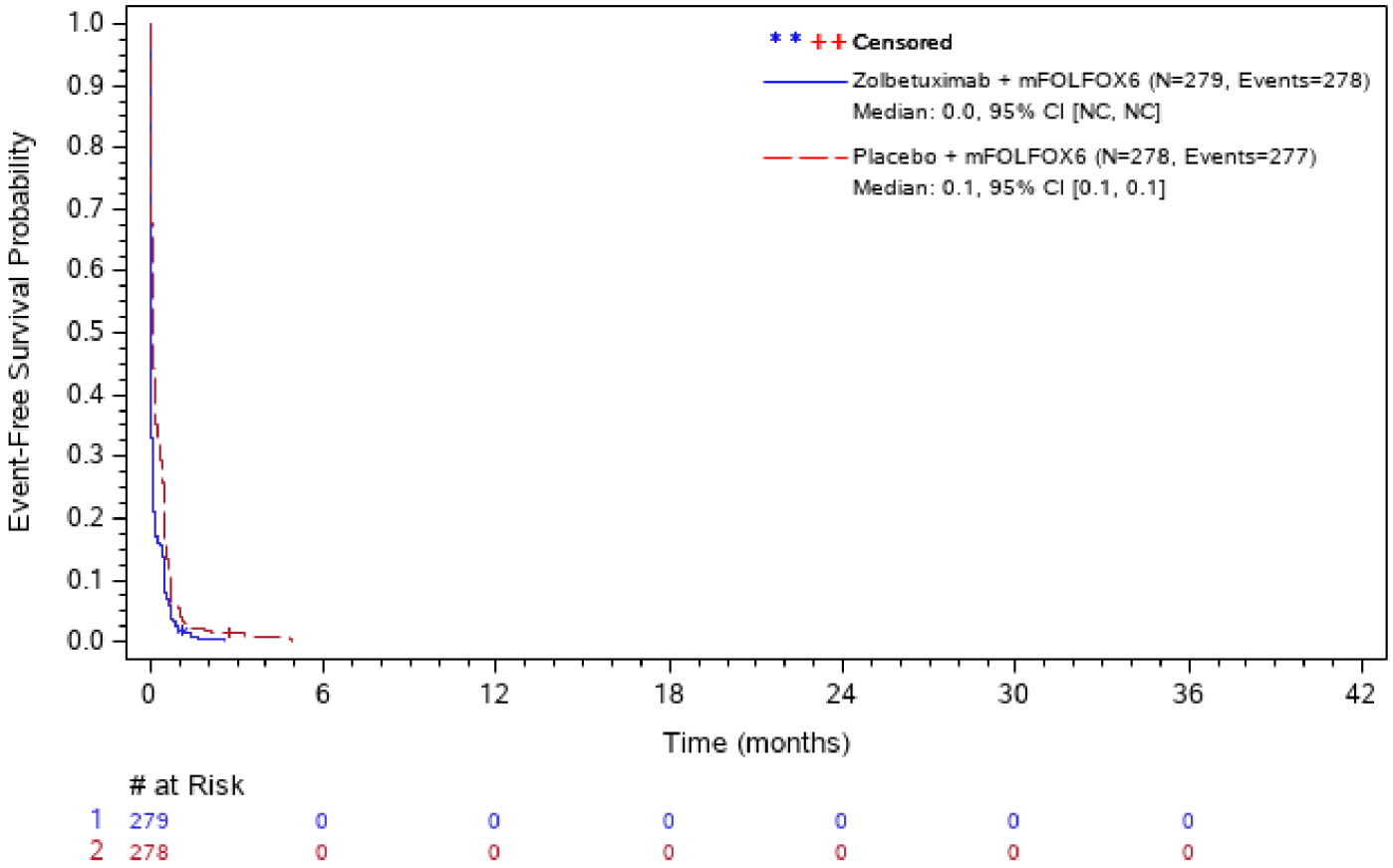
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	178	178 (100.0)	0.0 [NC, NC]	177	176 (99.4)	0.1 [0.1, 0.1]	1.761 [1.421, 2.183]	<.0001	0.4905
>65 years	101	100 (99.0)	0.0 [NC, NC]	101	101 (100.0)	0.1 [0.1, 0.1]	1.505 [1.136, 1.993]	0.0122	
Sex									
Male	174	173 (99.4)	0.0 [NC, NC]	173	172 (99.4)	0.1 [0.1, 0.1]	1.488 [1.200, 1.845]	0.0014	0.3405
Female	105	105 (100.0)	0.0 [NC, NC]	105	105 (100.0)	0.1 [0.1, 0.1]	2.143 [1.617, 2.839]	<.0001	
Region									
Asia	87	87 (100.0)	0.0 [NC, NC]	88	87 (98.9)	0.1 [0.1, 0.1]	1.951 [1.435, 2.654]	<.0001	0.1628
Non-Asia	192	191 (99.5)	0.0 [NC, NC]	190	190 (100.0)	0.1 [0.1, 0.1]	1.503 [1.224, 1.845]	0.0021	
Number of Organs with Metastatic Sites									
0-2	216	215 (99.5)	0.0 [NC, NC]	216	215 (99.5)	0.1 [0.1, 0.1]	1.808 [1.488, 2.196]	<.0001	0.1164
>=3	63	63 (100.0)	0.0 [NC, NC]	62	62 (100.0)	0.1 [0.0, 0.2]	1.202 [0.839, 1.723]	0.5691	

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 studytreatment + 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.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure 301.1.2001.1: 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 301.1.2001.3.1: Summary and Results of Severe TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	242 (86.7%)	216 (77.7%)	
Number of patients censored	37 (13.3%)	62 (22.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.1 [0.8, 1.4]	2.2 [1.9, 2.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.526 [1.266, 1.839]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 09SEP22

Table 301.1.2001.3.2: Summary and Results of Severe TEAEs by Subgroups - Safety Analysis Set

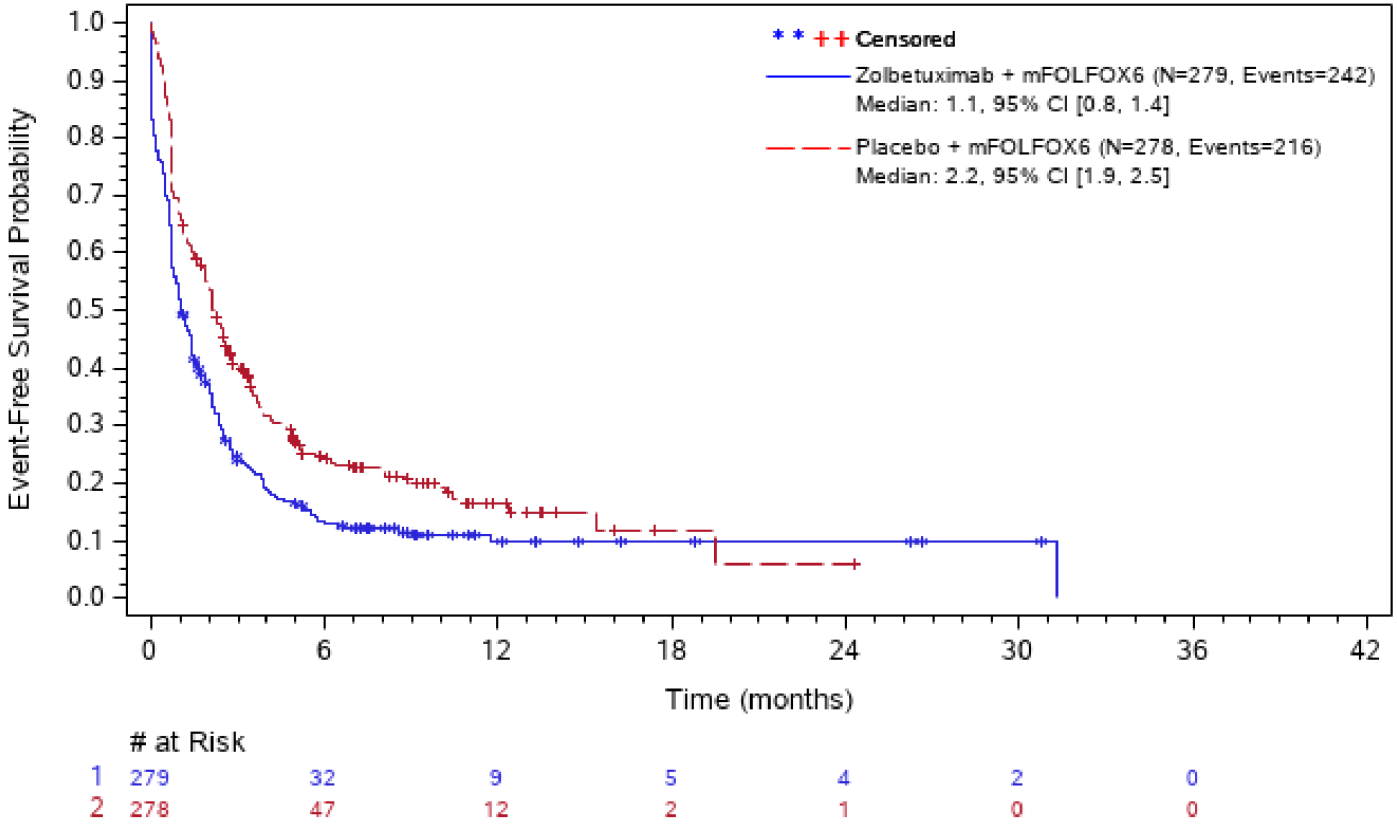
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	178	154 (86.5)	0.9 [0.7, 1.4]	177	139 (78.5)	2.2 [1.6, 2.8]	1.480 [1.175, 1.863]	0.0010	0.8946
>65 years	101	88 (87.1)	1.3 [0.9, 1.4]	101	77 (76.2)	2.1 [1.5, 2.8]	1.542 [1.134, 2.095]	0.0054	
Sex									
Male	174	146 (83.9)	1.3 [1.0, 2.0]	173	131 (75.7)	2.7 [2.1, 3.4]	1.454 [1.147, 1.843]	0.0021	0.6182
Female	105	96 (91.4)	0.8 [0.6, 1.2]	105	85 (81.0)	1.9 [1.0, 2.2]	1.632 [1.216, 2.190]	0.0011	
Region									
Asia	87	71 (81.6)	1.4 [1.0, 2.2]	88	65 (73.9)	2.1 [1.4, 3.7]	1.204 [0.858, 1.688]	0.2741	0.1096
Non-Asia	192	171 (89.1)	0.9 [0.7, 1.4]	190	151 (79.5)	2.3 [1.7, 2.8]	1.694 [1.359, 2.111]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	183 (84.7)	1.0 [0.8, 1.4]	216	166 (76.9)	2.2 [1.9, 2.6]	1.473 [1.193, 1.819]	0.0004	0.6923
>=3	63	59 (93.7)	1.1 [0.7, 1.4]	62	50 (80.6)	2.1 [0.8, 3.2]	1.636 [1.116, 2.400]	0.0102	

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 studytreatment + 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.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure 301.1.2001.3: 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 301.1.2001.4.1: Summary and Results of TESAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	125 (44.8%)	121 (43.5%)	
Number of patients censored	154 (55.2%)	157 (56.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	16.7 [8.1, NC]	11.6 [9.4, 17.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.136 [0.882, 1.461]
Log-rank test			
Two-sided stratified log-rank p-value			0.3306

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 09SEP22

Table 301.1.2001.4.2: Summary and Results of TESAEs by Subgroups - Safety Analysis Set

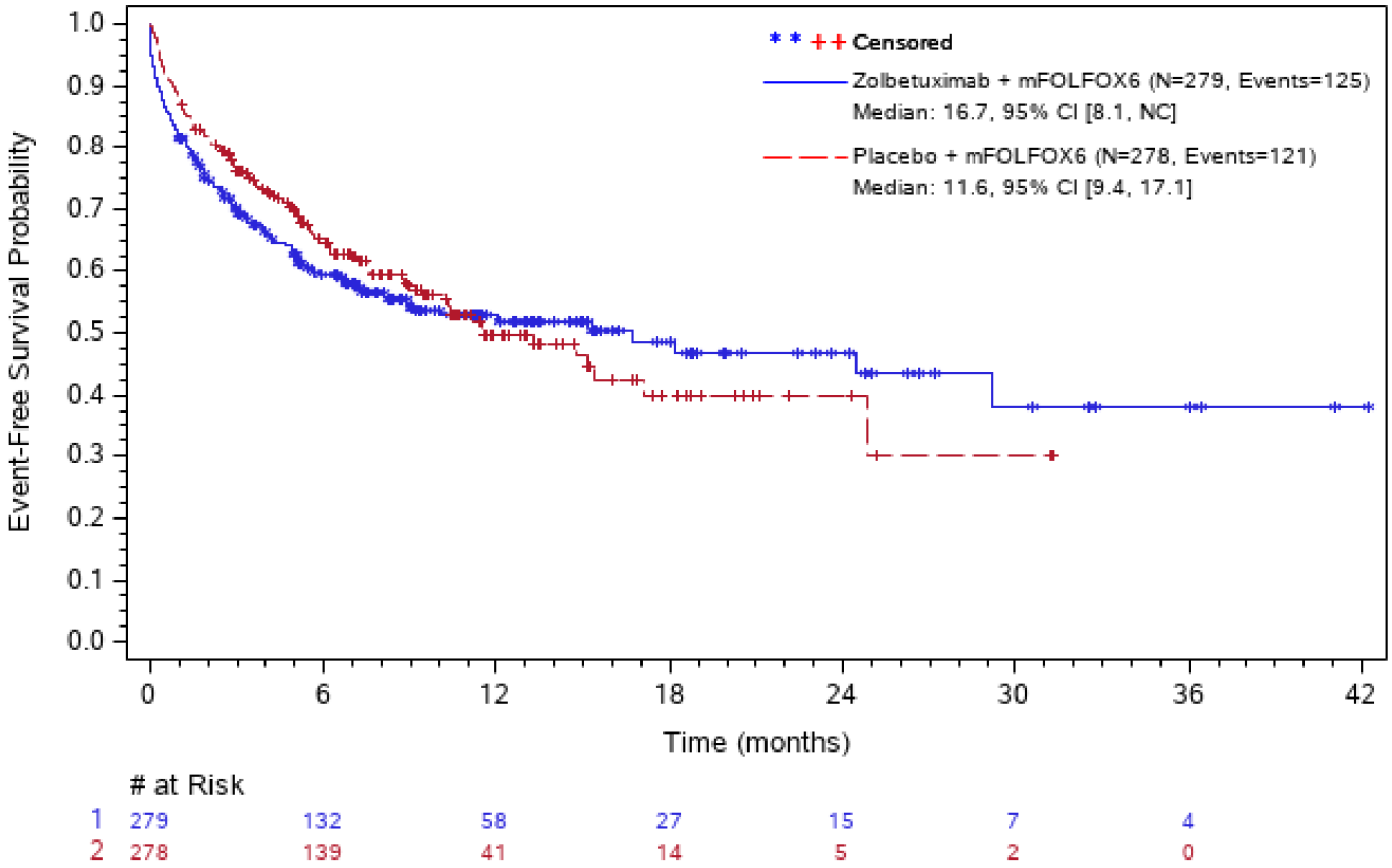
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	178	78 (43.8)	24.5 [7.1, NC]	177	77 (43.5)	13.3 [8.7, NC]	1.096 [0.799, 1.503]	0.5772	0.8630
>65 years	101	47 (46.5)	9.1 [6.6, NC]	101	44 (43.6)	11.2 [8.8, 24.9]	1.035 [0.684, 1.564]	0.8738	
Sex									
Male	174	77 (44.3)	15.3 [7.2, NC]	173	76 (43.9)	11.6 [8.7, 17.1]	1.025 [0.746, 1.408]	0.8843	0.6326
Female	105	48 (45.7)	18.1 [4.9, NC]	105	45 (42.9)	11.5 [7.6, NC]	1.166 [0.775, 1.755]	0.4708	
Region									
Asia	87	30 (34.5)	29.2 [16.7, NC]	88	28 (31.8)	NC [10.2, NC]	0.929 [0.552, 1.564]	0.7828	0.5316
Non-Asia	192	95 (49.5)	7.3 [4.7, NC]	190	93 (48.9)	10.4 [7.5, 15.3]	1.156 [0.868, 1.539]	0.3294	
Number of Organs with Metastatic Sites									
0-2	216	89 (41.2)	18.1 [10.1, NC]	216	85 (39.4)	14.8 [10.3, NC]	1.082 [0.803, 1.458]	0.6094	0.8781
>=3	63	36 (57.1)	4.7 [2.4, NC]	62	36 (58.1)	6.2 [3.0, 24.9]	1.067 [0.671, 1.698]	0.7868	

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 studytreatment + 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.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse

2. Kaplan-Meier-Plots

Figure 301.1.2001.4: 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

1. Time-to-Event-Analysen

Table 301.1.2001.5.1: Summary and Results of Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	120 (43.0%)	106 (38.1%)	
Number of patients censored	159 (57.0%)	172 (61.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	12.0 [6.9, NC]	24.1 [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.147 [0.881, 1.493]
Log-rank test			
Two-sided stratified log-rank p-value			0.3073

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 09SEP22

Table 301.1.2001.5.2: Summary and Results of Permanent Treatment Discontinuation due to TEAEs by Subgroups - Safety Analysis Set

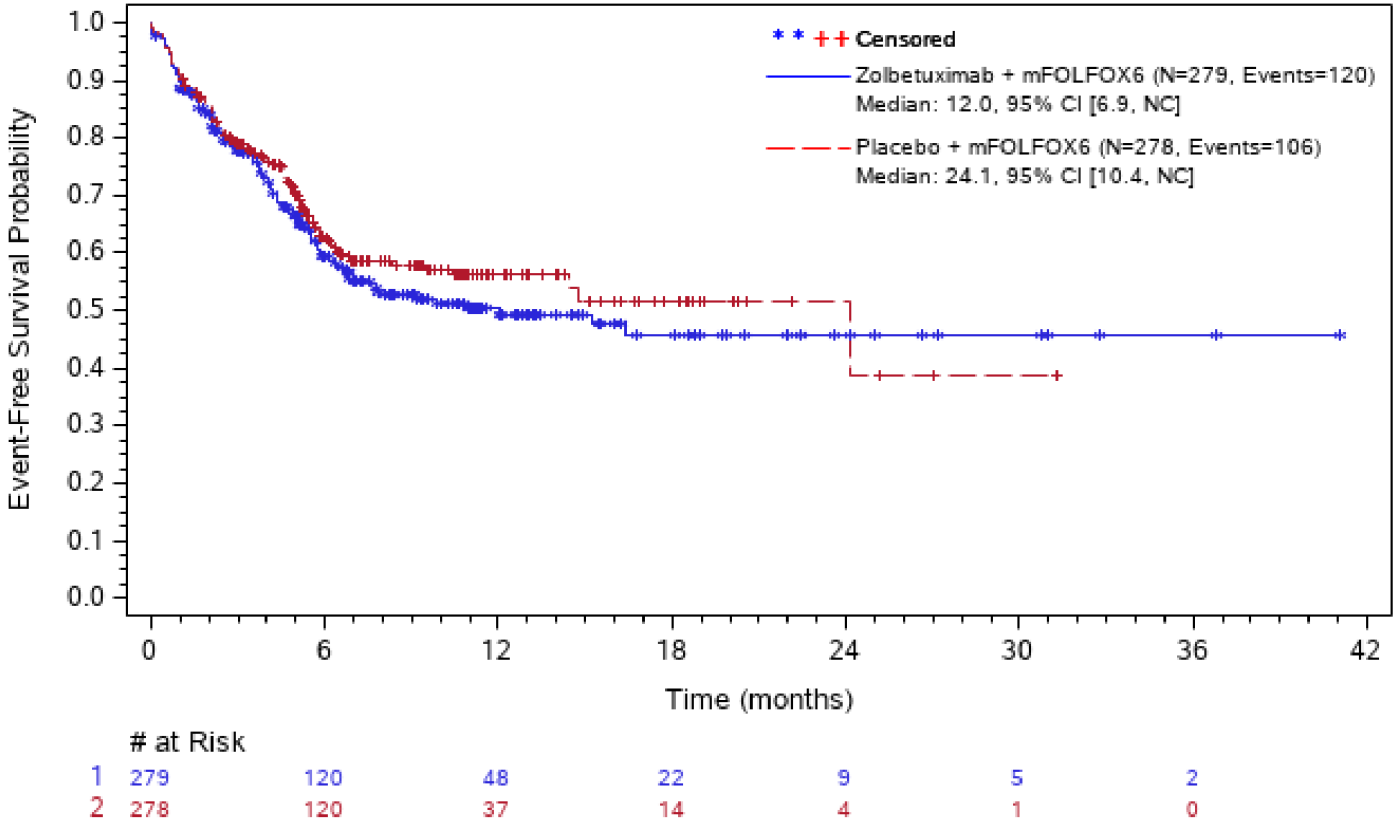
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	178	72 (40.4)	15.2 [7.8, NC]	177	62 (35.0)	NC [14.5, NC]	1.167 [0.831, 1.639]	0.3726	0.8095
>65 years	101	48 (47.5)	6.9 [5.1, NC]	101	44 (43.6)	9.5 [5.5, NC]	1.095 [0.727, 1.650]	0.6680	
Sex									
Male	174	75 (43.1)	12.0 [6.4, NC]	173	61 (35.3)	24.1 [14.8, NC]	1.246 [0.889, 1.748]	0.2020	0.3808
Female	105	45 (42.9)	16.4 [5.5, NC]	105	45 (42.9)	9.5 [5.3, NC]	0.990 [0.655, 1.498]	0.9579	
Region									
Asia	87	32 (36.8)	NC [7.6, NC]	88	31 (35.2)	14.8 [6.5, NC]	0.940 [0.573, 1.544]	0.8042	0.3109
Non-Asia	192	88 (45.8)	7.9 [5.8, 16.4]	190	75 (39.5)	24.1 [6.9, NC]	1.251 [0.919, 1.702]	0.1543	
Number of Organs with Metastatic Sites									
0-2	216	90 (41.7)	15.2 [6.9, NC]	216	81 (37.5)	24.1 [14.5, NC]	1.089 [0.807, 1.471]	0.5768	0.5572
>=3	63	30 (47.6)	6.7 [4.5, NC]	62	25 (40.3)	10.4 [6.0, NC]	1.291 [0.758, 2.201]	0.3458	

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 studytreatment + 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.
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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

2. Kaplan-Meier-Plots

Figure 301.1.2001.5: 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.1.2001.6.1: Summary and Results of TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	166 (59.5%)	167 (60.1%)	
Number of patients censored	113 (40.5%)	111 (39.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [2.1, 3.9]	3.0 [2.1, 4.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.982 [0.791, 1.219]
Log-rank test			
Two-sided stratified log-rank p-value			0.8929

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.7.1: Summary and Results of TEAEs - Anaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	100 (35.8%)	104 (37.4%)	
Number of patients censored	179 (64.2%)	174 (62.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [13.1, NC]	18.1 [12.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.938 [0.712, 1.237]
Log-rank test			
Two-sided stratified log-rank p-value			0.6607

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.8.1: Summary and Results of TEAEs - Leukopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	12 (4.3%)	
Number of patients censored	264 (94.6%)	266 (95.7%)	
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			1.318 [0.616, 2.821]
Log-rank test			
Two-sided stratified log-rank p-value			0.4799

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.9.1: Summary and Results of TEAEs - Neutropenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	102 (36.6%)	94 (33.8%)	
Number of patients censored	177 (63.4%)	184 (66.2%)	
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			1.155 [0.872, 1.529]
Log-rank test			
Two-sided stratified log-rank p-value			0.3081

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.10.1: Summary and Results of TEAEs - Thrombocytopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	28 (10.0%)	45 (16.2%)	
Number of patients censored	251 (90.0%)	233 (83.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.619 [0.386, 0.993]
Log-rank test			
Two-sided stratified log-rank p-value			0.0448

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.10.2: Summary and Results of TEAEs by Subgroups - Thrombocytopenia (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	18 (10.1)	NC [NC, NC]	177	31 (17.5)	NC [NC, NC]	0.577 [0.323, 1.032]	0.0610	0.6932
>65 years	101	10 (9.9)	NC [NC, NC]	101	14 (13.9)	NC [NC, NC]	0.695 [0.309, 1.565]	0.3772	
Sex									
Male	174	18 (10.3)	NC [NC, NC]	173	30 (17.3)	NC [NC, NC]	0.587 [0.327, 1.053]	0.0707	0.7831
Female	105	10 (9.5)	NC [NC, NC]	105	15 (14.3)	NC [NC, NC]	0.667 [0.299, 1.484]	0.3180	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.74E7 [0.000, NC]	0.1741	0.9812
Non-Asia	192	26 (13.5)	NC [NC, NC]	190	45 (23.7)	NC [NC, NC]	0.575 [0.354, 0.931]	0.0228	
Number of Organs with Metastatic Sites									
0-2	216	16 (7.4)	NC [NC, NC]	216	33 (15.3)	NC [NC, NC]	0.475 [0.261, 0.863]	0.0125	0.1430
>=3	63	12 (19.0)	NC [NC, NC]	62	12 (19.4)	NC [NC, NC]	0.997 [0.448, 2.219]	0.9927	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.11.1: Summary and Results of TEAEs - Cardiac Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	22 (7.9%)	
Number of patients censored	254 (91.0%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.186 [0.668, 2.107]
Log-rank test			
Two-sided stratified log-rank p-value			0.5591

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.12.1: Summary and Results of TEAEs - Palpitations (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.555 [0.506, 4.779]
Log-rank test			
Two-sided stratified log-rank p-value			0.4371

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.13.1: Summary and Results of TEAEs - Tachycardia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	2 (0.7%)	
Number of patients censored	270 (96.8%)	276 (99.3%)	
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			4.409 [0.949, 20.477]
Log-rank test			
Two-sided stratified log-rank p-value			0.0386

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.13.2: Summary and Results of TEAEs by Subgroups - Tachycardia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	4 (2.2)		177	1 (0.6)				
>65 years	101	5 (5.0)		101	1 (1.0)				
Sex									
Male	174	7 (4.0)		173	2 (1.2)				
Female	105	2 (1.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.3145	0.9939
Non-Asia	192	8 (4.2)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	4.153 [0.881, 19.568]	0.0505	
Number of Organs with Metastatic Sites									
0-2	216	6 (2.8)		216	2 (0.9)				
>=3	63	3 (4.8)		62	0 (0.0)				

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.14.1: Summary and Results of TEAEs - Ear and Labyrinth Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	12 (4.3%)	
Number of patients censored	270 (96.8%)	266 (95.7%)	
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			0.686 [0.287, 1.643]
Log-rank test			
Two-sided stratified log-rank p-value			0.3953

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.15.1: Summary and Results of TEAEs - Tinnitus (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	5 (1.8%)	
Number of patients censored	273 (97.8%)	273 (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			1.023 [0.307, 3.410]
Log-rank test			
Two-sided stratified log-rank p-value			0.9705

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.16.1: Summary and Results of TEAEs - Endocrine Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	6 (2.2%)	
Number of patients censored	272 (97.5%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.130 [0.376, 3.396]
Log-rank test			
Two-sided stratified log-rank p-value			0.8268

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.17.1: Summary and Results of TEAEs - Eye Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	26 (9.4%)	
Number of patients censored	259 (92.8%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.705 [0.388, 1.281]
Log-rank test			
Two-sided stratified log-rank p-value			0.2486

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.18.1: Summary and Results of TEAEs - Dry Eye (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	6 (2.2%)	
Number of patients censored	275 (98.6%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.506 [0.126, 2.034]
Log-rank test			
Two-sided stratified log-rank p-value			0.3281

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.19.1: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	264 (94.6%)	250 (89.9%)	
Number of patients censored	15 (5.4%)	28 (10.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.3 [0.2, 0.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.870 [1.560, 2.241]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.19.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	171 (96.1)	0.0 [NC, NC]	177	162 (91.5)	0.2 [0.1, 0.4]	1.898 [1.526, 2.362]	<.0001	0.9855
>65 years	101	93 (92.1)	0.0 [0.0, 0.1]	101	88 (87.1)	0.4 [0.2, 0.6]	1.845 [1.374, 2.477]	0.0003	
Sex									
Male	174	162 (93.1)	0.0 [NC, NC]	173	159 (91.9)	0.4 [0.2, 0.5]	1.685 [1.351, 2.102]	<.0001	0.2164
Female	105	102 (97.1)	0.0 [NC, NC]	105	91 (86.7)	0.2 [0.1, 0.4]	2.336 [1.751, 3.117]	<.0001	
Region									
Asia	87	85 (97.7)	0.0 [0.0, 0.1]	88	77 (87.5)	0.1 [0.1, 0.6]	2.298 [1.676, 3.151]	<.0001	0.1603
Non-Asia	192	179 (93.2)	0.0 [NC, NC]	190	173 (91.1)	0.4 [0.2, 0.5]	1.696 [1.373, 2.095]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	205 (94.9)	0.0 [NC, NC]	216	194 (89.8)	0.3 [0.1, 0.5]	2.014 [1.650, 2.459]	<.0001	0.3109
>=3	63	59 (93.7)	0.0 [0.0, 0.1]	62	56 (90.3)	0.4 [0.2, 0.5]	1.483 [1.025, 2.146]	0.0904	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.20.1: Summary and Results of TEAEs - Abdominal Discomfort (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	7 (2.5%)	
Number of patients censored	270 (96.8%)	271 (97.5%)	
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			1.084 [0.391, 3.009]
Log-rank test			
Two-sided stratified log-rank p-value			0.8765

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.21.1: Summary and Results of TEAEs - Abdominal Distension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	22 (7.9%)	
Number of patients censored	263 (94.3%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.720 [0.378, 1.374]
Log-rank test			
Two-sided stratified log-rank p-value			0.3175

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.22.1: Summary and Results of TEAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	67 (24.0%)	82 (29.5%)	
Number of patients censored	212 (76.0%)	196 (70.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [14.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.844 [0.610, 1.168]
Log-rank test			
Two-sided stratified log-rank p-value			0.2943

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.23.1: Summary and Results of TEAEs - Abdominal Pain Upper (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	47 (16.8%)	32 (11.5%)	
Number of patients censored	232 (83.2%)	246 (88.5%)	
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			1.529 [0.973, 2.401]
Log-rank test			
Two-sided stratified log-rank p-value			0.0642

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.24.1: Summary and Results of TEAEs - Ascites (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	12 (4.3%)	
Number of patients censored	274 (98.2%)	266 (95.7%)	
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			0.393 [0.135, 1.146]
Log-rank test			
Two-sided stratified log-rank p-value			0.0774

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.25.1: Summary and Results of TEAEs - Constipation (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	99 (35.5%)	112 (40.3%)	
Number of patients censored	180 (64.5%)	166 (59.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	17.6 [12.7, NC]	NC [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.785 [0.597, 1.033]
Log-rank test			
Two-sided stratified log-rank p-value			0.0838

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.26.1: Summary and Results of TEAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	110 (39.4%)	122 (43.9%)	
Number of patients censored	169 (60.6%)	156 (56.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	38.2 [10.9, NC]	16.0 [7.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.830 [0.640, 1.077]
Log-rank test			
Two-sided stratified log-rank p-value			0.1594

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.27.1: Summary and Results of TEAEs - Dry Mouth (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	10 (3.6%)	
Number of patients censored	267 (95.7%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.191 [0.514, 2.761]
Log-rank test			
Two-sided stratified log-rank p-value			0.6799

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.28.1: Summary and Results of TEAEs - Dyspepsia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	26 (9.3%)	18 (6.5%)	
Number of patients censored	253 (90.7%)	260 (93.5%)	
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			1.476 [0.806, 2.702]
Log-rank test			
Two-sided stratified log-rank p-value			0.2048

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.29.1: Summary and Results of TEAEs - Dysphagia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	22 (7.9%)	
Number of patients censored	258 (92.5%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.029 [0.565, 1.875]
Log-rank test			
Two-sided stratified log-rank p-value			0.9249

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.30.1: Summary and Results of TEAEs - Flatulence (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	8 (2.9%)	
Number of patients censored	272 (97.5%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.882 [0.319, 2.439]
Log-rank test			
Two-sided stratified log-rank p-value			0.8087

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.31.1: Summary and Results of TEAEs - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	15 (5.4%)	
Number of patients censored	267 (95.7%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [27.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.823 [0.383, 1.766]
Log-rank test			
Two-sided stratified log-rank p-value			0.6165

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.32.1: Summary and Results of TEAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	6 (2.2%)	
Number of patients censored	271 (97.1%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.194 [0.405, 3.521]
Log-rank test			
Two-sided stratified log-rank p-value			0.7473

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.33.1: Summary and Results of TEAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	230 (82.4%)	169 (60.8%)	
Number of patients censored	49 (17.6%)	109 (39.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	2.0 [0.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.177 [1.777, 2.668]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.33.2: Summary and Results of TEAEs by Subgroups - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	146 (82.0)	0.0 [0.0, 0.1]	177	117 (66.1)	1.0 [0.6, 2.2]	1.954 [1.530, 2.497]	<.0001	0.1070
>65 years	101	84 (83.2)	0.1 [0.0, 0.4]	101	52 (51.5)	3.5 [1.5, NC]	2.764 [1.949, 3.921]	<.0001	
Sex									
Male	174	137 (78.7)	0.1 [0.0, 0.4]	173	106 (61.3)	2.0 [0.8, 3.3]	1.890 [1.464, 2.439]	<.0001	0.0975
Female	105	93 (88.6)	0.0 [0.0, 0.1]	105	63 (60.0)	2.1 [0.7, 5.0]	2.914 [2.105, 4.034]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.1]	88	60 (68.2)	1.1 [0.5, 2.4]	2.029 [1.442, 2.857]	<.0001	0.4532
Non-Asia	192	155 (80.7)	0.0 [0.0, 0.1]	190	109 (57.4)	2.4 [0.9, 4.8]	2.301 [1.797, 2.946]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	182 (84.3)	0.0 [0.0, 0.1]	216	132 (61.1)	1.6 [0.9, 3.3]	2.321 [1.851, 2.910]	<.0001	0.4221
>=3	63	48 (76.2)	0.1 [0.0, 0.7]	62	37 (59.7)	2.2 [0.5, NC]	1.841 [1.197, 2.833]	0.0106	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.34.1: Summary and Results of TEAEs - Salivary Hypersecretion (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	2 (0.7%)	
Number of patients censored	268 (96.1%)	276 (99.3%)	
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			5.886 [1.304, 26.558]
Log-rank test			
Two-sided stratified log-rank p-value			0.0088

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.34.2: Summary and Results of TEAEs by Subgroups - Salivary Hypersecretion (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	7 (3.9)		177	1 (0.6)				
>65 years	101	4 (4.0)		101	1 (1.0)				
Sex									
Male	174	7 (4.0)		173	1 (0.6)				
Female	105	4 (3.8)		105	1 (1.0)				
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.3145	0.9936
Non-Asia	192	10 (5.2)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	5.276 [1.156, 24.083]	0.0163	
Number of Organs with Metastatic Sites									
0-2	216	10 (4.6)	NC [NC, NC]	216	2 (0.9)	NC [NC, NC]	5.105 [1.118, 23.301]	0.0190	0.9940
>=3	63	1 (1.6)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.15E7 [0.000, NC]	0.3023	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.35.1: Summary and Results of TEAEs - Stomatitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	58 (20.8%)	57 (20.5%)	
Number of patients censored	221 (79.2%)	221 (79.5%)	
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			1.022 [0.709, 1.475]
Log-rank test			
Two-sided stratified log-rank p-value			0.9031

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.36.1: Summary and Results of TEAEs - Toothache (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	7 (2.5%)	
Number of patients censored	276 (98.9%)	271 (97.5%)	
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			0.289 [0.060, 1.393]
Log-rank test			
Two-sided stratified log-rank p-value			0.0995

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.37.1: Summary and Results of TEAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	188 (67.4%)	99 (35.6%)	
Number of patients censored	91 (32.6%)	179 (64.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.7 [0.3, 1.4]	NC [16.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.958 [2.309, 3.790]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.37.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	127 (71.3)	0.5 [0.0, 0.9]	177	72 (40.7)	16.6 [12.0, NC]	2.710 [2.026, 3.625]	<.0001	0.4949
>65 years	101	61 (60.4)	1.6 [0.7, 5.9]	101	27 (26.7)	NC [NC, NC]	3.191 [2.025, 5.027]	<.0001	
Sex									
Male	174	111 (63.8)	0.9 [0.5, 2.9]	173	55 (31.8)	NC [16.6, NC]	2.942 [2.126, 4.071]	<.0001	0.6872
Female	105	77 (73.3)	0.2 [0.0, 1.1]	105	44 (41.9)	NC [5.2, NC]	2.730 [1.882, 3.961]	<.0001	
Region									
Asia	87	54 (62.1)	1.2 [0.1, 12.2]	88	28 (31.8)	16.6 [12.0, NC]	2.530 [1.596, 4.011]	<.0001	0.7147
Non-Asia	192	134 (69.8)	0.5 [0.1, 1.2]	190	71 (37.4)	NC [NC, NC]	2.961 [2.217, 3.956]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	148 (68.5)	0.7 [0.1, 1.1]	216	74 (34.3)	NC [16.6, NC]	3.059 [2.311, 4.050]	<.0001	0.2338
>=3	63	40 (63.5)	1.4 [0.2, 5.1]	62	25 (40.3)	NC [3.1, NC]	2.153 [1.304, 3.553]	0.0032	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.38.1: Summary and Results of TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	207 (74.2%)	202 (72.7%)	
Number of patients censored	72 (25.8%)	76 (27.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.4 [1.0, 1.8]	2.1 [1.5, 2.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.204 [0.989, 1.466]
Log-rank test			
Two-sided stratified log-rank p-value			0.0657

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.39.1: Summary and Results of TEAEs - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	74 (26.5%)	64 (23.0%)	
Number of patients censored	205 (73.5%)	214 (77.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [31.3, NC]	NC [26.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.175 [0.838, 1.646]
Log-rank test			
Two-sided stratified log-rank p-value			0.3461

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.40.1: Summary and Results of TEAEs - Chest Discomfort (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			1.167 [0.422, 3.225]
Log-rank test			
Two-sided stratified log-rank p-value			0.7652

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.41.1: Summary and Results of TEAEs - Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	5 (1.8%)	
Number of patients censored	270 (96.8%)	273 (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			1.895 [0.632, 5.680]
Log-rank test			
Two-sided stratified log-rank p-value			0.2468

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.42.1: Summary and Results of TEAEs - Chills (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	10 (3.6%)	
Number of patients censored	262 (93.9%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.715 [0.784, 3.750]
Log-rank test			
Two-sided stratified log-rank p-value			0.1713

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.43.1: Summary and Results of TEAEs - Fatigue (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	78 (28.0%)	91 (32.7%)	
Number of patients censored	201 (72.0%)	187 (67.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [25.1, NC]	NC [23.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.844 [0.623, 1.144]
Log-rank test			
Two-sided stratified log-rank p-value			0.2698

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.44.1: Summary and Results of TEAEs - General Physical Health Deterioration (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	7 (2.5%)	
Number of patients censored	276 (98.9%)	271 (97.5%)	
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			0.411 [0.104, 1.624]
Log-rank test			
Two-sided stratified log-rank p-value			0.1913

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.45.1: Summary and Results of TEAEs - Malaise (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	9 (3.2%)	
Number of patients censored	258 (92.5%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.466 [1.128, 5.390]
Log-rank test			
Two-sided stratified log-rank p-value			0.0193

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.45.2: Summary and Results of TEAEs by Subgroups - Malaise (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	12 (6.7)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	2.501 [0.881, 7.100]	0.0747	0.9120
>65 years	101	9 (8.9)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	2.330 [0.717, 7.565]	0.1473	
Sex									
Male	174	12 (6.9)	NC [NC, NC]	173	5 (2.9)	NC [NC, NC]	2.492 [0.878, 7.078]	0.0759	0.9265
Female	105	9 (8.6)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	2.340 [0.721, 7.599]	0.1449	
Region									
Asia	87	16 (18.4)	NC [NC, NC]	88	8 (9.1)	NC [NC, NC]	2.094 [0.895, 4.897]	0.0811	0.4350
Non-Asia	192	5 (2.6)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	5.235 [0.611, 44.823]	0.0912	
Number of Organs with Metastatic Sites									
0-2	216	19 (8.8)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	3.351 [1.338, 8.392]	0.0061	0.1176
>=3	63	2 (3.2)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.715 [0.119, 4.288]	0.7119	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.46.1: Summary and Results of TEAEs - Mucosal Inflammation (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	10 (3.6%)	
Number of patients censored	274 (98.2%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.494 [0.168, 1.452]
Log-rank test			
Two-sided stratified log-rank p-value			0.1908

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.47.1: Summary and Results of TEAEs - Non-Cardiac Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	11 (4.0%)	
Number of patients censored	270 (96.8%)	267 (96.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [31.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.827 [0.342, 1.998]
Log-rank test			
Two-sided stratified log-rank p-value			0.6724

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.48.1: Summary and Results of TEAEs - Oedema Peripheral (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	49 (17.6%)	26 (9.4%)	
Number of patients censored	230 (82.4%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [34.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.140 [1.328, 3.448]
Log-rank test			
Two-sided stratified log-rank p-value			0.0014

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.48.2: Summary and Results of TEAEs by Subgroups - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	30 (16.9)	34.5 [34.5, NC]	177	10 (5.6)	NC [NC, NC]	3.196 [1.561, 6.545]	0.0008	0.0484
>65 years	101	19 (18.8)	NC [NC, NC]	101	16 (15.8)	NC [NC, NC]	1.235 [0.635, 2.402]	0.5333	
Sex									
Male	174	30 (17.2)	34.5 [34.5, NC]	173	19 (11.0)	NC [NC, NC]	1.593 [0.893, 2.842]	0.1118	0.2470
Female	105	19 (18.1)	NC [NC, NC]	105	7 (6.7)	NC [NC, NC]	2.983 [1.253, 7.099]	0.0095	
Region									
Asia	87	10 (11.5)	NC [34.5, NC]	88	1 (1.1)	NC [NC, NC]	9.611 [1.224, 75.439]	0.0085	0.1262
Non-Asia	192	39 (20.3)	NC [NC, NC]	190	25 (13.2)	NC [NC, NC]	1.743 [1.054, 2.881]	0.0283	
Number of Organs with Metastatic Sites									
0-2	216	33 (15.3)	34.5 [34.5, NC]	216	19 (8.8)	NC [NC, NC]	1.816 [1.032, 3.195]	0.0358	0.5573
>=3	63	16 (25.4)	NC [NC, NC]	62	7 (11.3)	NC [NC, NC]	2.592 [1.065, 6.307]	0.0294	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.49.1: Summary and Results of TEAEs - Pyrexia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	54 (19.4%)	48 (17.3%)	
Number of patients censored	225 (80.6%)	230 (82.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.058 [0.715, 1.567]
Log-rank test			
Two-sided stratified log-rank p-value			0.7768

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.50.1: Summary and Results of TEAEs - Temperature Intolerance (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	10 (3.6%)	
Number of patients censored	271 (97.1%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.806 [0.318, 2.042]
Log-rank test			
Two-sided stratified log-rank p-value			0.6492

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.51.1: Summary and Results of TEAEs - Hepatobiliary Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	18 (6.5%)	
Number of patients censored	254 (91.0%)	260 (93.5%)	
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			1.393 [0.755, 2.570]
Log-rank test			
Two-sided stratified log-rank p-value			0.2883

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.52.1: Summary and Results of TEAEs - Immune System Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	12 (4.3%)	
Number of patients censored	272 (97.5%)	266 (95.7%)	
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			0.530 [0.207, 1.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.1787

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.53.1: Summary and Results of TEAEs - Drug Hypersensitivity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	6 (2.2%)	
Number of patients censored	275 (98.6%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.644 [0.181, 2.290]
Log-rank test			
Two-sided stratified log-rank p-value			0.4933

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.54.1: Summary and Results of TEAEs - Infections And Infestations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	111 (39.8%)	95 (34.2%)	
Number of patients censored	168 (60.2%)	183 (65.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	15.5 [11.1, 18.8]	16.4 [11.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.130 [0.856, 1.492]
Log-rank test			
Two-sided stratified log-rank p-value			0.3873

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.55.1: Summary and Results of TEAEs - Conjunctivitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [23.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.878 [0.467, 7.560]
Log-rank test			
Two-sided stratified log-rank p-value			0.3671

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.56.1: Summary and Results of TEAEs - Covid-19 (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	25 (9.0%)	
Number of patients censored	258 (92.5%)	253 (91.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	29.9 [26.3, NC]	30.1 [24.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.649 [0.350, 1.206]
Log-rank test			
Two-sided stratified log-rank p-value			0.1687

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.57.1: Summary and Results of TEAEs - Nasopharyngitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			0.837 [0.297, 2.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.7353

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.58.1: Summary and Results of TEAEs - Oral Candidiasis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	14 (5.0%)	
Number of patients censored	274 (98.2%)	264 (95.0%)	
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			0.362 [0.130, 1.006]
Log-rank test			
Two-sided stratified log-rank p-value			0.0420

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.58.2: Summary and Results of TEAEs by Subgroups - Oral Candidiasis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)	NC [NC, NC]	177	10 (5.6)	NC [NC, NC]	0.192 [0.042, 0.878]	0.0174	0.2342
>65 years	101	3 (3.0)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	0.754 [0.169, 3.372]	0.7113	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	0.325 [0.088, 1.200]	0.0757	0.8481
Female	105	2 (1.9)	NC [NC, NC]	105	5 (4.8)	NC [NC, NC]	0.393 [0.076, 2.029]	0.2479	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	0.829 [0.052, 13.284]	0.8941	0.4893
Non-Asia	192	4 (2.1)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	0.310 [0.101, 0.952]	0.0305	
Number of Organs with Metastatic Sites									
0-2	216	5 (2.3)	NC [NC, NC]	216	12 (5.6)	NC [NC, NC]	0.404 [0.142, 1.147]	0.0781	0.9917
>=3	63	0 (0.0)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.000 [0.000, NC]	0.1655	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.59.1: Summary and Results of TEAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	14 (5.0%)	
Number of patients censored	266 (95.3%)	264 (95.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [34.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.717 [0.332, 1.552]
Log-rank test			
Two-sided stratified log-rank p-value			0.3969

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.60.1: Summary and Results of TEAEs - Urinary Tract Infection (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	8 (2.9%)	
Number of patients censored	263 (94.3%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.969 [0.833, 4.659]
Log-rank test			
Two-sided stratified log-rank p-value			0.1168

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.61.1: Summary and Results of TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	39 (14.0%)	
Number of patients censored	234 (83.9%)	239 (86.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.164 [0.753, 1.798]
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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.62.1: Summary and Results of TEAEs - Fall (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	9 (3.2%)	
Number of patients censored	267 (95.7%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.409 [0.592, 3.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.4364

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.63.1: Summary and Results of TEAEs - Infusion Related Reaction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	5 (1.8%)	
Number of patients censored	273 (97.8%)	273 (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			1.202 [0.367, 3.938]
Log-rank test			
Two-sided stratified log-rank p-value			0.7613

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.64.1: Summary and Results of TEAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	182 (65.2%)	171 (61.5%)	
Number of patients censored	97 (34.8%)	107 (38.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.5 [1.8, 3.7]	2.8 [2.1, 3.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.136 [0.920, 1.404]
Log-rank test			
Two-sided stratified log-rank p-value			0.2346

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.65.1: Summary and Results of TEAEs - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	34 (12.2%)	47 (16.9%)	
Number of patients censored	245 (87.8%)	231 (83.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.720 [0.462, 1.122]
Log-rank test			
Two-sided stratified log-rank p-value			0.1448

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.66.1: Summary and Results of TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	49 (17.6%)	44 (15.8%)	
Number of patients censored	230 (82.4%)	234 (84.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [23.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.126 [0.748, 1.694]
Log-rank test			
Two-sided stratified log-rank p-value			0.5728

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.67.1: Summary and Results of TEAEs - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	24 (8.6%)	
Number of patients censored	261 (93.5%)	254 (91.4%)	
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			0.773 [0.418, 1.428]
Log-rank test			
Two-sided stratified log-rank p-value			0.4102

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.68.1: Summary and Results of TEAEs - Blood Bilirubin Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	13 (4.7%)	
Number of patients censored	272 (97.5%)	265 (95.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [23.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.493 [0.192, 1.269]
Log-rank test			
Two-sided stratified log-rank p-value			0.1354

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.69.1: Summary and Results of TEAEs - Blood Creatinine Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	6 (2.2%)	
Number of patients censored	272 (97.5%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.126 [0.374, 3.395]
Log-rank test			
Two-sided stratified log-rank p-value			0.8320

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.70.1: Summary and Results of TEAEs - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	6 (2.2%)	
Number of patients censored	270 (96.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.519 [0.539, 4.280]
Log-rank test			
Two-sided stratified log-rank p-value			0.4258

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.71.1: Summary and Results of TEAEs - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	6 (2.2%)	
Number of patients censored	272 (97.5%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.269 [0.426, 3.782]
Log-rank test			
Two-sided stratified log-rank p-value			0.6681

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.72.1: Summary and Results of TEAEs - Neutrophil Count Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	95 (34.1%)	91 (32.7%)	
Number of patients censored	184 (65.9%)	187 (67.3%)	
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			1.054 [0.790, 1.407]
Log-rank test			
Two-sided stratified log-rank p-value			0.6944

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.73.1: Summary and Results of TEAEs - Platelet Count Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	40 (14.3%)	49 (17.6%)	
Number of patients censored	239 (85.7%)	229 (82.4%)	
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			0.822 [0.540, 1.249]
Log-rank test			
Two-sided stratified log-rank p-value			0.3562

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.74.1: Summary and Results of TEAEs - Weight Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	55 (19.7%)	54 (19.4%)	
Number of patients censored	224 (80.3%)	224 (80.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.019 [0.699, 1.487]
Log-rank test			
Two-sided stratified log-rank p-value			0.9215

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.75.1: Summary and Results of TEAEs - Weight Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	8 (2.9%)	
Number of patients censored	273 (97.8%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.716 [0.246, 2.079]
Log-rank test			
Two-sided stratified log-rank p-value			0.5369

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.76.1: Summary and Results of TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	50 (17.9%)	46 (16.5%)	
Number of patients censored	229 (82.1%)	232 (83.5%)	
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			1.088 [0.728, 1.626]
Log-rank test			
Two-sided stratified log-rank p-value			0.6653

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.77.1: Summary and Results of TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	189 (67.7%)	159 (57.2%)	
Number of patients censored	90 (32.3%)	119 (42.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.8 [1.1, 2.2]	3.7 [2.9, 5.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.466 [1.184, 1.815]
Log-rank test			
Two-sided stratified log-rank p-value			0.0004

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.77.2: Summary and Results of TEAEs by Subgroups - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	113 (63.5)	2.0 [1.3, 3.5]	177	95 (53.7)	4.5 [3.3, 12.4]	1.462 [1.112, 1.922]	0.0065	0.9078
>65 years	101	76 (75.2)	1.4 [0.6, 2.1]	101	64 (63.4)	2.6 [1.4, 4.8]	1.406 [1.008, 1.962]	0.0424	
Sex									
Male	174	120 (69.0)	2.1 [1.1, 3.3]	173	95 (54.9)	3.9 [3.3, 17.2]	1.529 [1.167, 2.002]	0.0019	0.5132
Female	105	69 (65.7)	1.4 [0.6, 1.9]	105	64 (61.0)	3.2 [1.5, 5.7]	1.313 [0.934, 1.846]	0.1209	
Region									
Asia	87	63 (72.4)	0.7 [0.5, 3.9]	88	50 (56.8)	3.6 [2.2, NC]	1.464 [1.007, 2.128]	0.0468	0.8203
Non-Asia	192	126 (65.6)	1.9 [1.4, 2.2]	190	109 (57.4)	3.9 [2.8, 6.5]	1.431 [1.106, 1.851]	0.0062	
Number of Organs with Metastatic Sites									
0-2	216	145 (67.1)	2.0 [1.4, 3.1]	216	123 (56.9)	4.0 [3.2, 7.4]	1.410 [1.108, 1.793]	0.0052	0.7250
>=3	63	44 (69.8)	0.9 [0.5, 2.0]	62	36 (58.1)	2.9 [1.2, NC]	1.510 [0.970, 2.349]	0.0665	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.78.1: Summary and Results of TEAEs - Decreased Appetite (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	131 (47.0%)	93 (33.5%)	
Number of patients censored	148 (53.0%)	185 (66.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	14.0 [4.3, NC]	NC [16.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.640 [1.255, 2.144]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.78.2: Summary and Results of TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	72 (40.4)	21.2 [5.8, NC]	177	53 (29.9)	NC [NC, NC]	1.540 [1.079, 2.197]	0.0171	0.6442
>65 years	101	59 (58.4)	3.0 [1.1, 7.9]	101	40 (39.6)	NC [5.5, NC]	1.748 [1.169, 2.614]	0.0056	
Sex									
Male	174	87 (50.0)	6.1 [2.9, 17.4]	173	57 (32.9)	NC [16.9, NC]	1.805 [1.292, 2.523]	0.0004	0.3057
Female	105	44 (41.9)	21.2 [4.7, NC]	105	36 (34.3)	NC [NC, NC]	1.363 [0.876, 2.121]	0.1744	
Region									
Asia	87	48 (55.2)	3.1 [0.6, NC]	88	34 (38.6)	NC [5.8, NC]	1.652 [1.062, 2.568]	0.0255	0.9901
Non-Asia	192	83 (43.2)	14.0 [5.3, NC]	190	59 (31.1)	NC [16.9, NC]	1.645 [1.177, 2.298]	0.0033	
Number of Organs with Metastatic Sites									
0-2	216	98 (45.4)	17.4 [5.2, NC]	216	73 (33.8)	NC [16.9, NC]	1.538 [1.135, 2.083]	0.0054	0.4489
>=3	63	33 (52.4)	4.7 [1.8, NC]	62	20 (32.3)	NC [NC, NC]	1.882 [1.079, 3.283]	0.0231	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.79.1: Summary and Results of TEAEs - Dehydration (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	9 (3.2%)	
Number of patients censored	269 (96.4%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.146 [0.465, 2.824]
Log-rank test			
Two-sided stratified log-rank p-value			0.7663

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.80.1: Summary and Results of TEAEs - Hyperglycaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	11 (4.0%)	
Number of patients censored	267 (95.7%)	267 (96.0%)	
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			1.080 [0.476, 2.450]
Log-rank test			
Two-sided stratified log-rank p-value			0.8537

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.81.1: Summary and Results of TEAEs - Hypoalbuminaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	43 (15.4%)	17 (6.1%)	
Number of patients censored	236 (84.6%)	261 (93.9%)	
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			2.761 [1.573, 4.844]
Log-rank test			
Two-sided stratified log-rank p-value			0.0002

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.81.2: Summary and Results of TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	28 (15.7)	NC [NC, NC]	177	12 (6.8)	NC [NC, NC]	2.509 [1.275, 4.934]	0.0058	0.7398
>65 years	101	15 (14.9)	NC [NC, NC]	101	5 (5.0)	NC [NC, NC]	3.085 [1.121, 8.491]	0.0216	
Sex									
Male	174	31 (17.8)	NC [NC, NC]	173	7 (4.0)	NC [NC, NC]	4.760 [2.095, 10.811]	<.0001	0.0242
Female	105	12 (11.4)	NC [NC, NC]	105	10 (9.5)	NC [NC, NC]	1.225 [0.529, 2.836]	0.6356	
Region									
Asia	87	14 (16.1)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	2.743 [0.986, 7.634]	0.0442	0.9236
Non-Asia	192	29 (15.1)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	2.635 [1.344, 5.167]	0.0033	
Number of Organs with Metastatic Sites									
0-2	216	33 (15.3)	NC [NC, NC]	216	15 (6.9)	NC [NC, NC]	2.305 [1.252, 4.244]	0.0058	0.3201
>=3	63	10 (15.9)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	5.328 [1.167, 24.327]	0.0155	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.82.1: Summary and Results of TEAEs - Hypocalcaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	30 (10.8%)	9 (3.2%)	
Number of patients censored	249 (89.2%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.530 [1.670, 7.461]
Log-rank test			
Two-sided stratified log-rank p-value			0.0004

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.82.2: Summary and Results of TEAEs by Subgroups - Hypocalcaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	16 (9.0)	NC [28.3, NC]	177	3 (1.7)	NC [NC, NC]	5.443 [1.584, 18.698]	0.0025	0.2729
>65 years	101	14 (13.9)	NC [NC, NC]	101	6 (5.9)	NC [NC, NC]	2.291 [0.878, 5.979]	0.0813	
Sex									
Male	174	18 (10.3)	NC [NC, NC]	173	6 (3.5)	NC [NC, NC]	3.131 [1.242, 7.895]	0.0107	0.6978
Female	105	12 (11.4)	NC [28.3, NC]	105	3 (2.9)	NC [NC, NC]	3.918 [1.103, 13.916]	0.0227	
Region									
Asia	87	10 (11.5)	NC [28.3, NC]	88	1 (1.1)	NC [NC, NC]	9.164 [1.166, 72.021]	0.0107	0.2791
Non-Asia	192	20 (10.4)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	2.674 [1.177, 6.074]	0.0145	
Number of Organs with Metastatic Sites									
0-2	216	20 (9.3)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	3.247 [1.299, 8.116]	0.0077	0.8999
>=3	63	10 (15.9)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	3.484 [0.957, 12.684]	0.0438	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.83.1: Summary and Results of TEAEs - Hypokalaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	50 (17.9%)	41 (14.7%)	
Number of patients censored	229 (82.1%)	237 (85.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [23.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.279 [0.842, 1.944]
Log-rank test			
Two-sided stratified log-rank p-value			0.2452

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.84.1: Summary and Results of TEAEs - Hypomagnesaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	11 (4.0%)	
Number of patients censored	268 (96.1%)	267 (96.0%)	
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			1.083 [0.469, 2.500]
Log-rank test			
Two-sided stratified log-rank p-value			0.8529

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.85.1: Summary and Results of TEAEs - Hyponatraemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	10 (3.6%)	
Number of patients censored	265 (95.0%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.417 [0.628, 3.200]
Log-rank test			
Two-sided stratified log-rank p-value			0.3992

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.86.1: Summary and Results of TEAEs - Hypophosphataemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	13 (4.7%)	
Number of patients censored	262 (93.9%)	265 (95.3%)	
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			1.288 [0.622, 2.669]
Log-rank test			
Two-sided stratified log-rank p-value			0.4929

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.87.1: Summary and Results of TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	81 (29.0%)	86 (30.9%)	
Number of patients censored	198 (71.0%)	192 (69.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [17.7, NC]	19.1 [12.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.889 [0.653, 1.210]
Log-rank test			
Two-sided stratified log-rank p-value			0.4538

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.88.1: Summary and Results of TEAEs - Arthralgia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	24 (8.6%)	
Number of patients censored	257 (92.1%)	254 (91.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [34.7, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.763 [0.423, 1.377]
Log-rank test			
Two-sided stratified log-rank p-value			0.3686

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.89.1: Summary and Results of TEAEs - Back Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	34 (12.2%)	30 (10.8%)	
Number of patients censored	245 (87.8%)	248 (89.2%)	
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			1.096 [0.666, 1.803]
Log-rank test			
Two-sided stratified log-rank p-value			0.7191

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.90.1: Summary and Results of TEAEs - Flank Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	2 (0.7%)	8 (2.9%)	
Number of patients censored	277 (99.3%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.233 [0.049, 1.109]
Log-rank test			
Two-sided stratified log-rank p-value			0.0468

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.90.2: Summary and Results of TEAEs by Subgroups - Flank Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	6 (3.4)				
>65 years	101	1 (1.0)		101	2 (2.0)				
Sex									
Male	174	1 (0.6)		173	7 (4.0)				
Female	105	1 (1.0)		105	1 (1.0)				
Region									
Asia	87	1 (1.1)		88	5 (5.7)				
Non-Asia	192	1 (0.5)		190	3 (1.6)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)	NC [NC, NC]	216	8 (3.7)	NC [NC, NC]	0.213 [0.045, 1.014]	0.0329	0.9996
>=3	63	0 (0.0)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.91.1: Summary and Results of TEAEs - Musculoskeletal Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	8 (2.9%)	
Number of patients censored	270 (96.8%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.185 [0.455, 3.087]
Log-rank test			
Two-sided stratified log-rank p-value			0.7277

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.92.1: Summary and Results of TEAEs - Myalgia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	12 (4.3%)	
Number of patients censored	267 (95.7%)	266 (95.7%)	
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			0.958 [0.429, 2.140]
Log-rank test			
Two-sided stratified log-rank p-value			0.9173

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.93.1: Summary and Results of TEAEs - Pain In Extremity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	15 (5.4%)	
Number of patients censored	270 (96.8%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.585 [0.255, 1.340]
Log-rank test			
Two-sided stratified log-rank p-value			0.1997

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.94.1: Summary and Results of TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	24 (8.6%)	
Number of patients censored	257 (92.1%)	254 (91.4%)	
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			0.902 [0.503, 1.617]
Log-rank test			
Two-sided stratified log-rank p-value			0.7284

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.95.1: Summary and Results of TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.909 [0.392, 2.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.8246

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.96.1: Summary and Results of TEAEs - Nervous System Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	209 (74.9%)	208 (74.8%)	
Number of patients censored	70 (25.1%)	70 (25.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.0 [1.5, 2.4]	1.9 [1.2, 2.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.923 [0.760, 1.120]
Log-rank test			
Two-sided stratified log-rank p-value			0.4397

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.97.1: Summary and Results of TEAEs - Dizziness (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	36 (12.9%)	27 (9.7%)	
Number of patients censored	243 (87.1%)	251 (90.3%)	
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			1.335 [0.805, 2.213]
Log-rank test			
Two-sided stratified log-rank p-value			0.2616

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.98.1: Summary and Results of TEAEs - Dysaesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	13 (4.7%)	
Number of patients censored	271 (97.1%)	265 (95.3%)	
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			0.611 [0.253, 1.474]
Log-rank test			
Two-sided stratified log-rank p-value			0.2682

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.99.1: Summary and Results of TEAEs - Dysgeusia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	41 (14.7%)	40 (14.4%)	
Number of patients censored	238 (85.3%)	238 (85.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.060 [0.685, 1.640]
Log-rank test			
Two-sided stratified log-rank p-value			0.7934

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.100.1: Summary and Results of TEAEs - Headache (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	31 (11.1%)	35 (12.6%)	
Number of patients censored	248 (88.9%)	243 (87.4%)	
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			0.834 [0.513, 1.355]
Log-rank test			
Two-sided stratified log-rank p-value			0.4627

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.101.1: Summary and Results of TEAEs - Hypoaesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	11 (4.0%)	
Number of patients censored	268 (96.1%)	267 (96.0%)	
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			0.938 [0.406, 2.167]
Log-rank test			
Two-sided stratified log-rank p-value			0.8803

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.102.1: Summary and Results of TEAEs - Neuropathy Peripheral (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	23 (8.2%)	22 (7.9%)	
Number of patients censored	256 (91.8%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.058 [0.589, 1.900]
Log-rank test			
Two-sided stratified log-rank p-value			0.8476

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.103.1: Summary and Results of TEAEs - Neurotoxicity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	12 (4.3%)	
Number of patients censored	267 (95.7%)	266 (95.7%)	
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			1.025 [0.460, 2.283]
Log-rank test			
Two-sided stratified log-rank p-value			0.9494

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.104.1: Summary and Results of TEAEs - Paraesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	44 (15.8%)	46 (16.5%)	
Number of patients censored	235 (84.2%)	232 (83.5%)	
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			0.906 [0.596, 1.375]
Log-rank test			
Two-sided stratified log-rank p-value			0.6436

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.105.1: Summary and Results of TEAEs - Peripheral Motor Neuropathy (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	6 (2.2%)	
Number of patients censored	274 (98.2%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.839 [0.256, 2.750]
Log-rank test			
Two-sided stratified log-rank p-value			0.7710

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.106.1: Summary and Results of TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	106 (38.0%)	118 (42.4%)	
Number of patients censored	173 (62.0%)	160 (57.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [7.8, NC]	15.9 [5.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.824 [0.633, 1.072]
Log-rank test			
Two-sided stratified log-rank p-value			0.1543

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.107.1: Summary and Results of TEAEs - Syncope (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	7 (2.5%)	
Number of patients censored	273 (97.8%)	271 (97.5%)	
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			0.902 [0.303, 2.686]
Log-rank test			
Two-sided stratified log-rank p-value			0.8532

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.108.1: Summary and Results of TEAEs - Taste Disorder (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.483 [0.418, 5.263]
Log-rank test			
Two-sided stratified log-rank p-value			0.5397

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.109.1: Summary and Results of TEAEs - Psychiatric Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	46 (16.5%)	44 (15.8%)	
Number of patients censored	233 (83.5%)	234 (84.2%)	
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			1.052 [0.695, 1.592]
Log-rank test			
Two-sided stratified log-rank p-value			0.8142

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.110.1: Summary and Results of TEAEs - Anxiety (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	8 (2.9%)	
Number of patients censored	267 (95.7%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.490 [0.607, 3.656]
Log-rank test			
Two-sided stratified log-rank p-value			0.3811

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.111.1: Summary and Results of TEAEs - Depression (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	9 (3.2%)	
Number of patients censored	271 (97.1%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.884 [0.339, 2.304]
Log-rank test			
Two-sided stratified log-rank p-value			0.8008

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.112.1: Summary and Results of TEAEs - Insomnia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	29 (10.4%)	25 (9.0%)	
Number of patients censored	250 (89.6%)	253 (91.0%)	
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			1.120 [0.655, 1.915]
Log-rank test			
Two-sided stratified log-rank p-value			0.6794

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.113.1: Summary and Results of TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	39 (14.0%)	34 (12.2%)	
Number of patients censored	240 (86.0%)	244 (87.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.2, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.052 [0.660, 1.677]
Log-rank test			
Two-sided stratified log-rank p-value			0.8294

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.114.1: Summary and Results of TEAEs - Dysuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	12 (4.3%)	
Number of patients censored	275 (98.6%)	266 (95.7%)	
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			0.279 [0.088, 0.878]
Log-rank test			
Two-sided stratified log-rank p-value			0.0204

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.114.2: Summary and Results of TEAEs by Subgroups - Dysuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	4 (2.2)	NC [NC, NC]	177	9 (5.1)	NC [NC, NC]	0.409 [0.126, 1.333]	0.1253	0.9900
>65 years	101	0 (0.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	0.000 [0.000, NC]	0.0852	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	0.348 [0.092, 1.317]	0.1039	0.7533
Female	105	1 (1.0)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	0.217 [0.024, 1.958]	0.1353	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	0.200 [0.020, 1.967]	0.1279	0.8110
Non-Asia	192	3 (1.6)	NC [NC, NC]	190	9 (4.7)	NC [NC, NC]	0.345 [0.093, 1.273]	0.0941	
Number of Organs with Metastatic Sites									
0-2	216	3 (1.4)	NC [NC, NC]	216	9 (4.2)	NC [NC, NC]	0.301 [0.081, 1.115]	0.0567	0.9932
>=3	63	1 (1.6)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.269 [0.027, 2.641]	0.2285	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.115.1: Summary and Results of TEAEs - Haematuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	9 (3.2%)	
Number of patients censored	269 (96.4%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.087 [0.437, 2.700]
Log-rank test			
Two-sided stratified log-rank p-value			0.8569

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.116.1: Summary and Results of TEAEs - Proteinuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	6 (2.2%)	
Number of patients censored	268 (96.1%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.008 [0.740, 5.450]
Log-rank test			
Two-sided stratified log-rank p-value			0.1622

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.117.1: Summary and Results of TEAEs - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	12 (4.3%)	
Number of patients censored	273 (97.8%)	266 (95.7%)	
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			0.520 [0.195, 1.388]
Log-rank test			
Two-sided stratified log-rank p-value			0.1837

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.118.1: Summary and Results of TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	106 (38.0%)	112 (40.3%)	
Number of patients censored	173 (62.0%)	166 (59.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	18.3 [14.8, NC]	15.3 [7.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.953 [0.730, 1.245]
Log-rank test			
Two-sided stratified log-rank p-value			0.7178

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.119.1: Summary and Results of TEAEs - Cough (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	28 (10.0%)	28 (10.1%)	
Number of patients censored	251 (90.0%)	250 (89.9%)	
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			1.016 [0.601, 1.720]
Log-rank test			
Two-sided stratified log-rank p-value			0.9521

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.120.1: Summary and Results of TEAEs - Dyspnoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	32 (11.5%)	
Number of patients censored	259 (92.8%)	246 (88.5%)	
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			0.648 [0.370, 1.135]
Log-rank test			
Two-sided stratified log-rank p-value			0.1258

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.1.2001.121.1: Summary and Results of TEAEs - Epistaxis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	25 (9.0%)	
Number of patients censored	266 (95.3%)	253 (91.0%)	
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			0.519 [0.264, 1.017]
Log-rank test			
Two-sided stratified log-rank p-value			0.0518

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.122.1: Summary and Results of TEAEs - Hiccups (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	12 (4.3%)	
Number of patients censored	263 (94.3%)	266 (95.7%)	
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			1.318 [0.621, 2.798]
Log-rank test			
Two-sided stratified log-rank p-value			0.4715

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.1.2001.123.1: Summary and Results of TEAEs - Oropharyngeal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	13 (4.7%)	
Number of patients censored	276 (98.9%)	265 (95.3%)	
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			0.229 [0.065, 0.805]
Log-rank test			
Two-sided stratified log-rank p-value			0.0121

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.1.2001.123.2: Summary and Results of TEAEs by Subgroups - Oropharyngeal Pain (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)	NC [NC, NC]	177	10 (5.6)	NC [NC, NC]	0.196 [0.043, 0.896]	0.0192	0.7113
>65 years	101	1 (1.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	0.333 [0.035, 3.199]	0.3163	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	0.372 [0.099, 1.401]	0.1281	0.9899
Female	105	0 (0.0)	NC [NC, NC]	105	5 (4.8)	NC [NC, NC]	0.000 [0.000, NC]	0.0239	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	0.191 [0.022, 1.633]	0.0908	0.7829
Non-Asia	192	2 (1.0)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	0.258 [0.055, 1.217]	0.0650	
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)	NC [NC, NC]	216	11 (5.1)	NC [NC, NC]	0.176 [0.039, 0.795]	0.0107	0.4707
>=3	63	1 (1.6)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.505 [0.046, 5.575]	0.5699	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 09SEP22

Table 301.1.2001.124.1: Summary and Results of TEAEs - Pleural Effusion (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	6 (2.2%)	
Number of patients censored	275 (98.6%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.721 [0.203, 2.558]
Log-rank test			
Two-sided stratified log-rank p-value			0.6112

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.125.1: Summary and Results of TEAEs - Productive Cough (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	7 (2.5%)	
Number of patients censored	266 (95.3%)	271 (97.5%)	
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			1.731 [0.688, 4.356]
Log-rank test			
Two-sided stratified log-rank p-value			0.2405

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.126.1: Summary and Results of TEAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	12 (4.3%)	
Number of patients censored	262 (93.9%)	266 (95.7%)	
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			1.464 [0.698, 3.071]
Log-rank test			
Two-sided stratified log-rank p-value			0.3104

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.127.1: Summary and Results of TEAEs - Rhinorrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	6 (2.2%)	
Number of patients censored	269 (96.4%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.641 [0.594, 4.534]
Log-rank test			
Two-sided stratified log-rank p-value			0.3350

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.128.1: Summary and Results of TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	125 (44.8%)	113 (40.6%)	
Number of patients censored	154 (55.2%)	165 (59.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.1 [7.8, 14.3]	12.2 [7.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.070 [0.827, 1.383]
Log-rank test			
Two-sided stratified log-rank p-value			0.6044

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.129.1: Summary and Results of TEAEs - Alopecia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	21 (7.6%)	
Number of patients censored	258 (92.5%)	257 (92.4%)	
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			0.980 [0.532, 1.804]
Log-rank test			
Two-sided stratified log-rank p-value			0.9481

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.130.1: Summary and Results of TEAEs - Dry Skin (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	12 (4.3%)	
Number of patients censored	262 (93.9%)	266 (95.7%)	
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			1.471 [0.702, 3.085]
Log-rank test			
Two-sided stratified log-rank p-value			0.3046

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.131.1: Summary and Results of TEAEs - Erythema (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	10 (3.6%)	
Number of patients censored	272 (97.5%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.705 [0.268, 1.856]
Log-rank test			
Two-sided stratified log-rank p-value			0.4769

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.132.1: Summary and Results of TEAEs - Hyperhidrosis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	5 (1.8%)	
Number of patients censored	270 (96.8%)	273 (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			1.887 [0.632, 5.636]
Log-rank test			
Two-sided stratified log-rank p-value			0.2475

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.133.1: Summary and Results of TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	19 (6.8%)	
Number of patients censored	255 (91.4%)	259 (93.2%)	
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			1.332 [0.727, 2.438]
Log-rank test			
Two-sided stratified log-rank p-value			0.3529

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.134.1: Summary and Results of TEAEs - Pruritus (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	24 (8.6%)	
Number of patients censored	255 (91.4%)	254 (91.4%)	
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			0.796 [0.442, 1.432]
Log-rank test			
Two-sided stratified log-rank p-value			0.4436

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.135.1: Summary and Results of TEAEs - Rash (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	22 (7.9%)	
Number of patients censored	261 (93.5%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.750 [0.399, 1.410]
Log-rank test			
Two-sided stratified log-rank p-value			0.3701

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.136.1: Summary and Results of TEAEs - Rash Maculo-Papular (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	15 (5.4%)	
Number of patients censored	271 (97.1%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.460 [0.191, 1.107]
Log-rank test			
Two-sided stratified log-rank p-value			0.0764

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.137.1: Summary and Results of TEAEs - Urticaria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	9 (3.2%)	
Number of patients censored	275 (98.6%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.398 [0.122, 1.296]
Log-rank test			
Two-sided stratified log-rank p-value			0.1133

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.138.1: Summary and Results of TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	77 (27.6%)	65 (23.4%)	
Number of patients censored	202 (72.4%)	213 (76.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.269 [0.911, 1.768]
Log-rank test			
Two-sided stratified log-rank p-value			0.1671

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.139.1: Summary and Results of TEAEs - Deep Vein Thrombosis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	10 (3.6%)	
Number of patients censored	265 (95.0%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.420 [0.629, 3.208]
Log-rank test			
Two-sided stratified log-rank p-value			0.3967

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.140.1: Summary and Results of TEAEs - Flushing (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.472 [0.467, 4.641]
Log-rank test			
Two-sided stratified log-rank p-value			0.5071

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.141.1: Summary and Results of TEAEs - Hot Flush (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	5 (1.8%)	
Number of patients censored	273 (97.8%)	273 (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			1.082 [0.326, 3.583]
Log-rank test			
Two-sided stratified log-rank p-value			0.8975

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.142.1: Summary and Results of TEAEs - Hypertension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	31 (11.1%)	22 (7.9%)	
Number of patients censored	248 (88.9%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.476 [0.854, 2.552]
Log-rank test			
Two-sided stratified log-rank p-value			0.1694

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.143.1: Summary and Results of TEAEs - Hypotension (PT)
- Safety Analysis Set

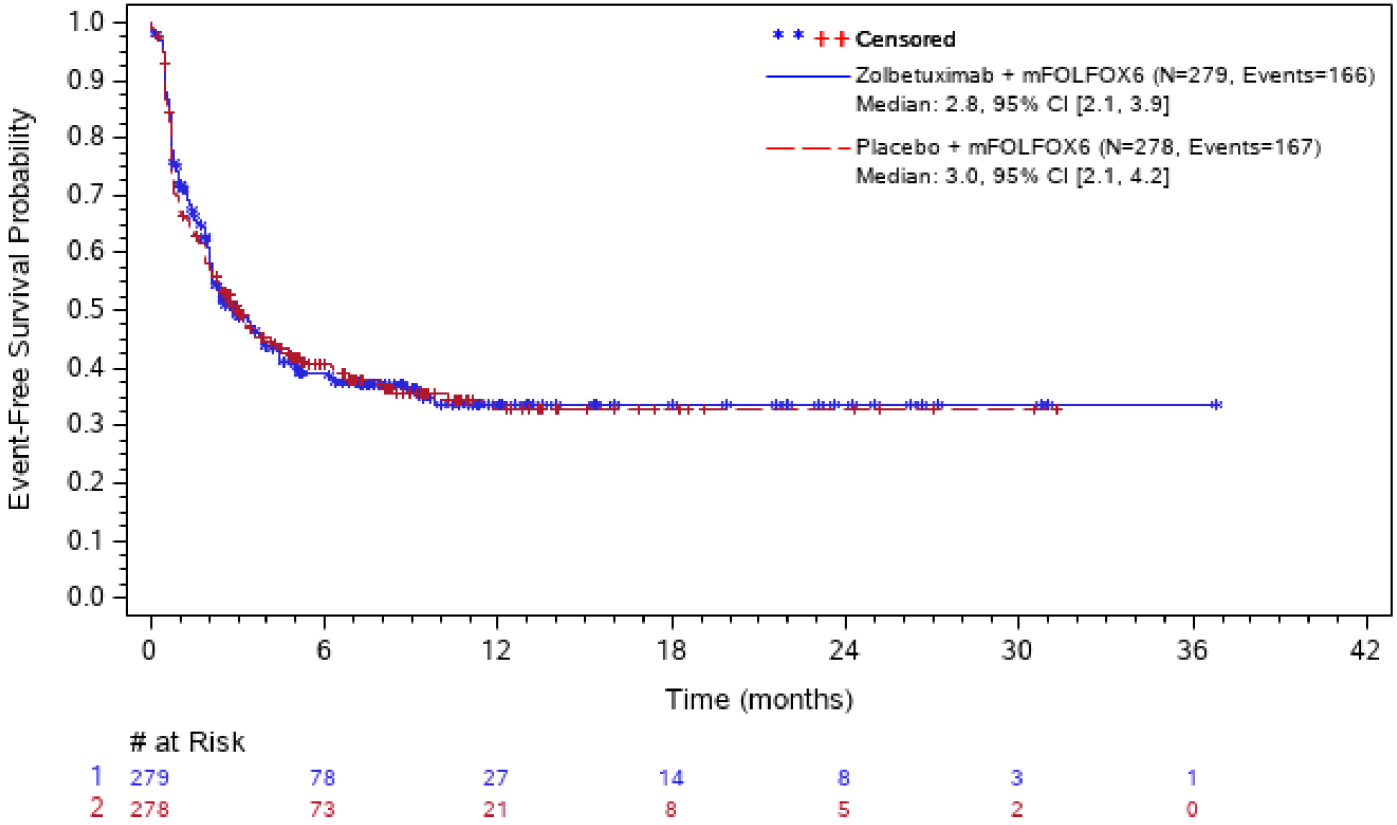
	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	14 (5.0%)	
Number of patients censored	266 (95.3%)	264 (95.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.948 [0.445, 2.020]
Log-rank test			
Two-sided stratified log-rank p-value			0.8903

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse - SOC und PT

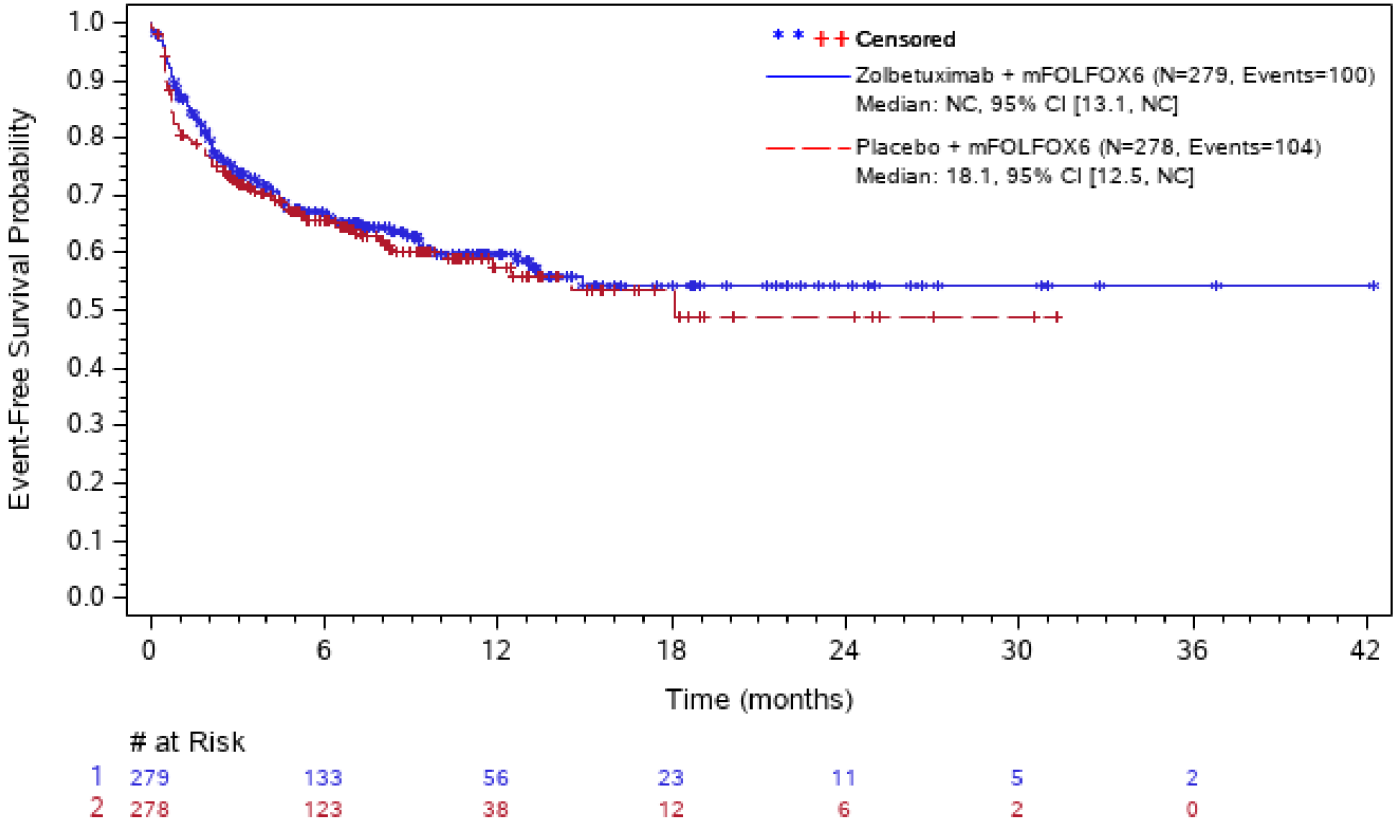
2. Kaplan-Meier-Plots

Figure 301.1.2001.6: Kaplan-Meier Plot of Time to first TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



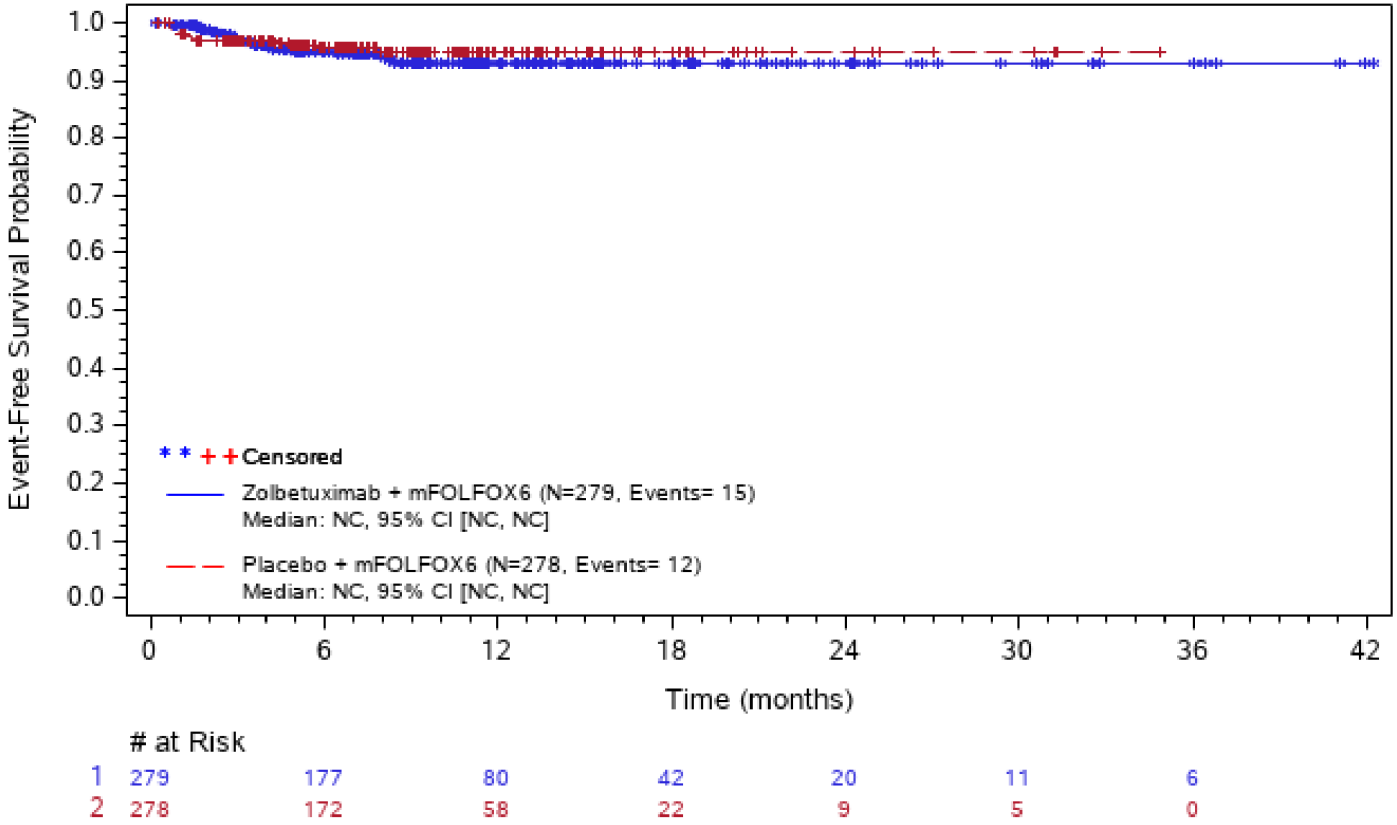
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.7: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Safety Analysis Set



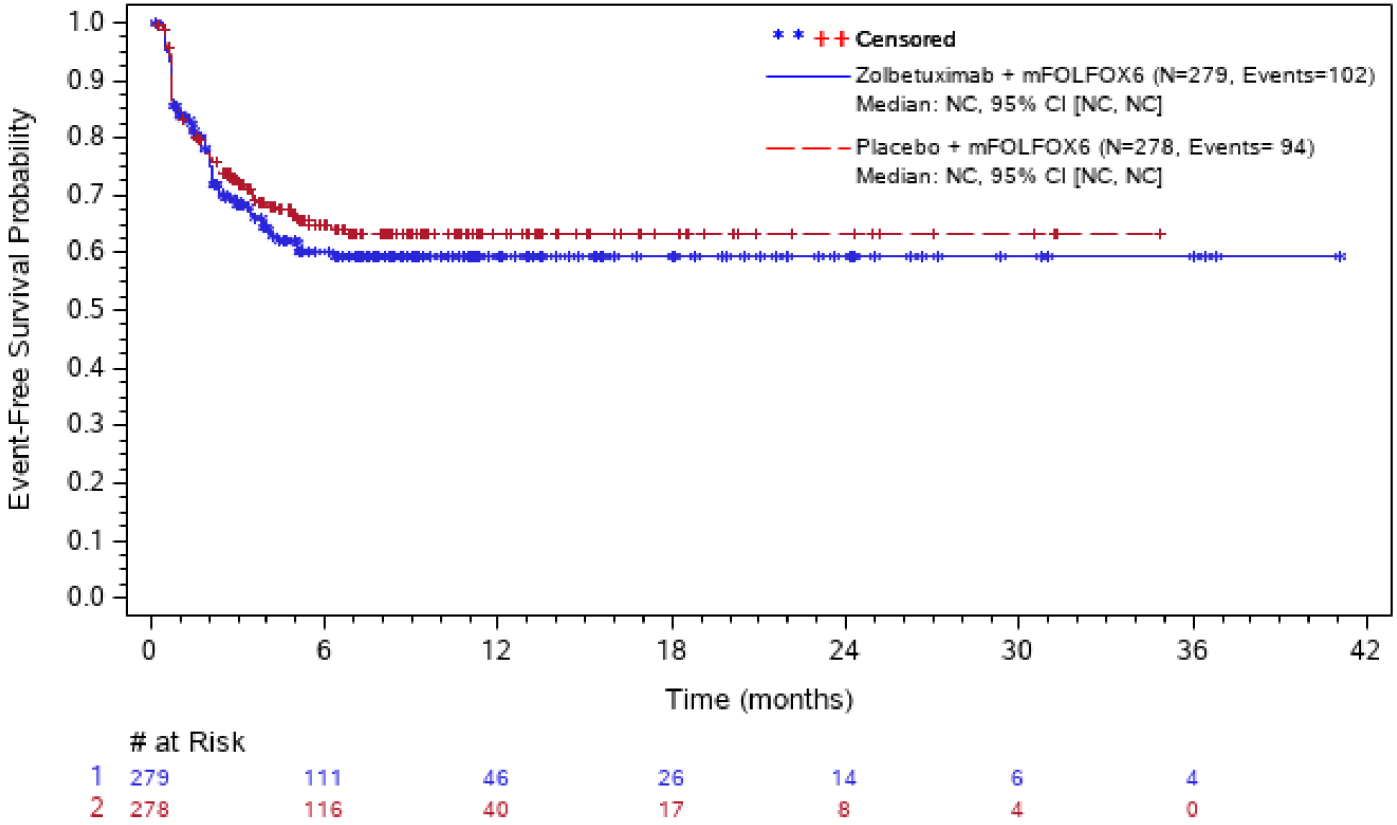
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.8: Kaplan-Meier Plot of Time to first TEAE - Leukopenia (PT) - Safety Analysis Set



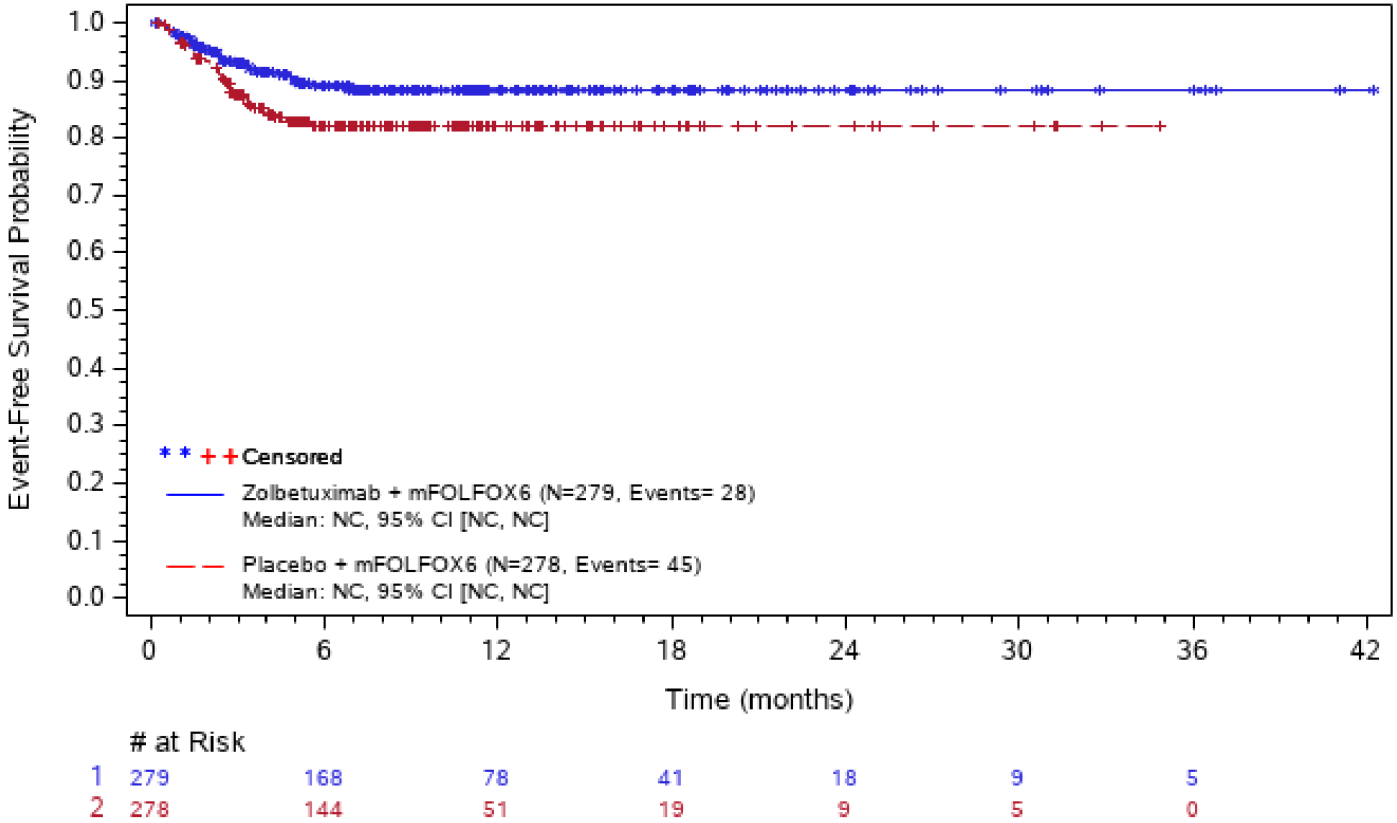
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.9: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Safety Analysis Set



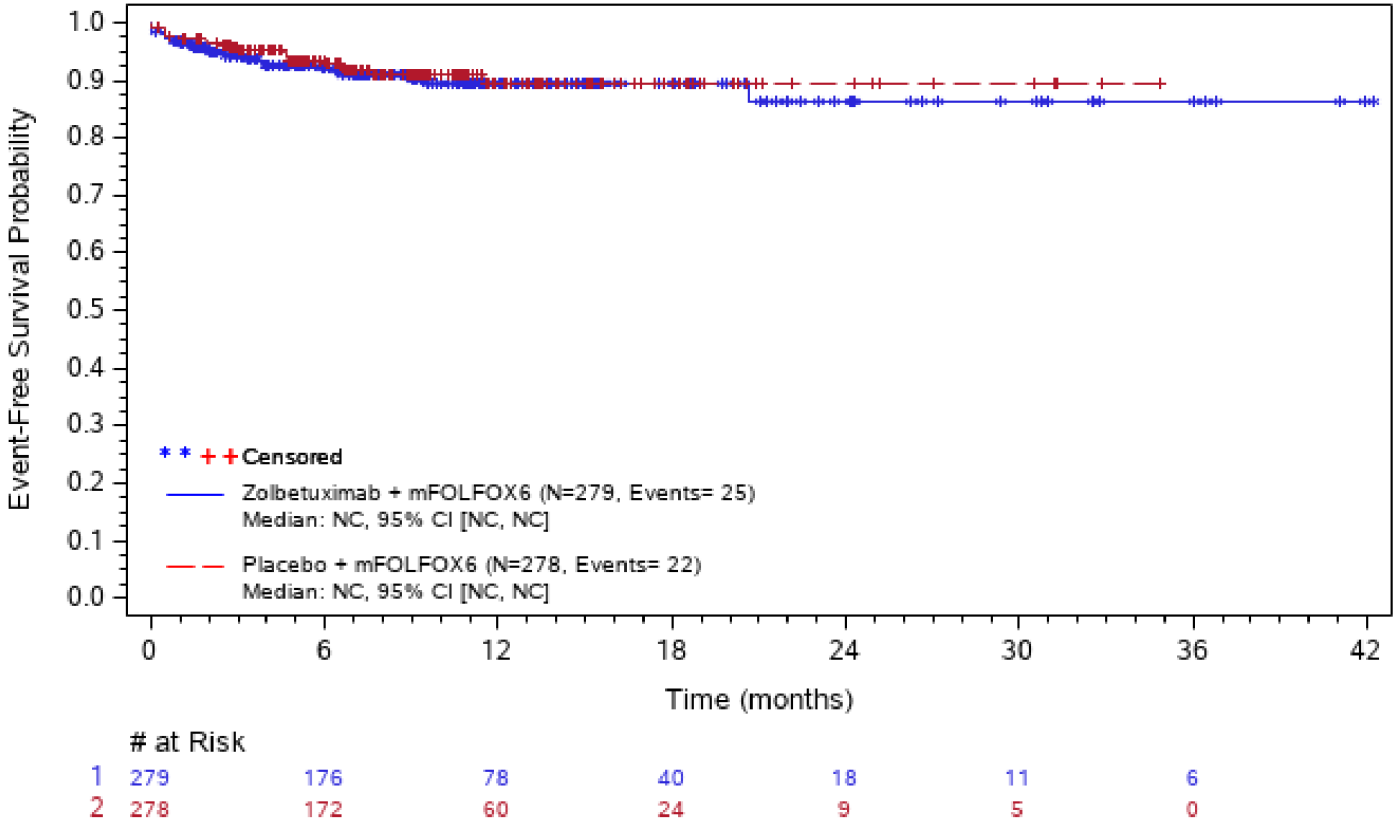
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.10: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Safety Analysis Set



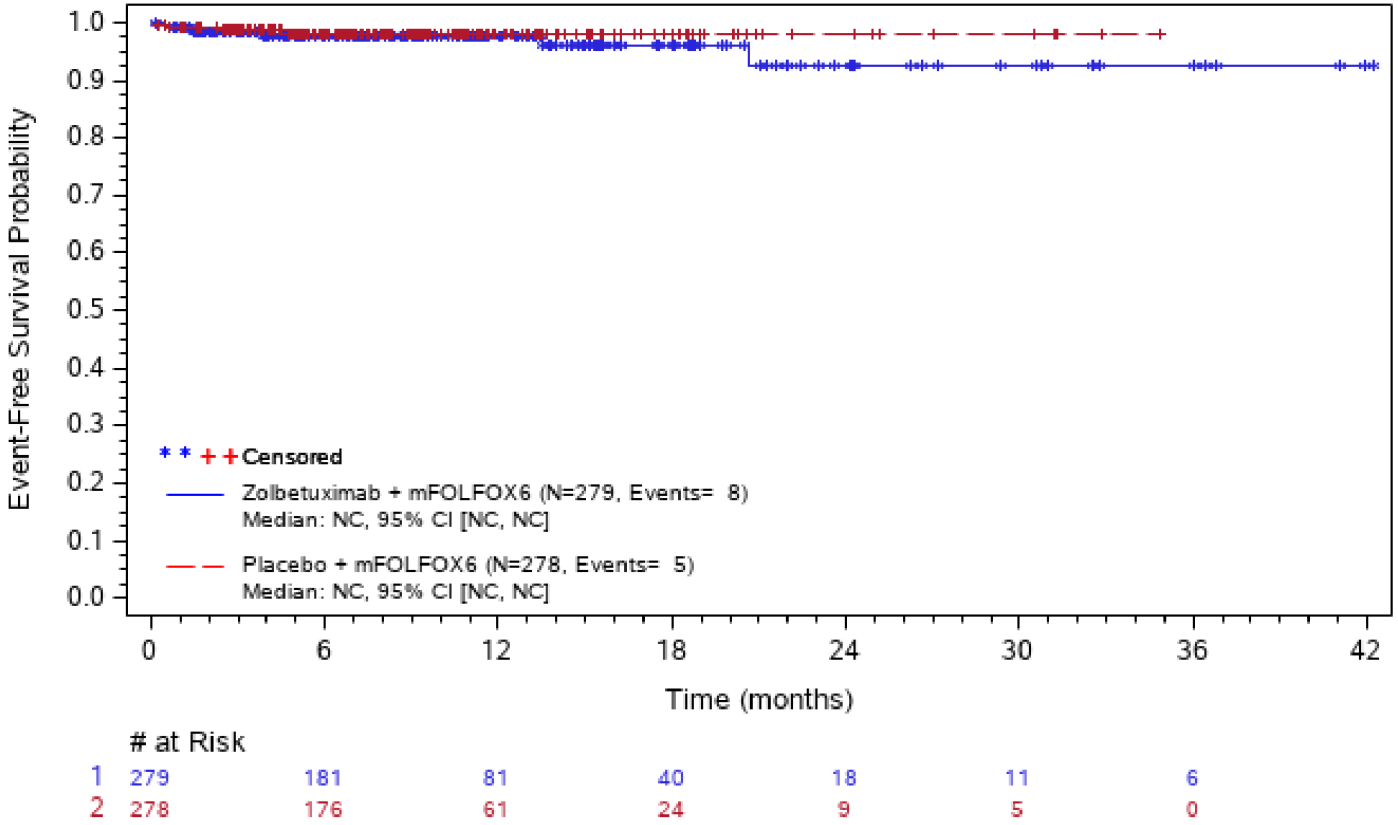
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.11: Kaplan-Meier Plot of Time to first TEAE - Cardiac Disorders (SOC) - Safety Analysis Set



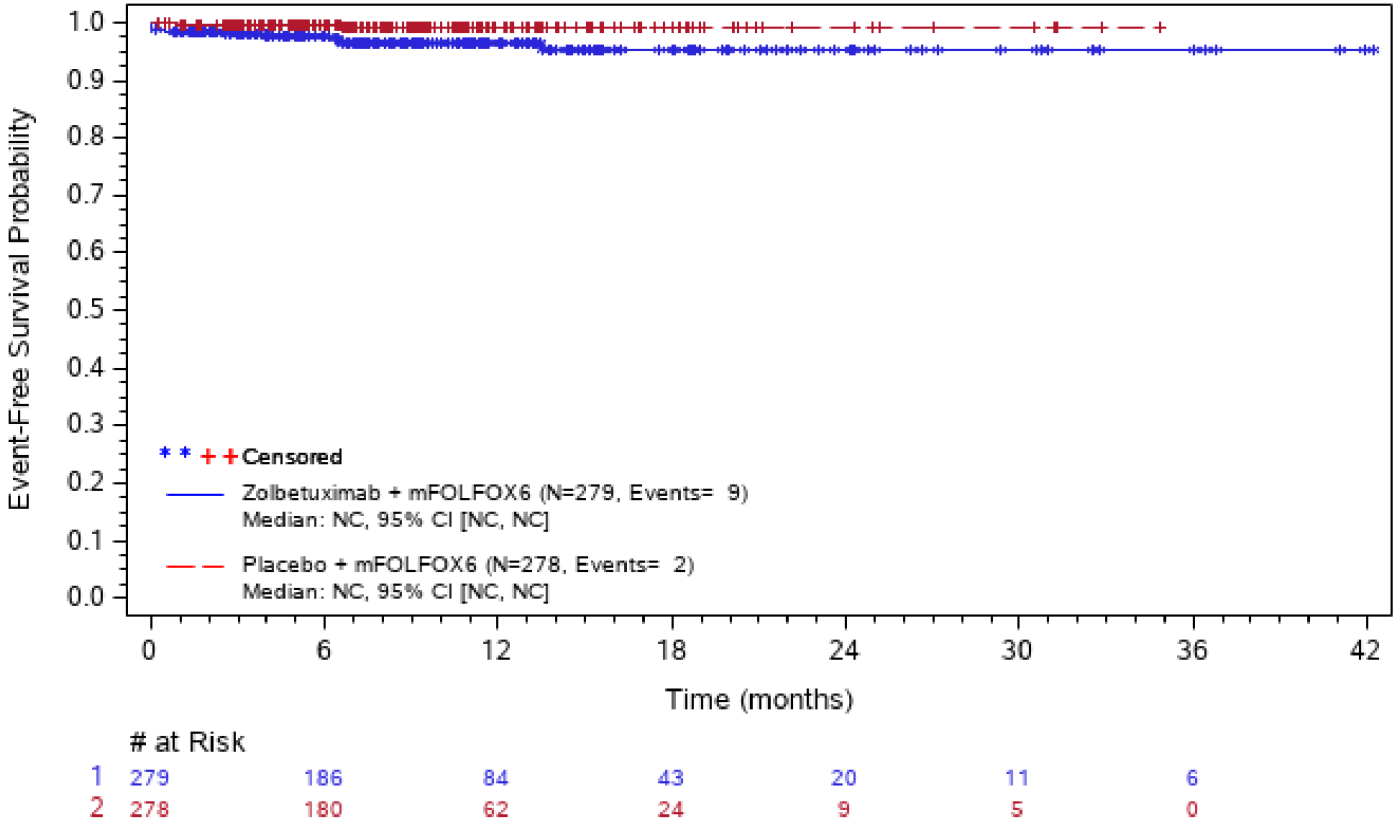
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.12: Kaplan-Meier Plot of Time to first TEAE - Palpitations (PT) - Safety Analysis Set



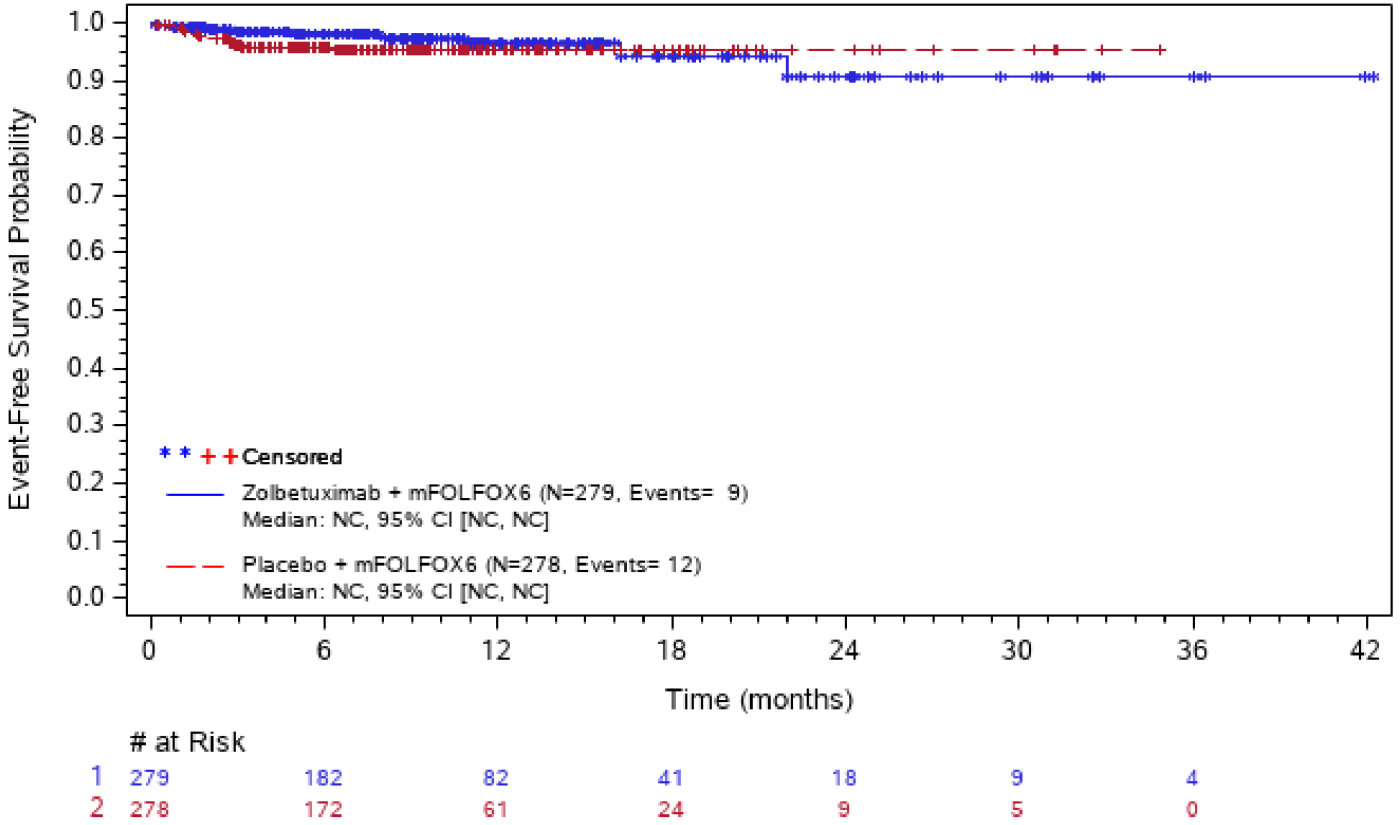
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.13: Kaplan-Meier Plot of Time to first TEAE - Tachycardia (PT) - Safety Analysis Set



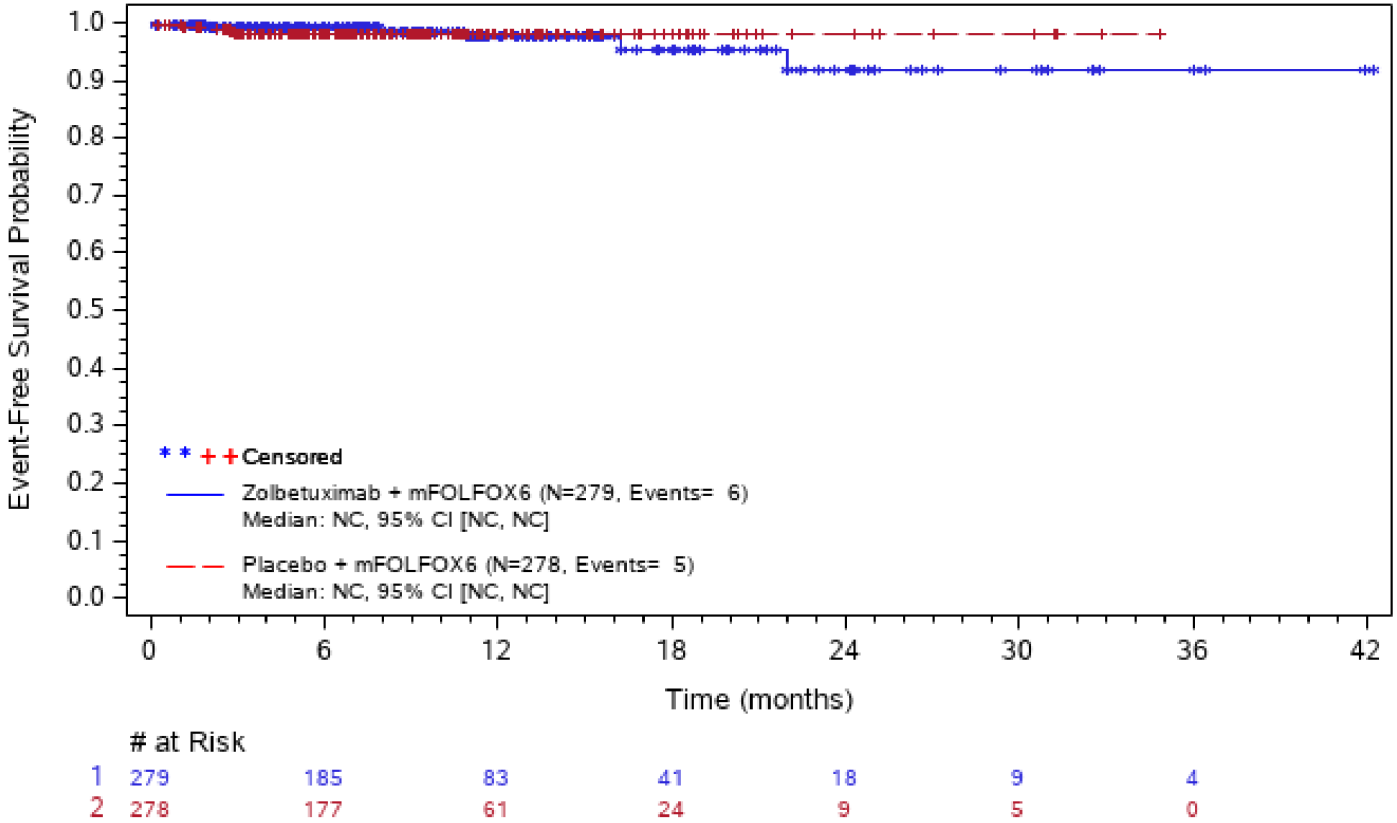
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.14: Kaplan-Meier Plot of Time to first TEAE - Ear and Labyrinth Disorders (SOC) - Safety Analysis Set



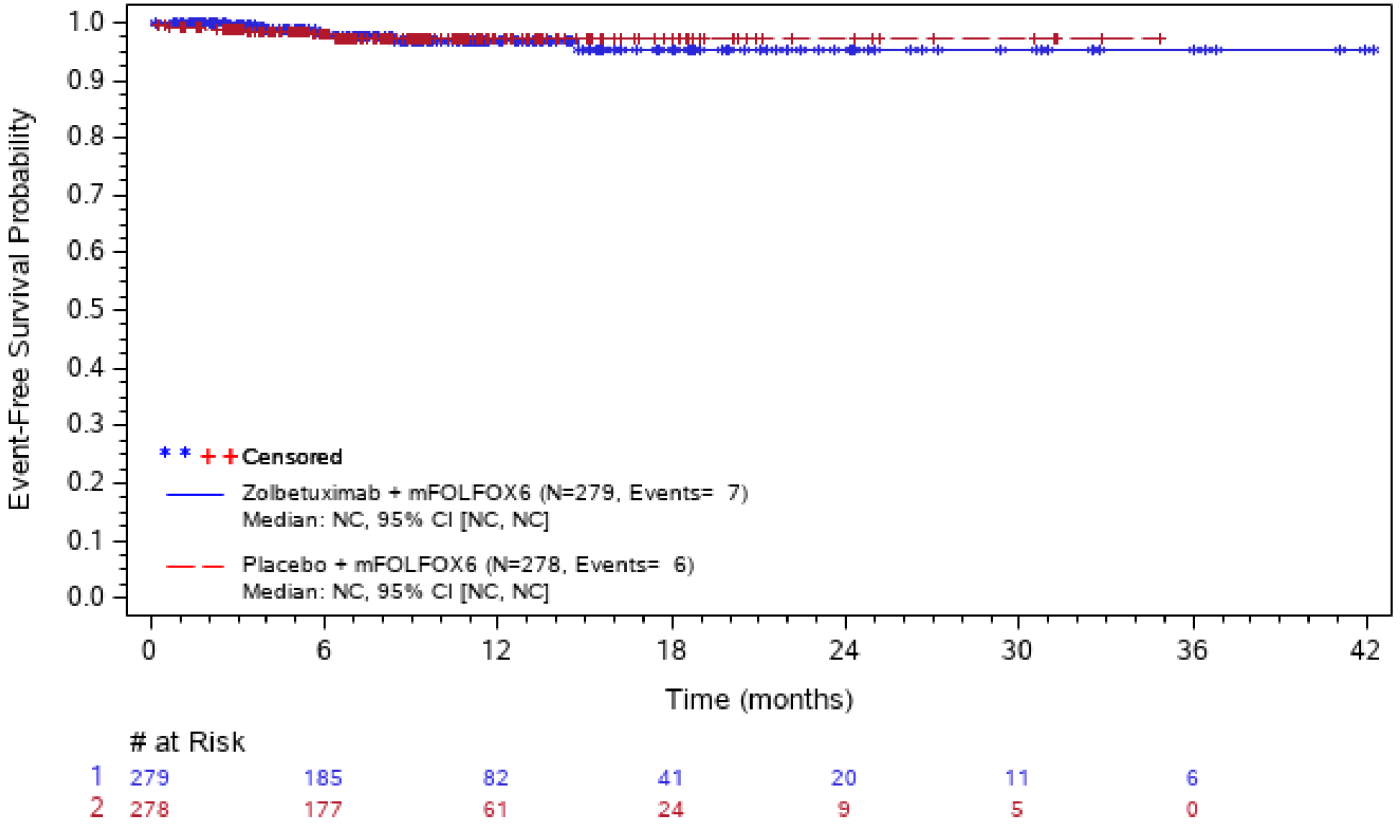
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.15: Kaplan-Meier Plot of Time to first TEAE - Tinnitus (PT) - Safety Analysis Set



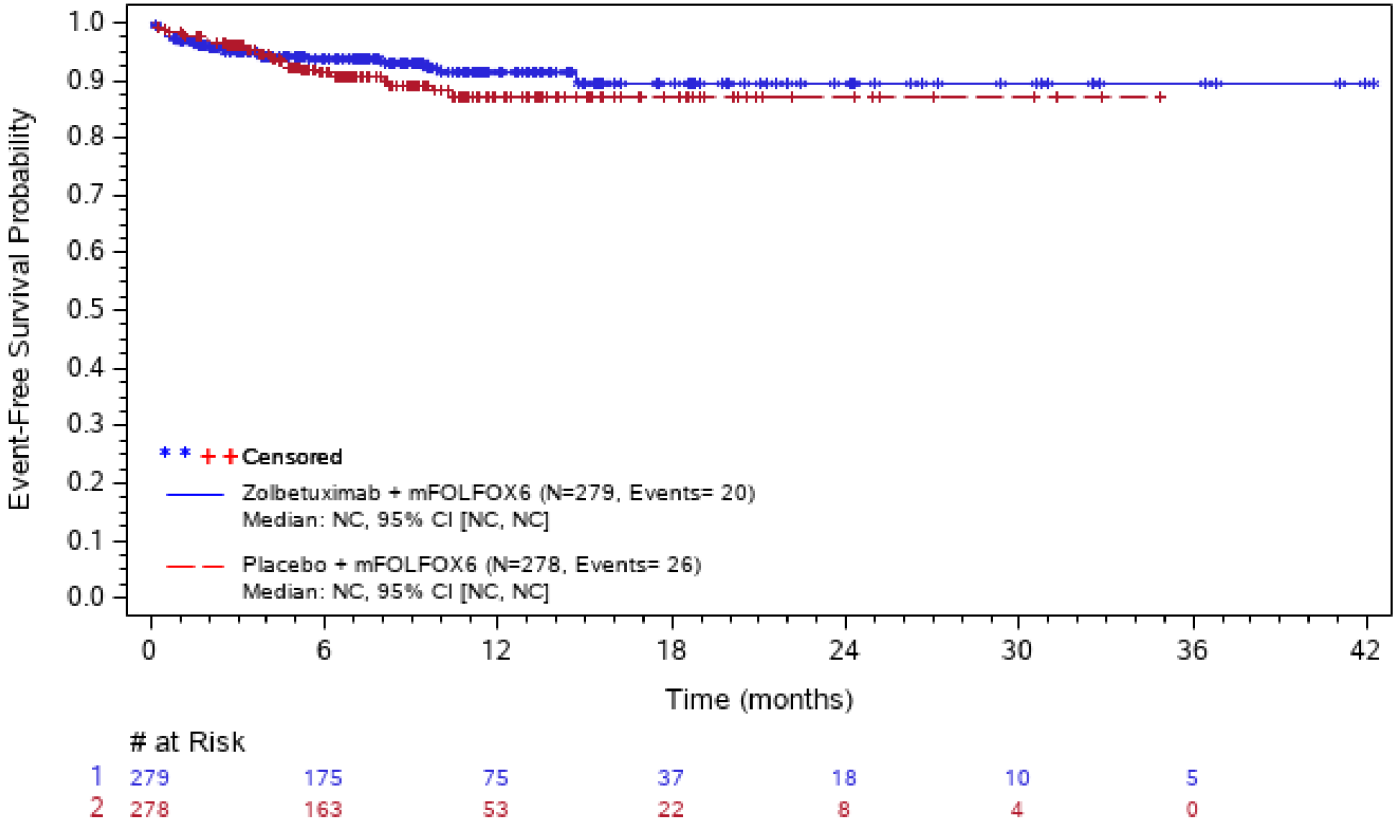
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.16: Kaplan-Meier Plot of Time to first TEAE - Endocrine Disorders (SOC) - Safety Analysis Set



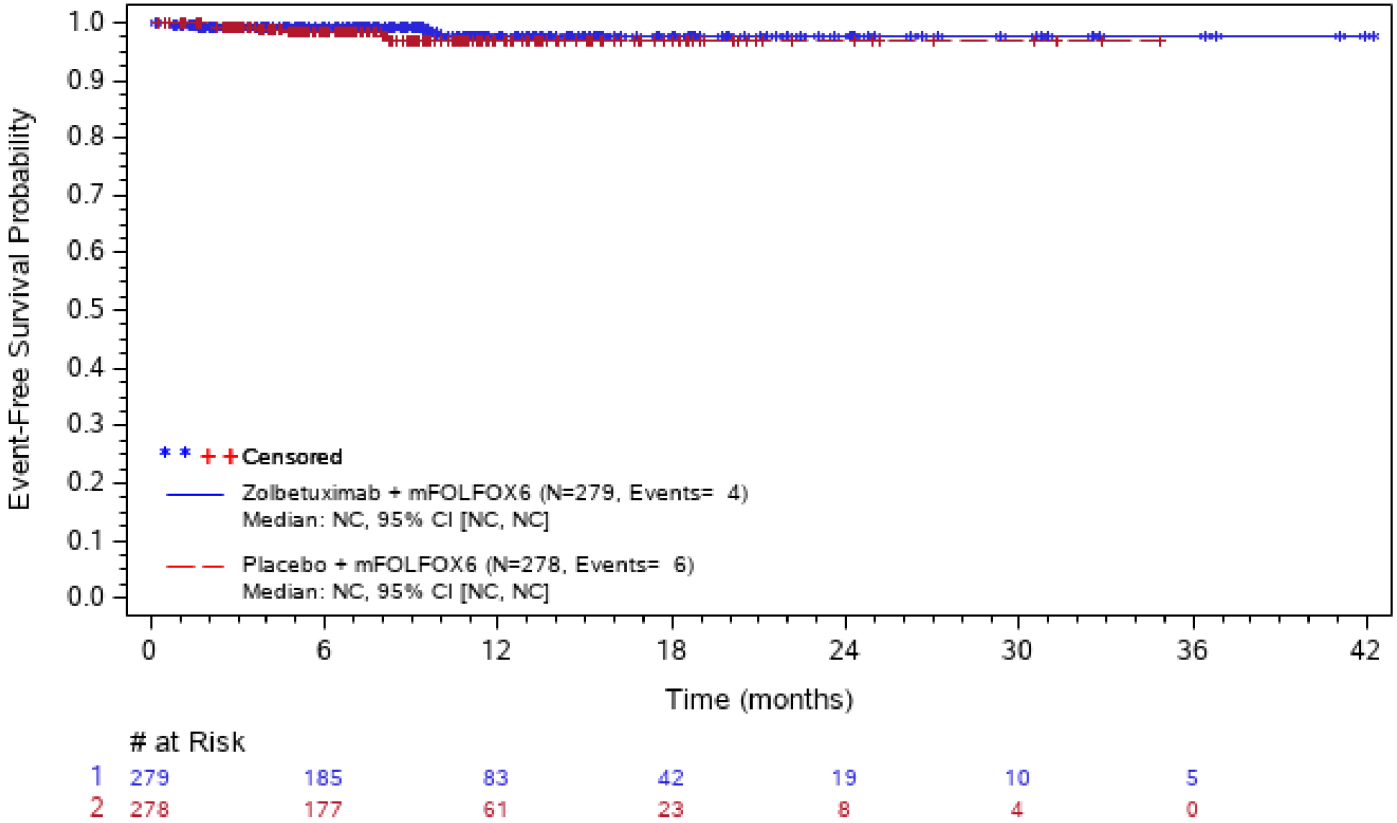
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.17: Kaplan-Meier Plot of Time to first TEAE - Eye Disorders (SOC) - Safety Analysis Set



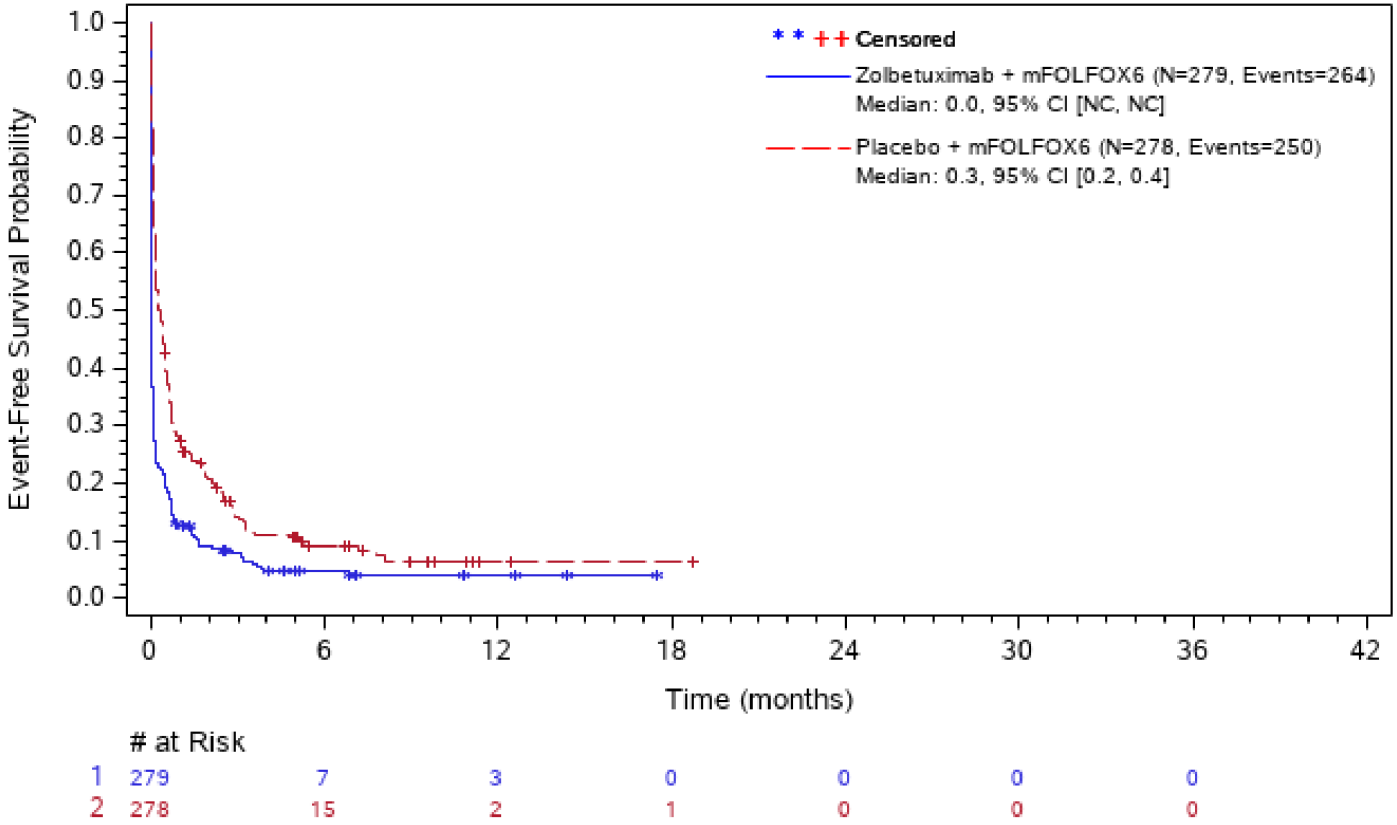
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.18: Kaplan-Meier Plot of Time to first TEAE - Dry Eye (PT) - Safety Analysis Set



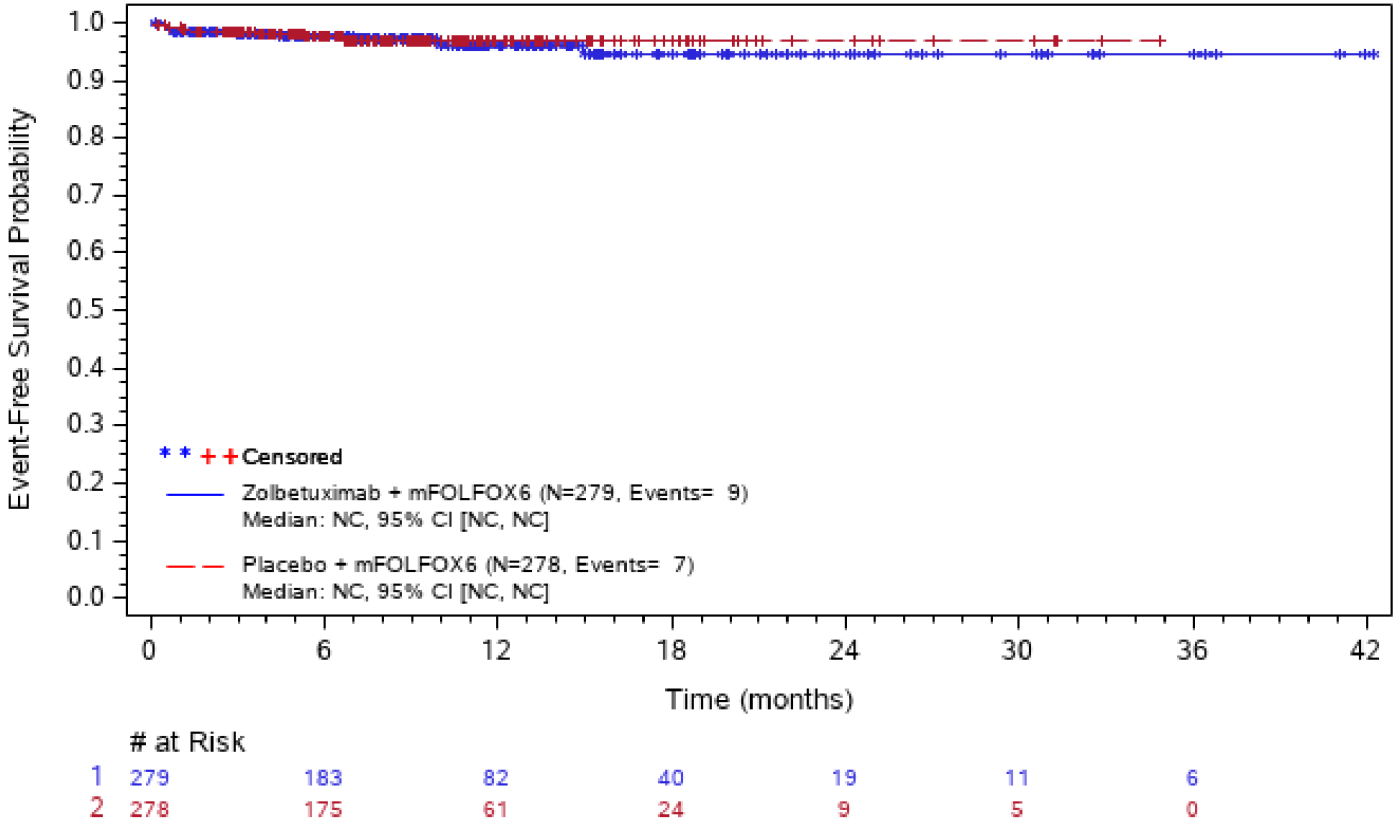
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.19: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



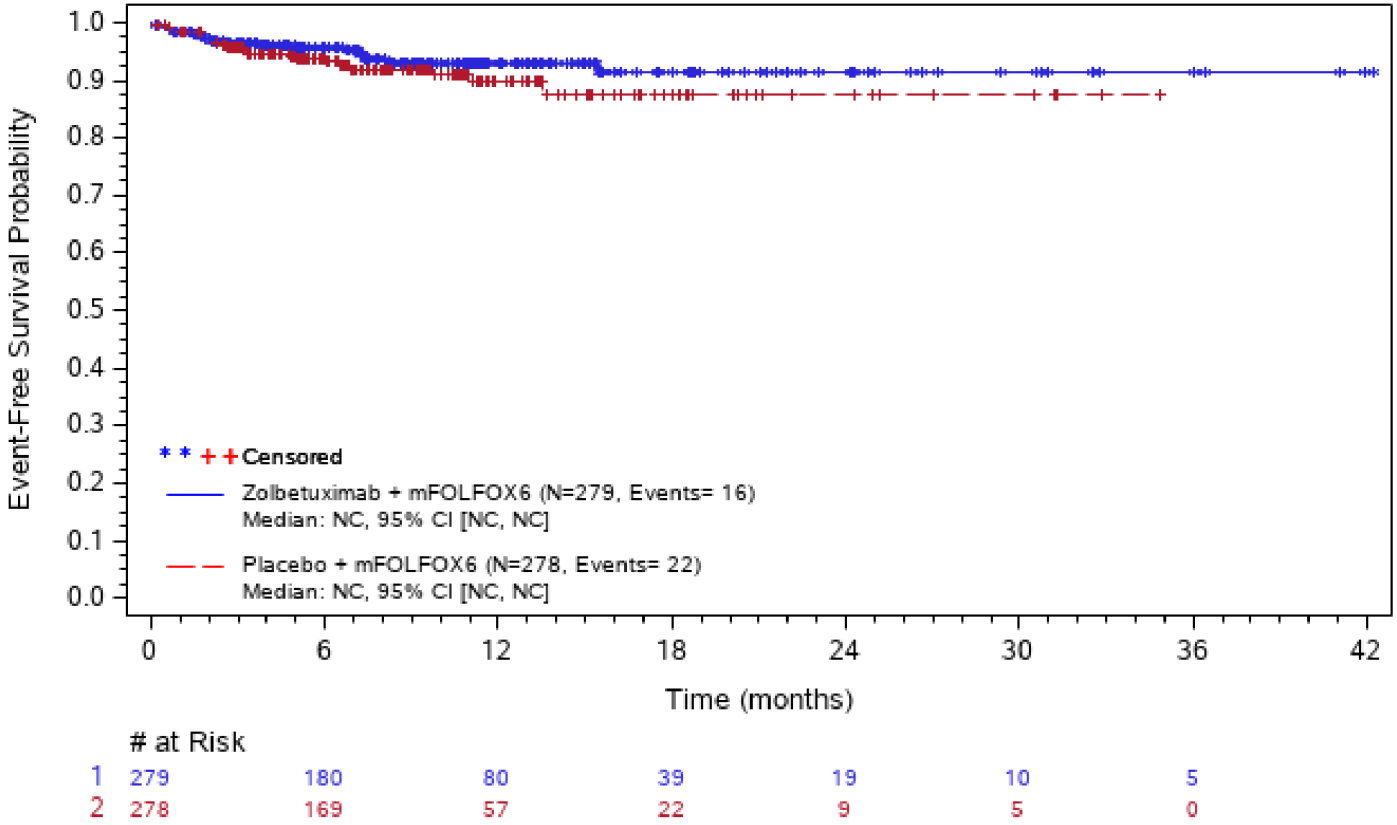
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.20: Kaplan-Meier Plot of Time to first TEAE - Abdominal Discomfort (PT) - Safety Analysis Set



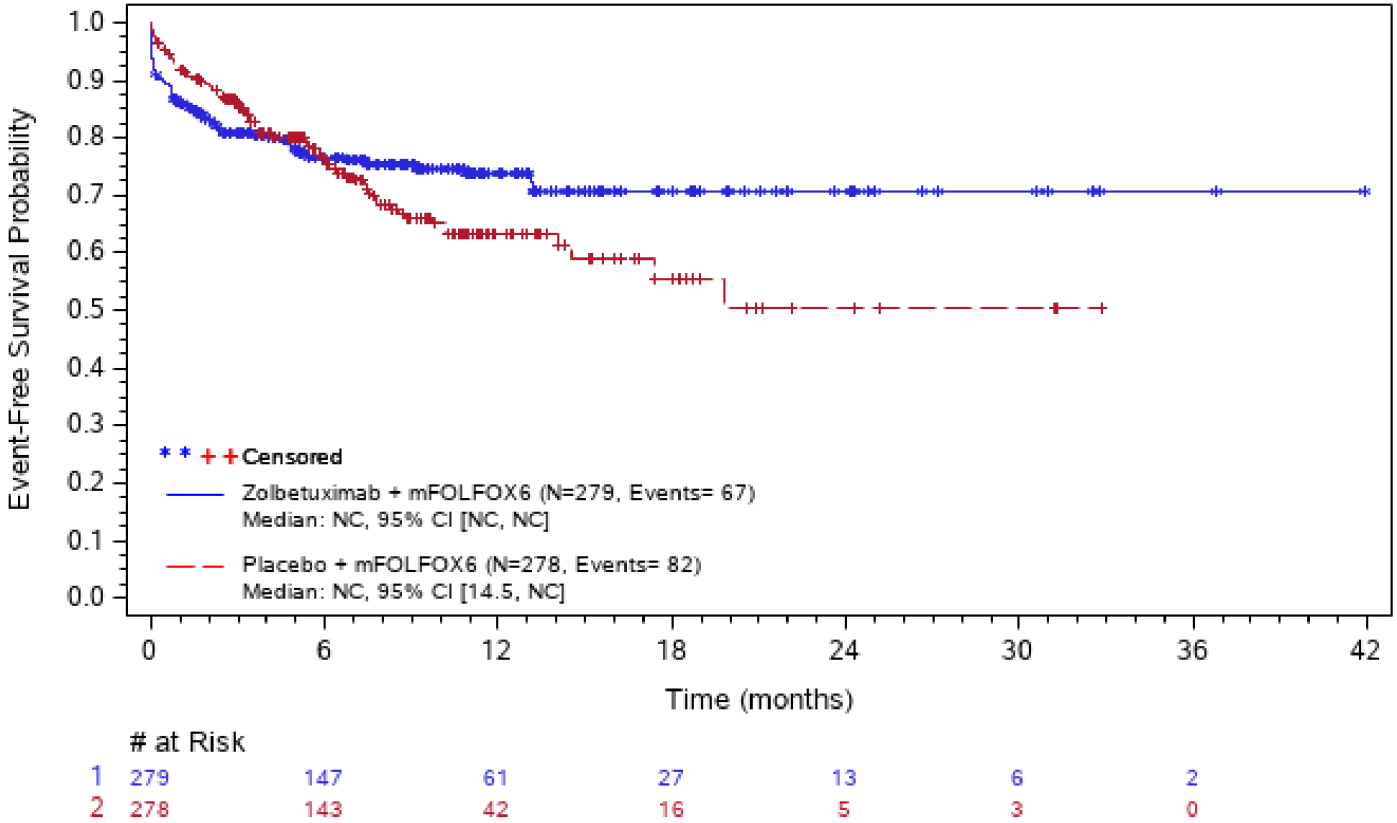
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.21: Kaplan-Meier Plot of Time to first TEAE - Abdominal Distension (PT) - Safety Analysis Set



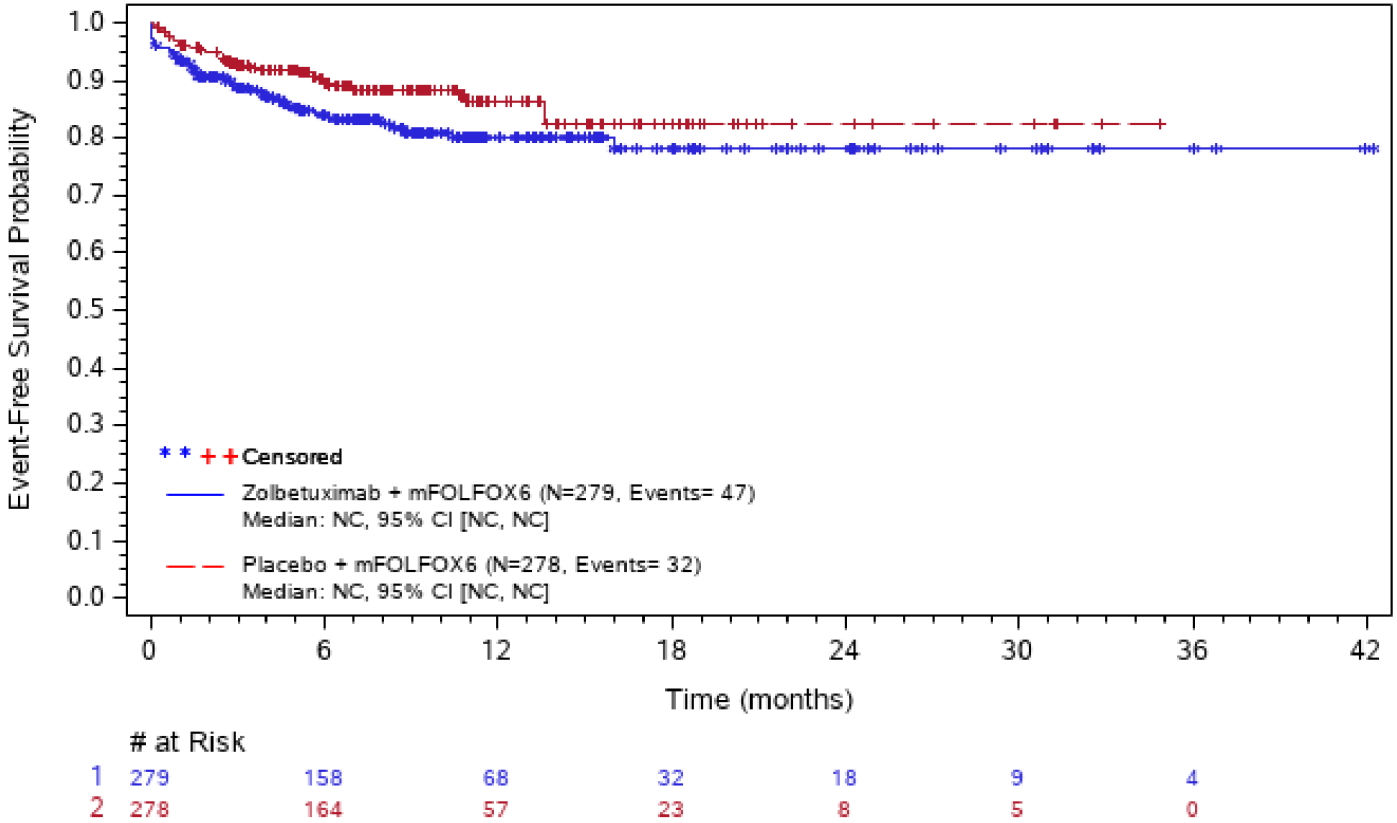
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.22: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (PT) - Safety Analysis Set



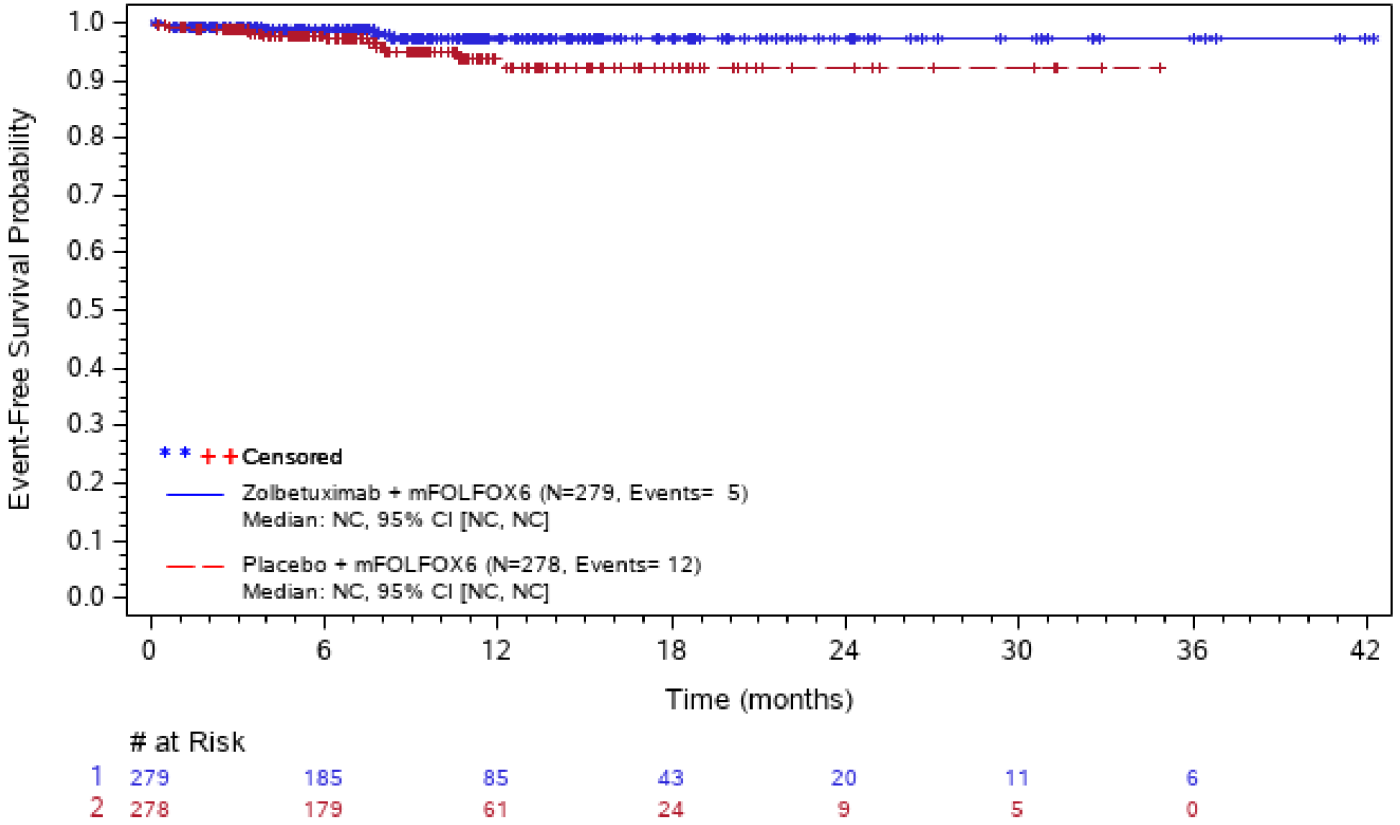
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.23: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain Upper (PT) - Safety Analysis Set



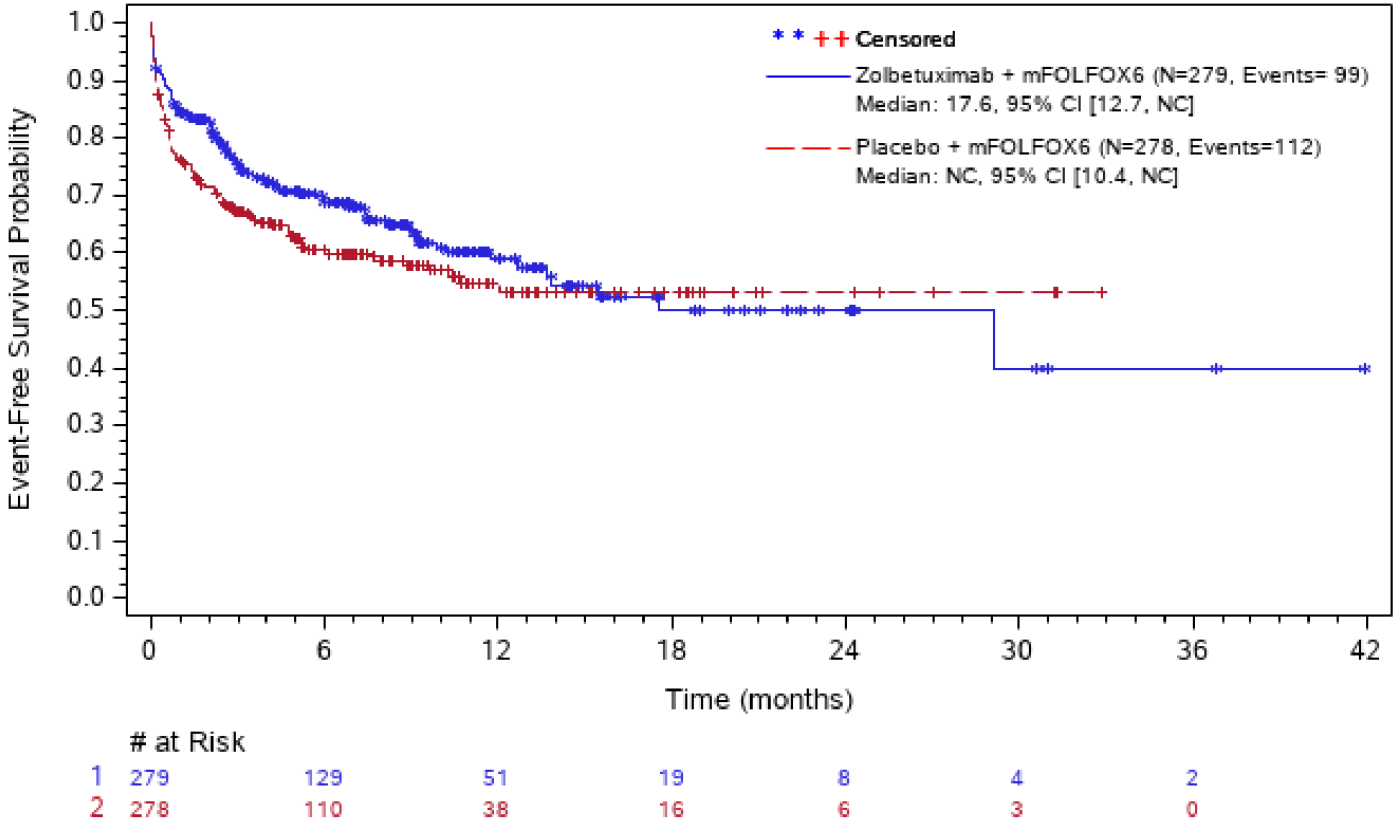
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.24: Kaplan-Meier Plot of Time to first TEAE - Ascites (PT) - Safety Analysis Set



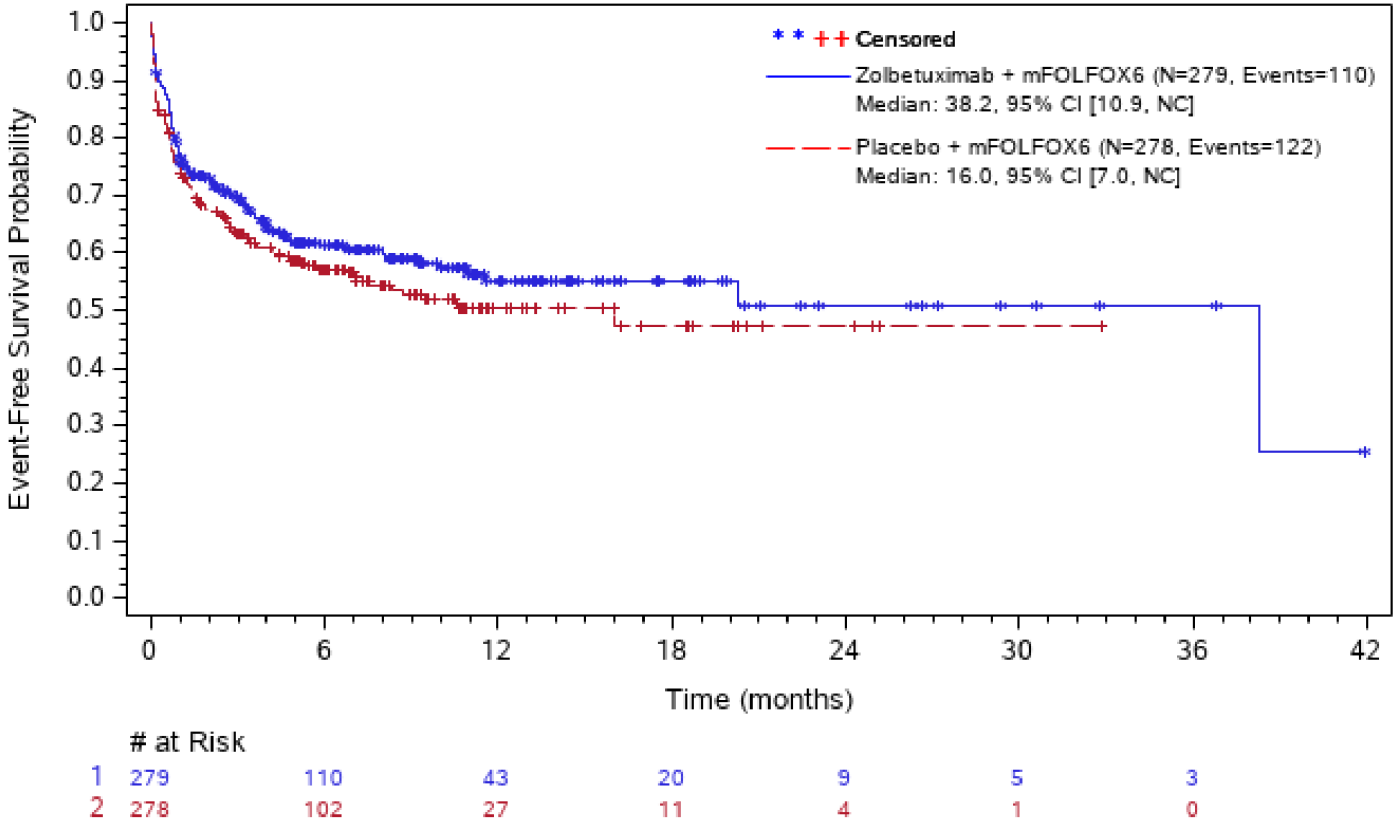
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.25: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Safety Analysis Set



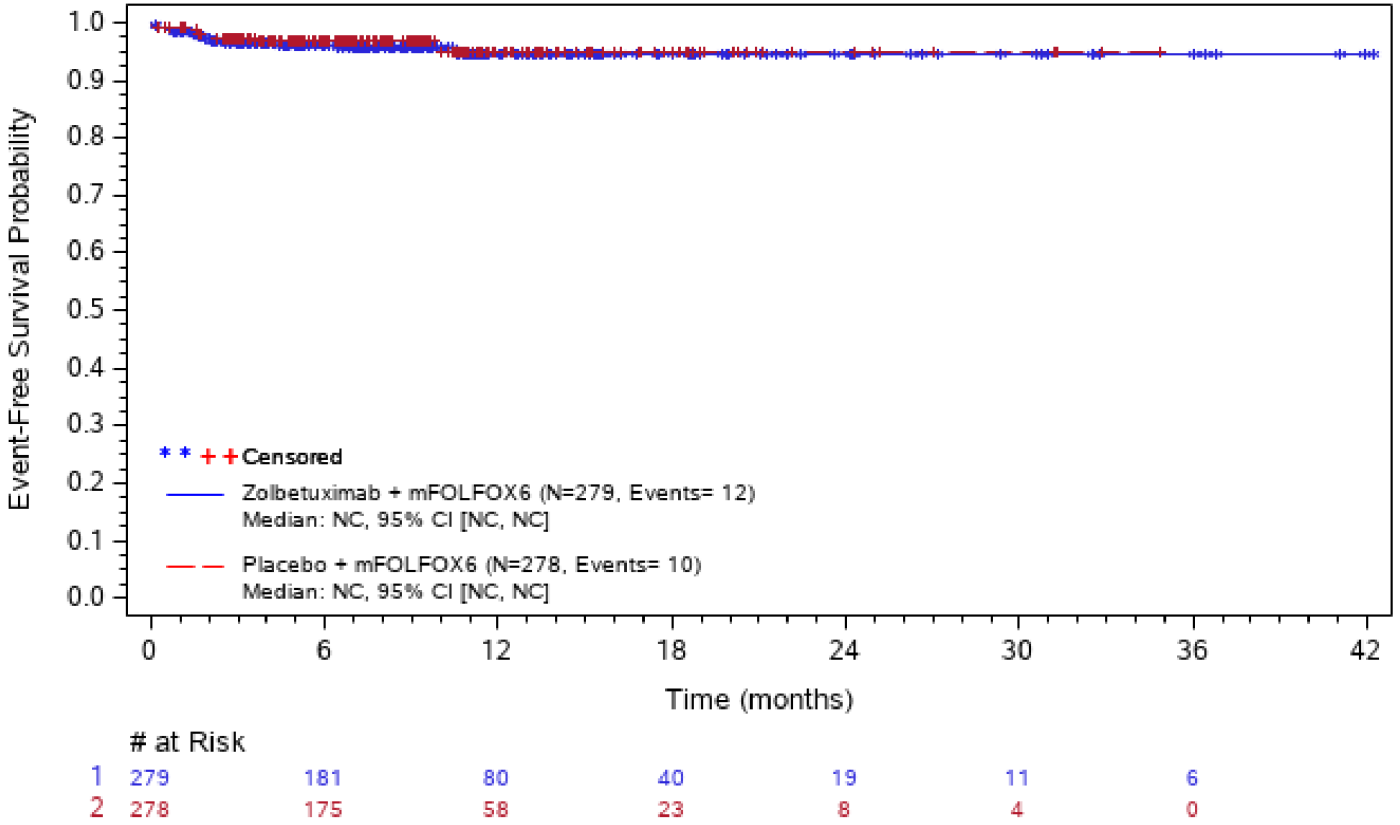
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.26: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Safety Analysis Set



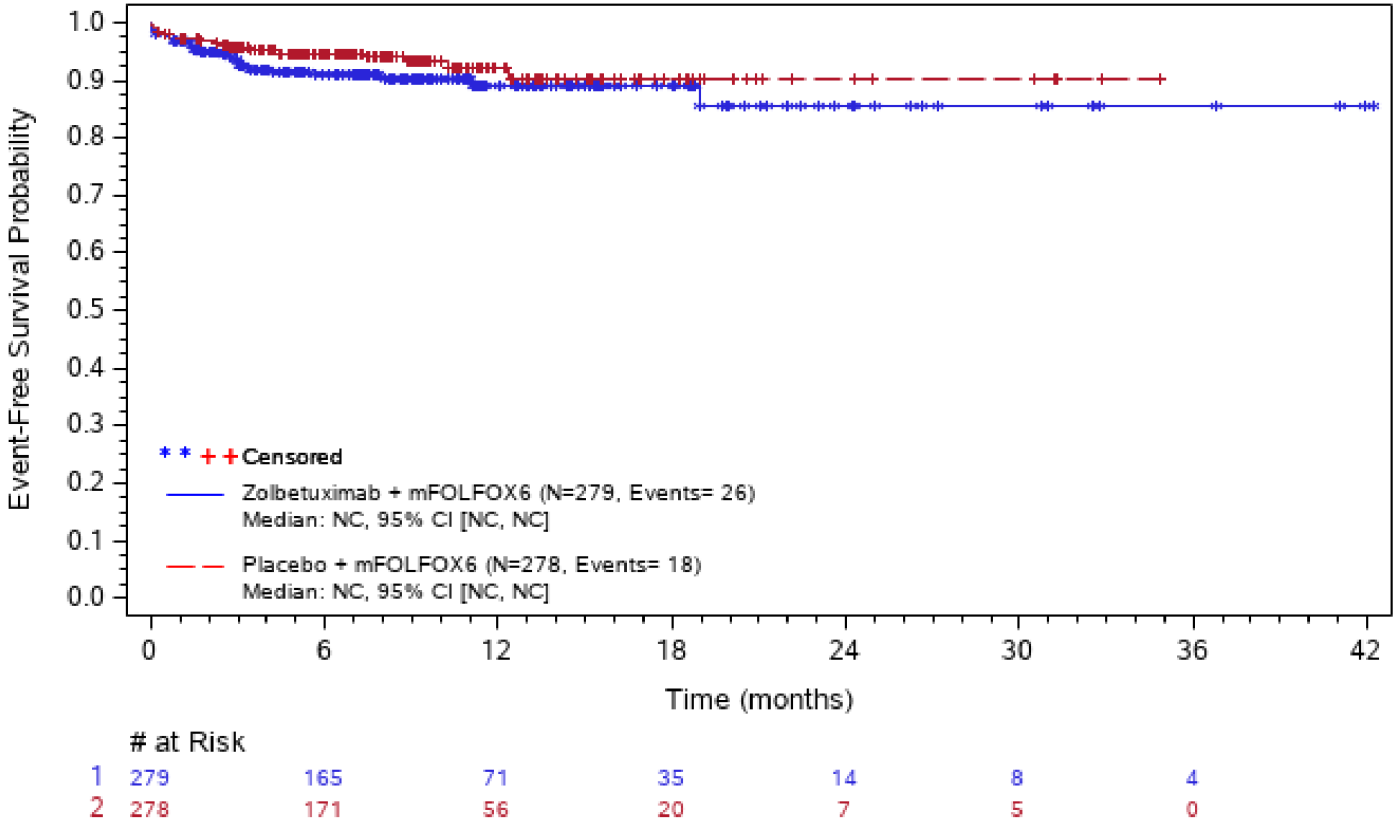
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.27: Kaplan-Meier Plot of Time to first TEAE - Dry Mouth (PT) - Safety Analysis Set



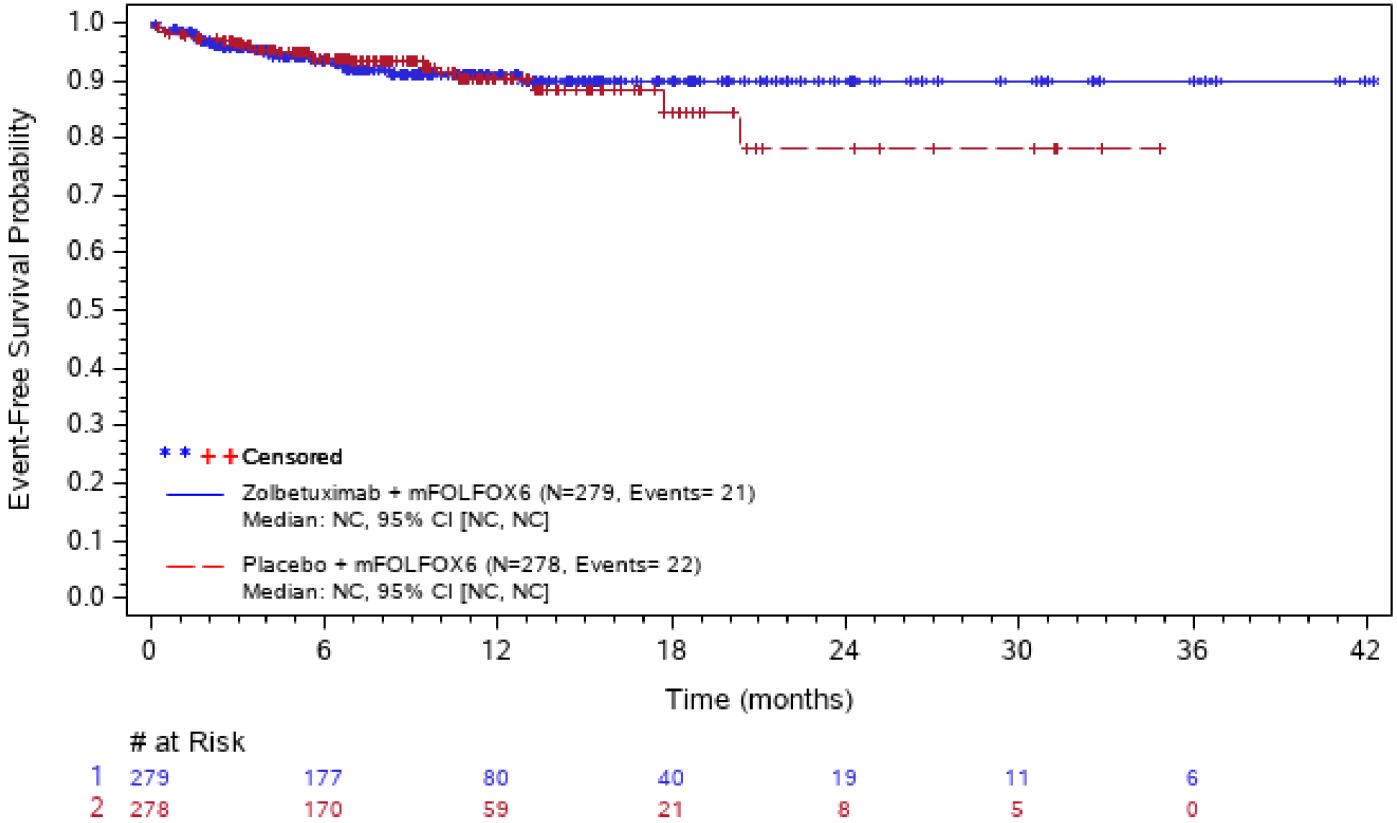
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.28: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Safety Analysis Set



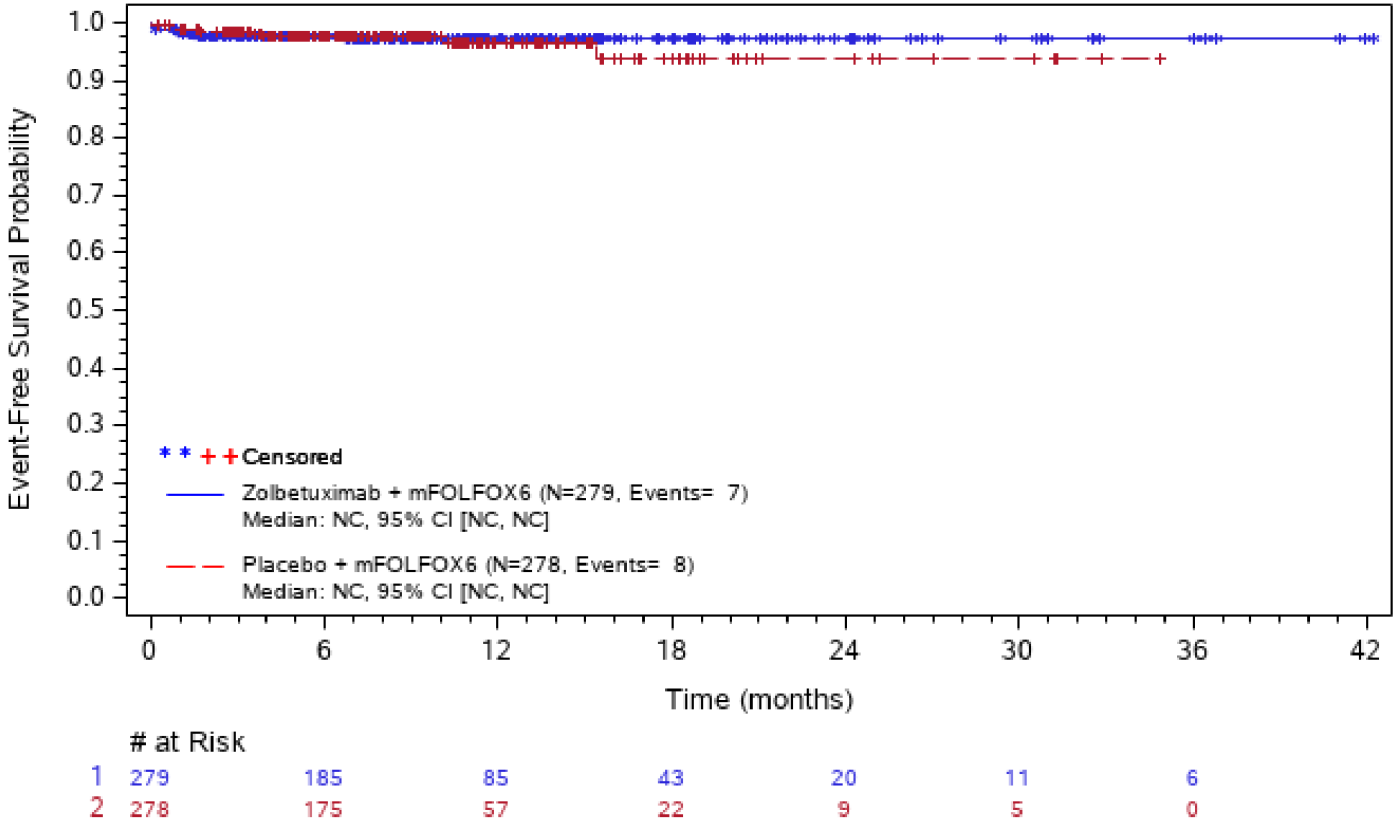
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.29: Kaplan-Meier Plot of Time to first TEAE - Dysphagia (PT) - Safety Analysis Set



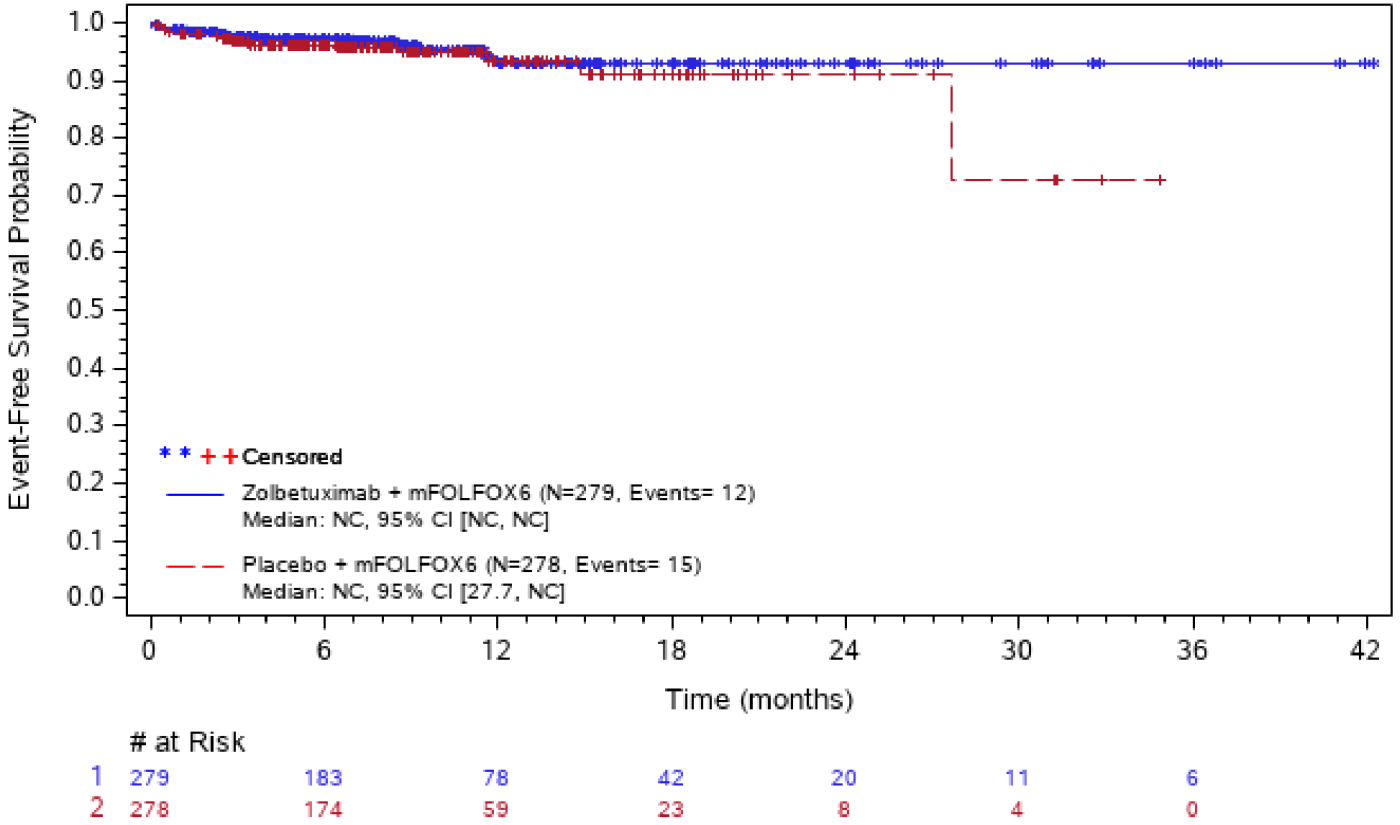
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.30: Kaplan-Meier Plot of Time to first TEAE - Flatulence (PT) - Safety Analysis Set



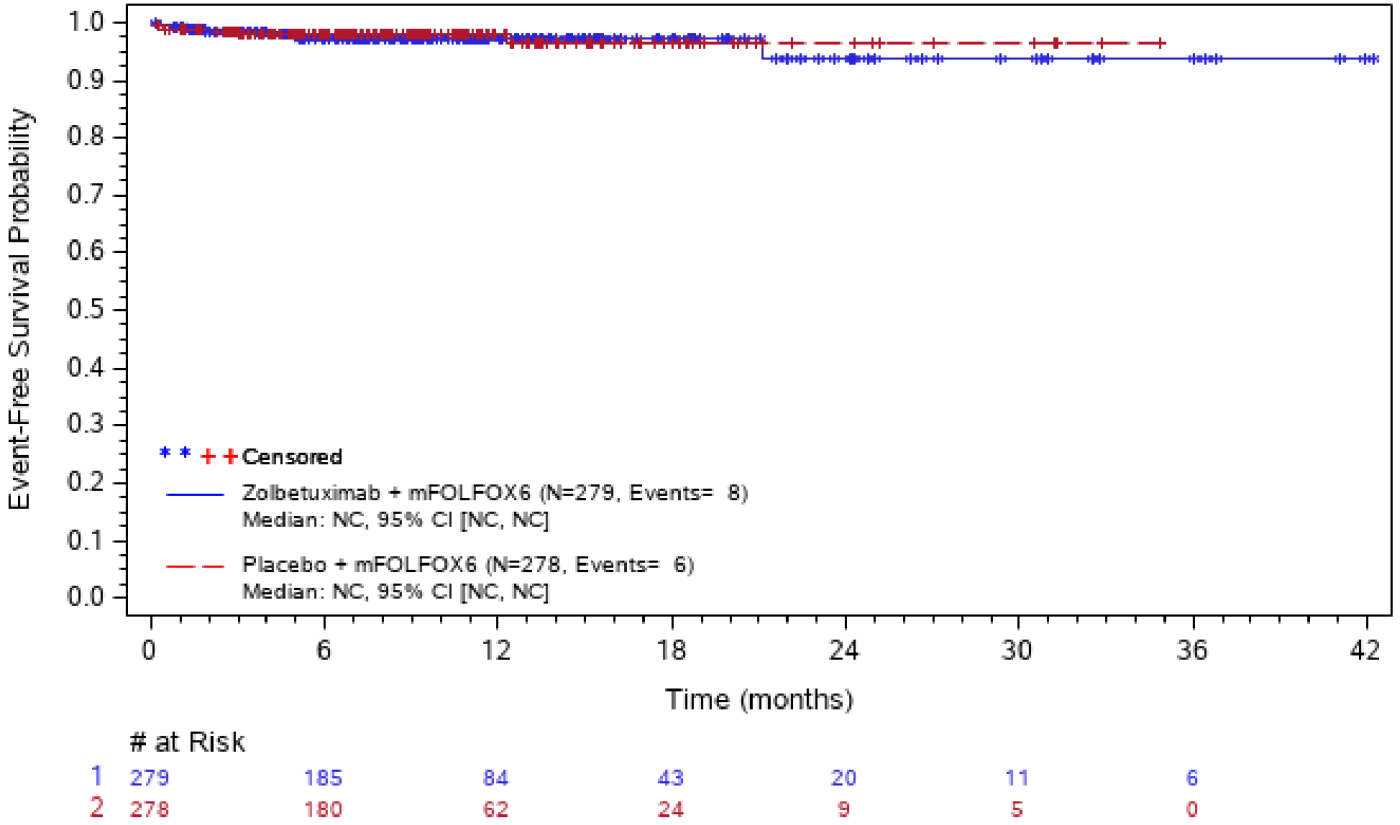
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.31: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set



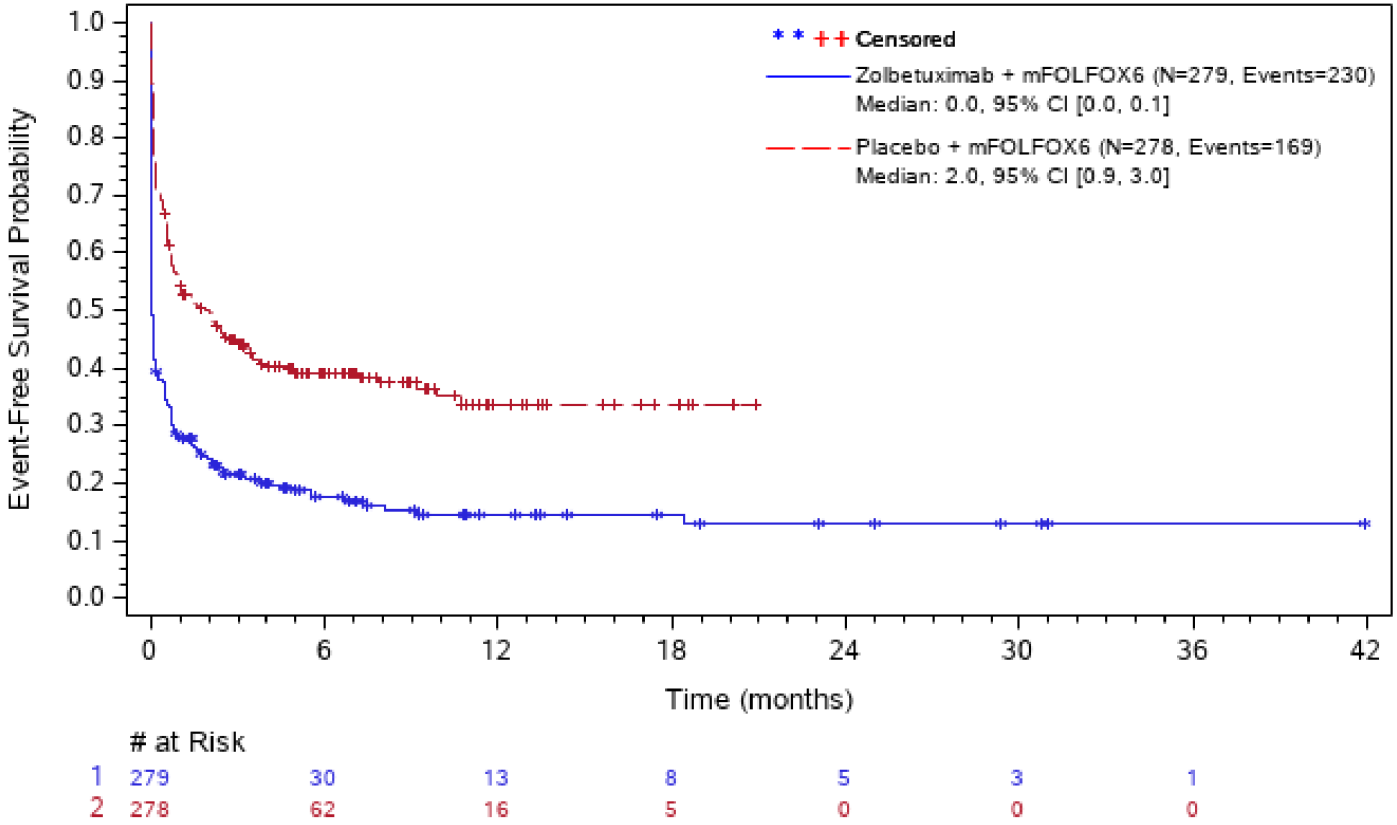
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.32: Kaplan-Meier Plot of Time to first TEAE - Intestinal Obstruction (PT) - Safety Analysis Set



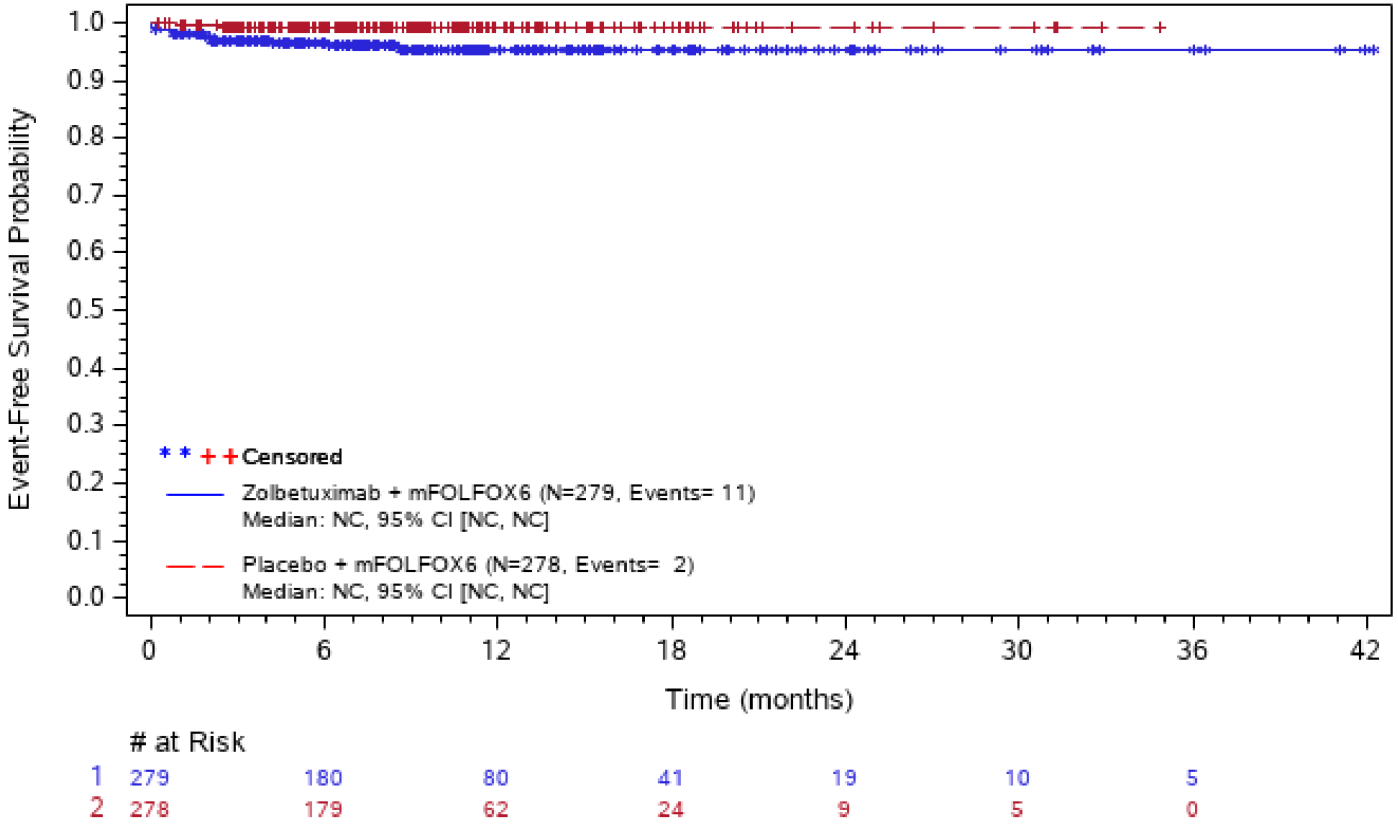
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.33: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Safety Analysis Set



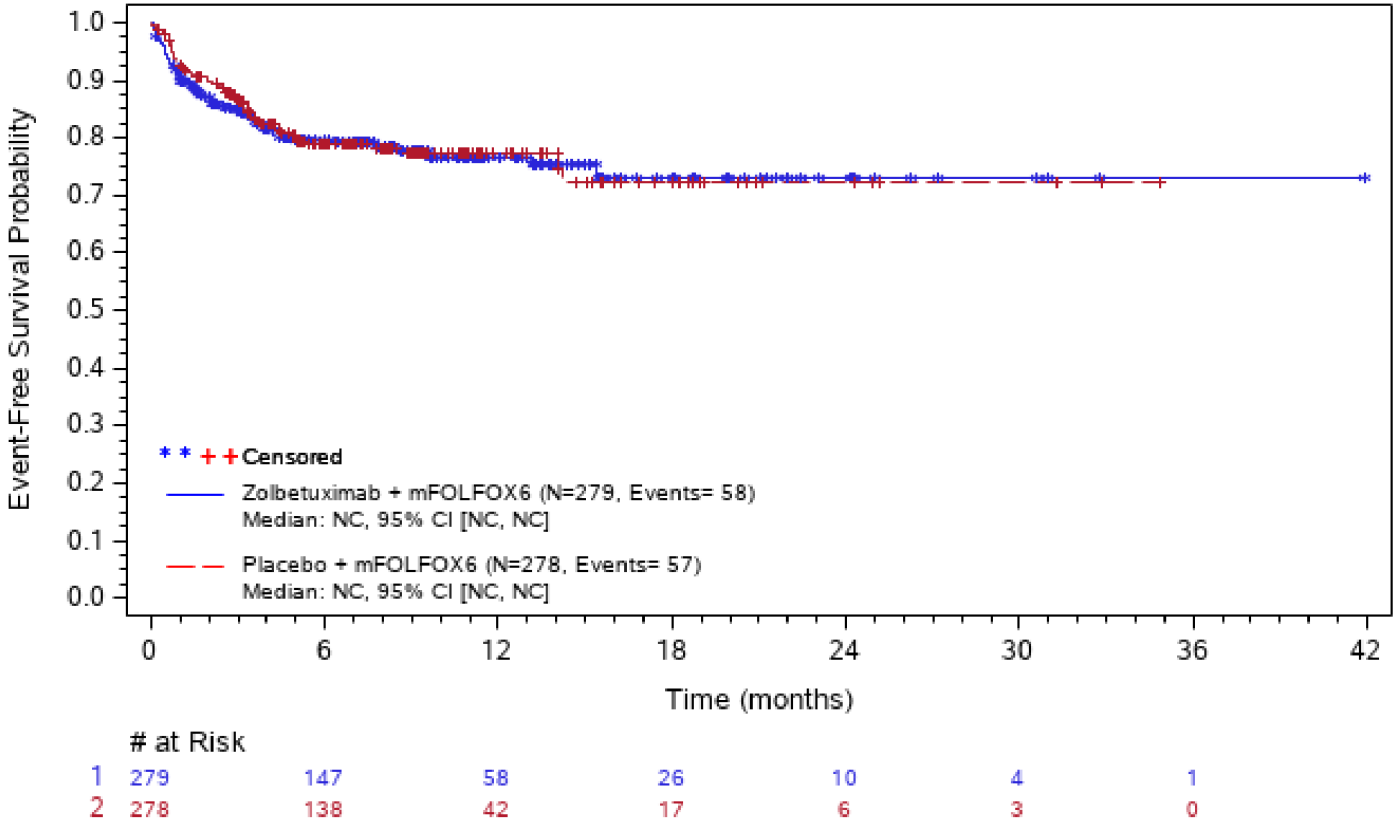
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.34: Kaplan-Meier Plot of Time to first TEAE - Salivary Hypersecretion (PT) - Safety Analysis Set



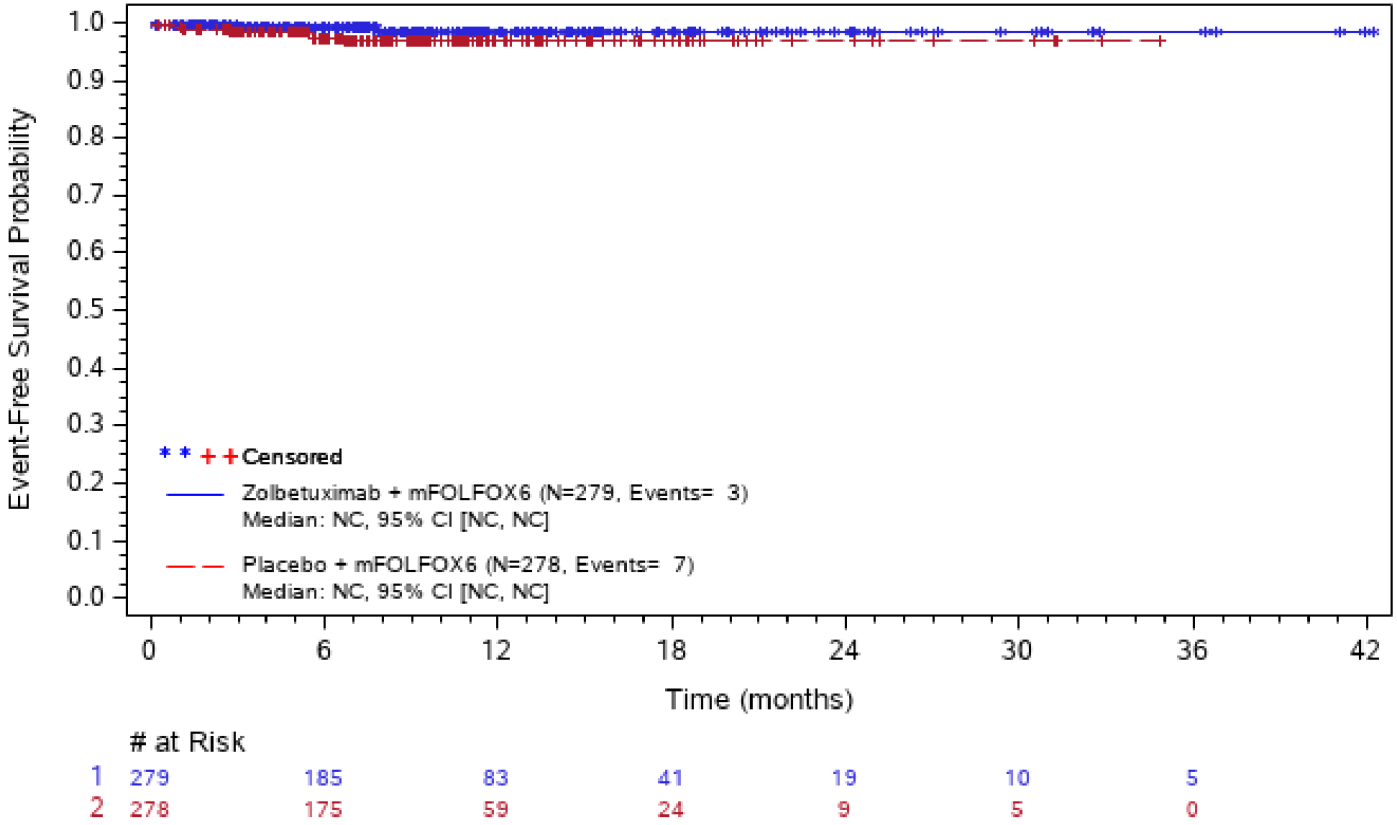
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.35: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Safety Analysis Set



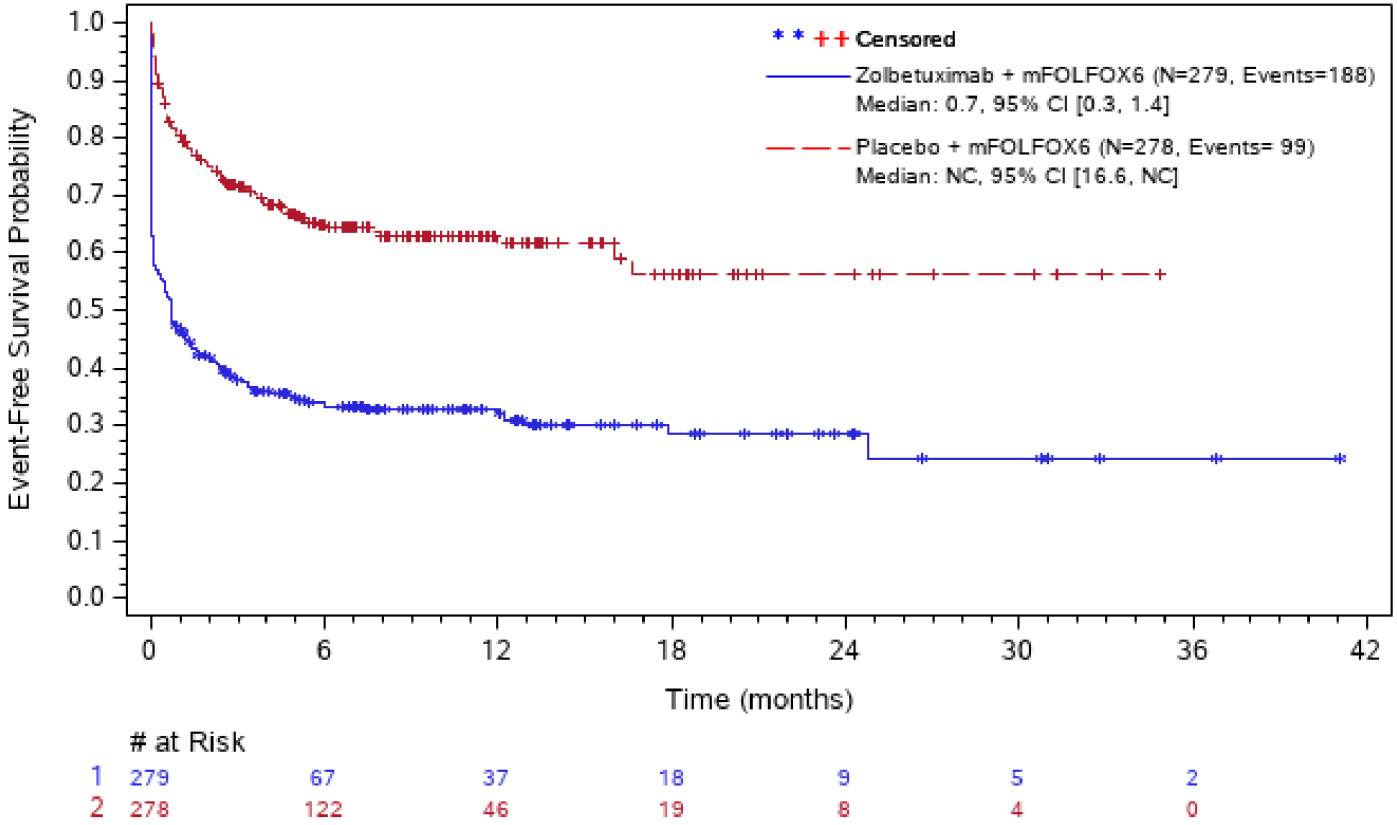
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.36: Kaplan-Meier Plot of Time to first TEAE - Toothache (PT) - Safety Analysis Set



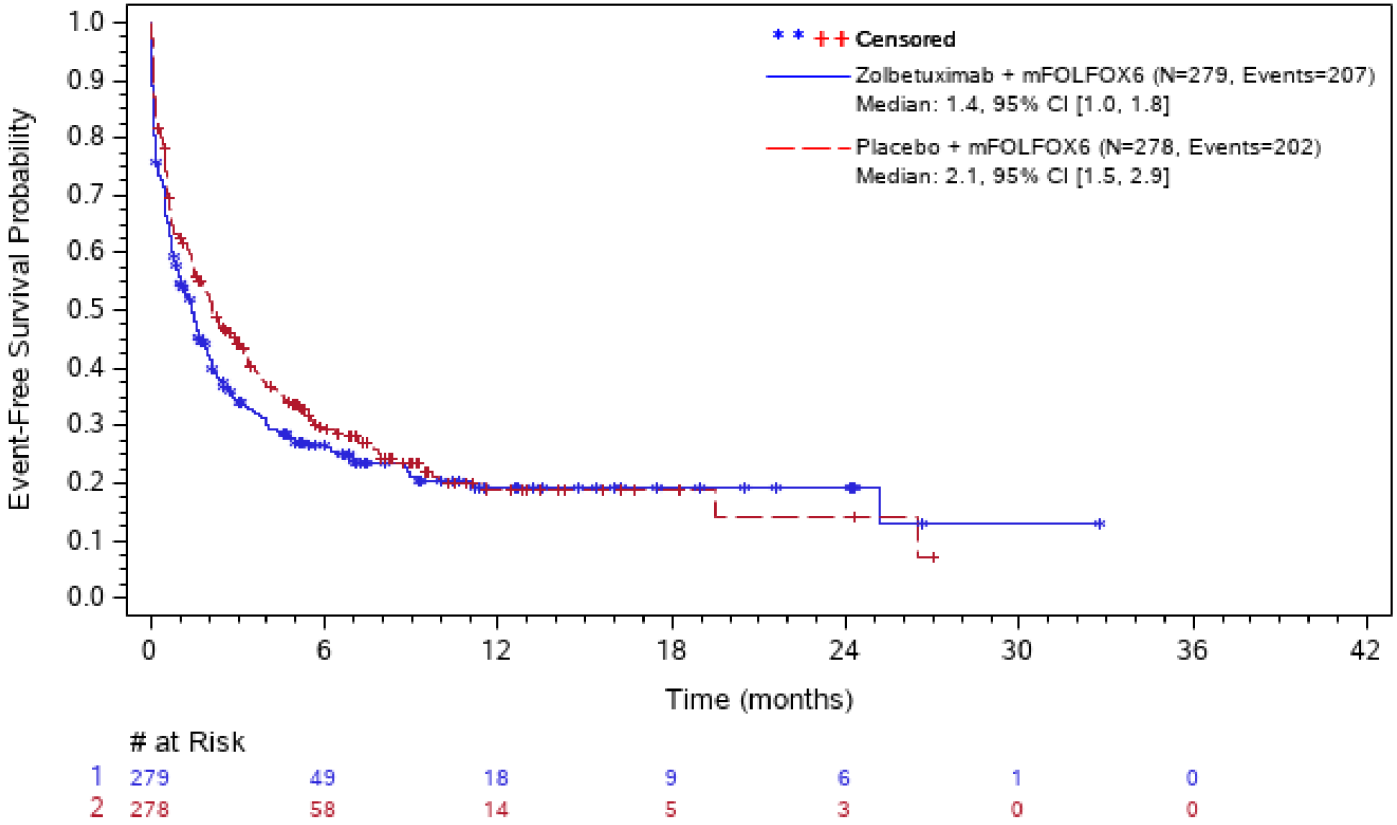
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.37: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Safety Analysis Set



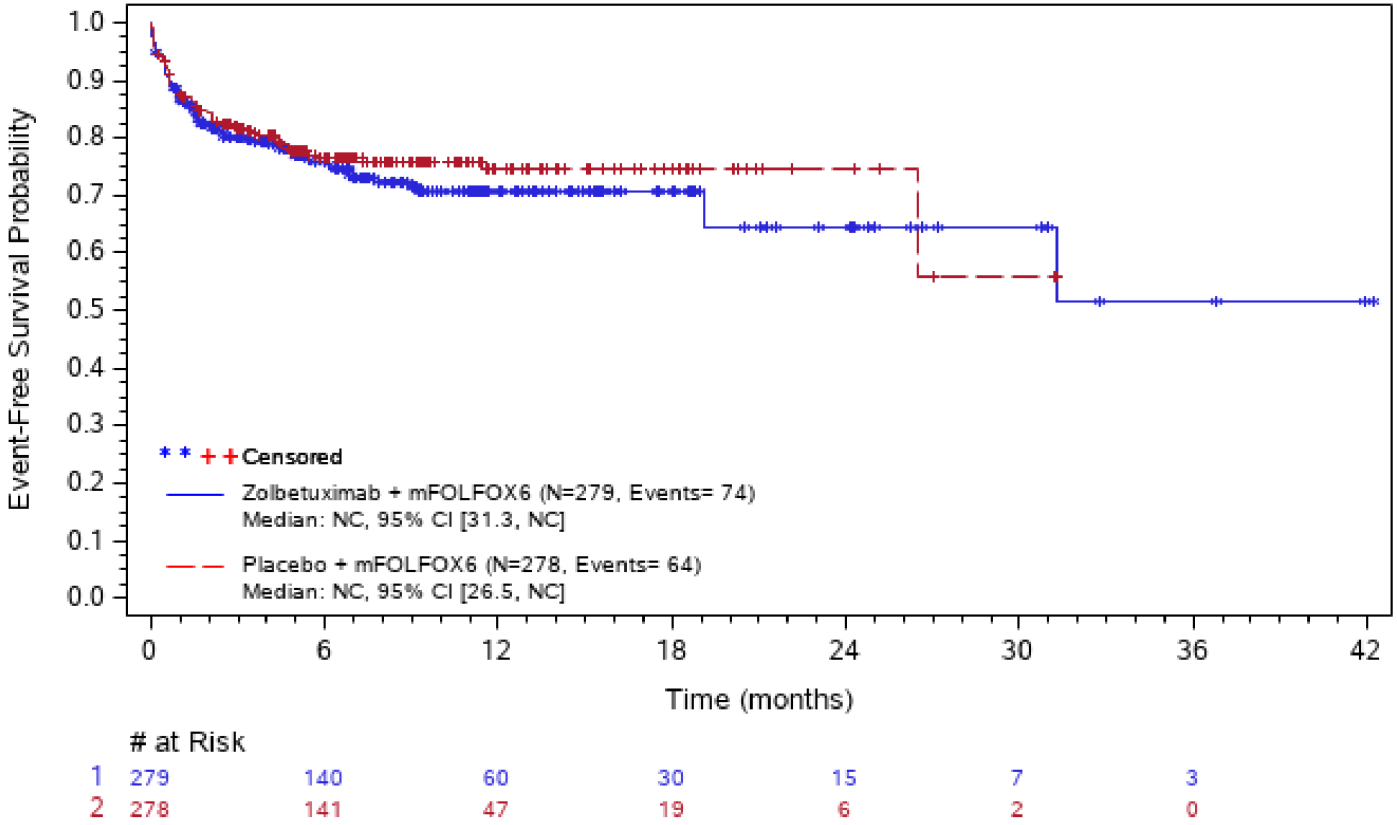
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.38: Kaplan-Meier Plot of Time to first TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



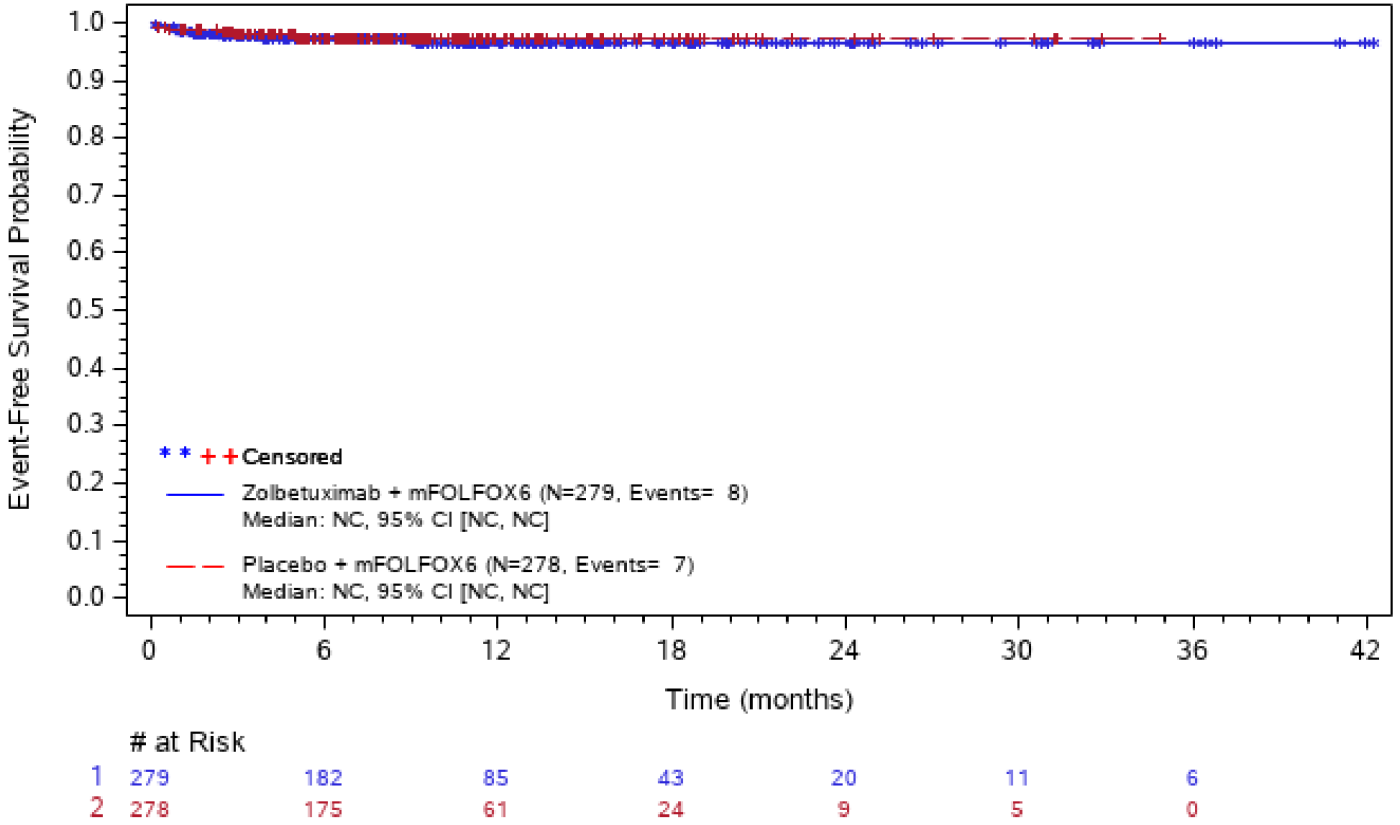
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.39: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Safety Analysis Set



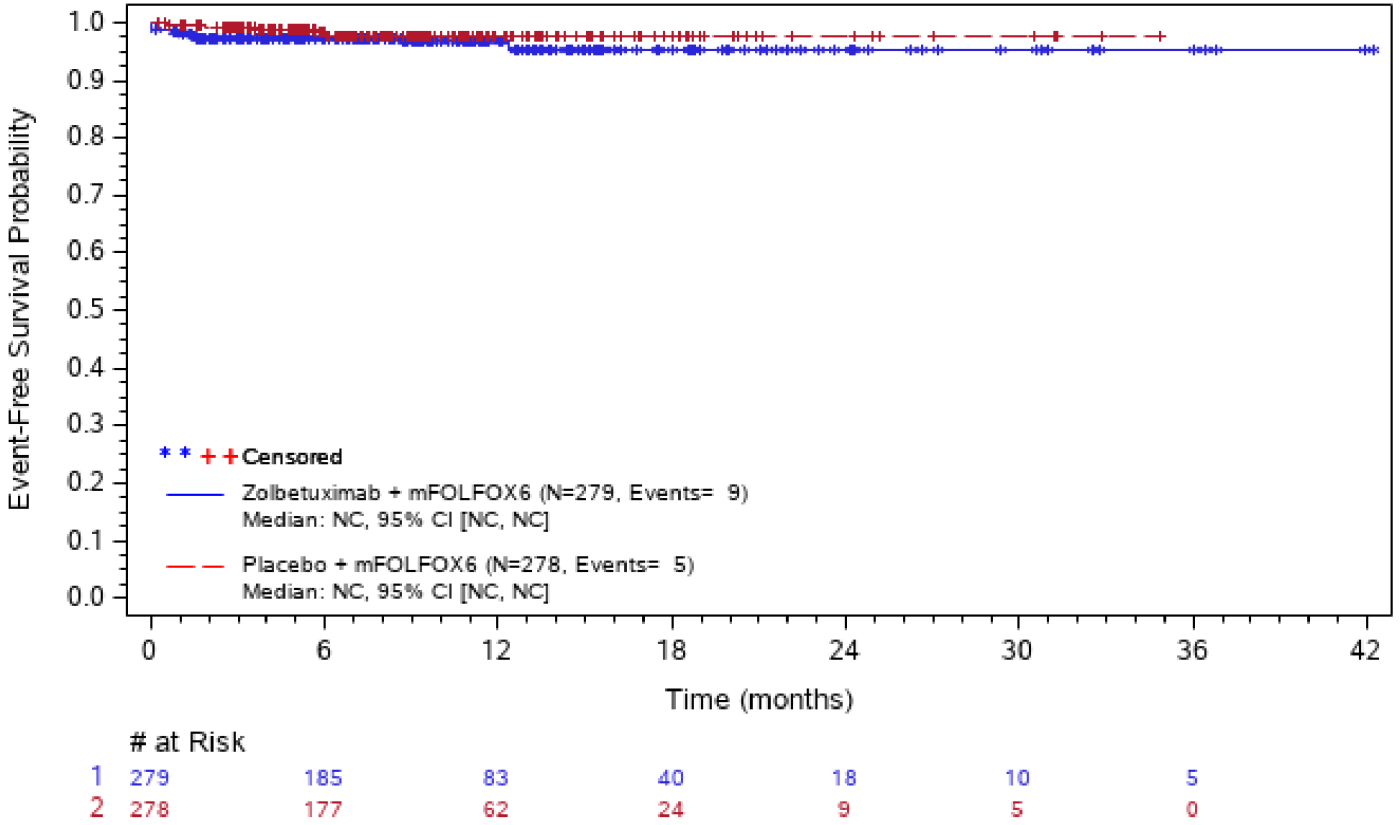
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.40: Kaplan-Meier Plot of Time to first TEAE - Chest Discomfort (PT) - Safety Analysis Set



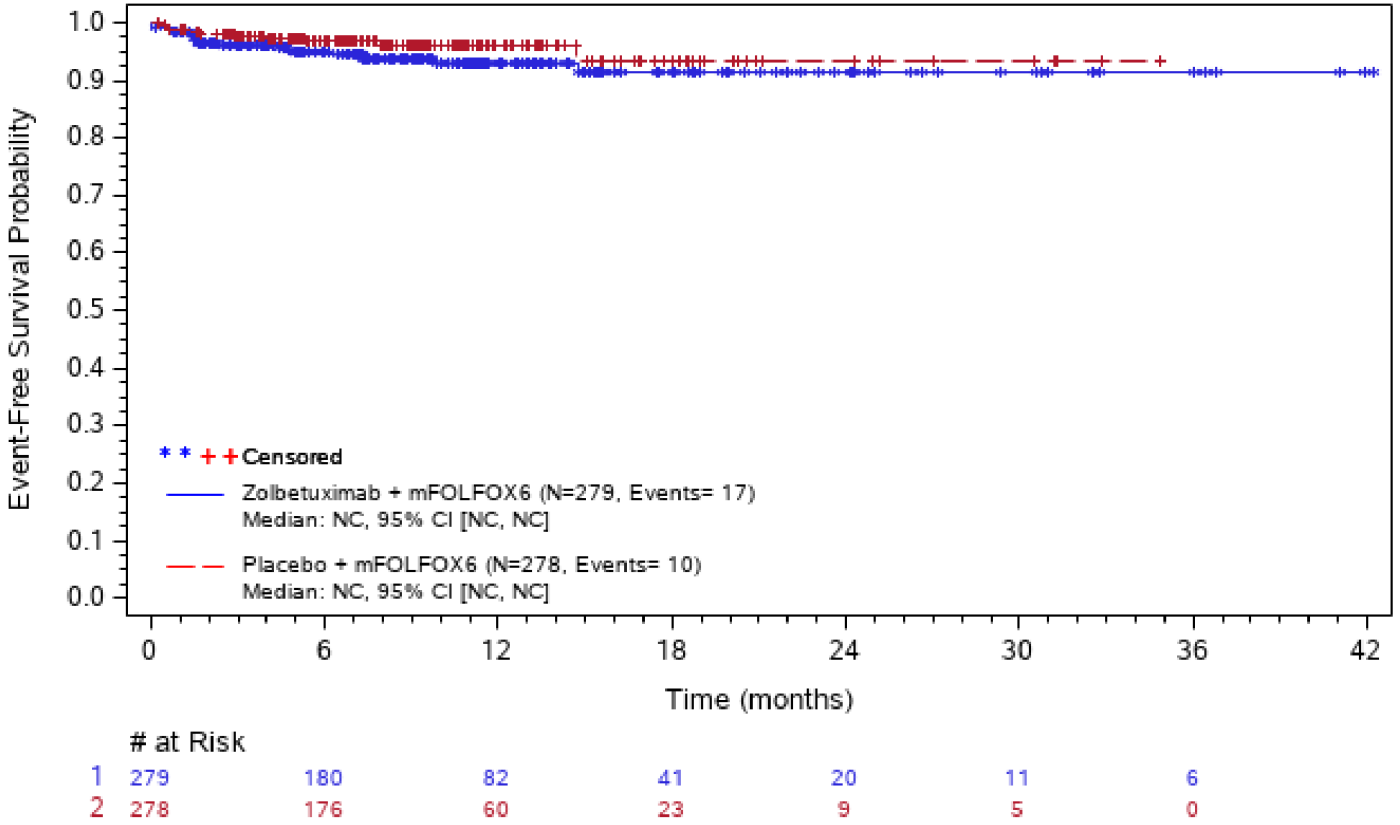
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.41: Kaplan-Meier Plot of Time to first TEAE - Chest Pain (PT) - Safety Analysis Set



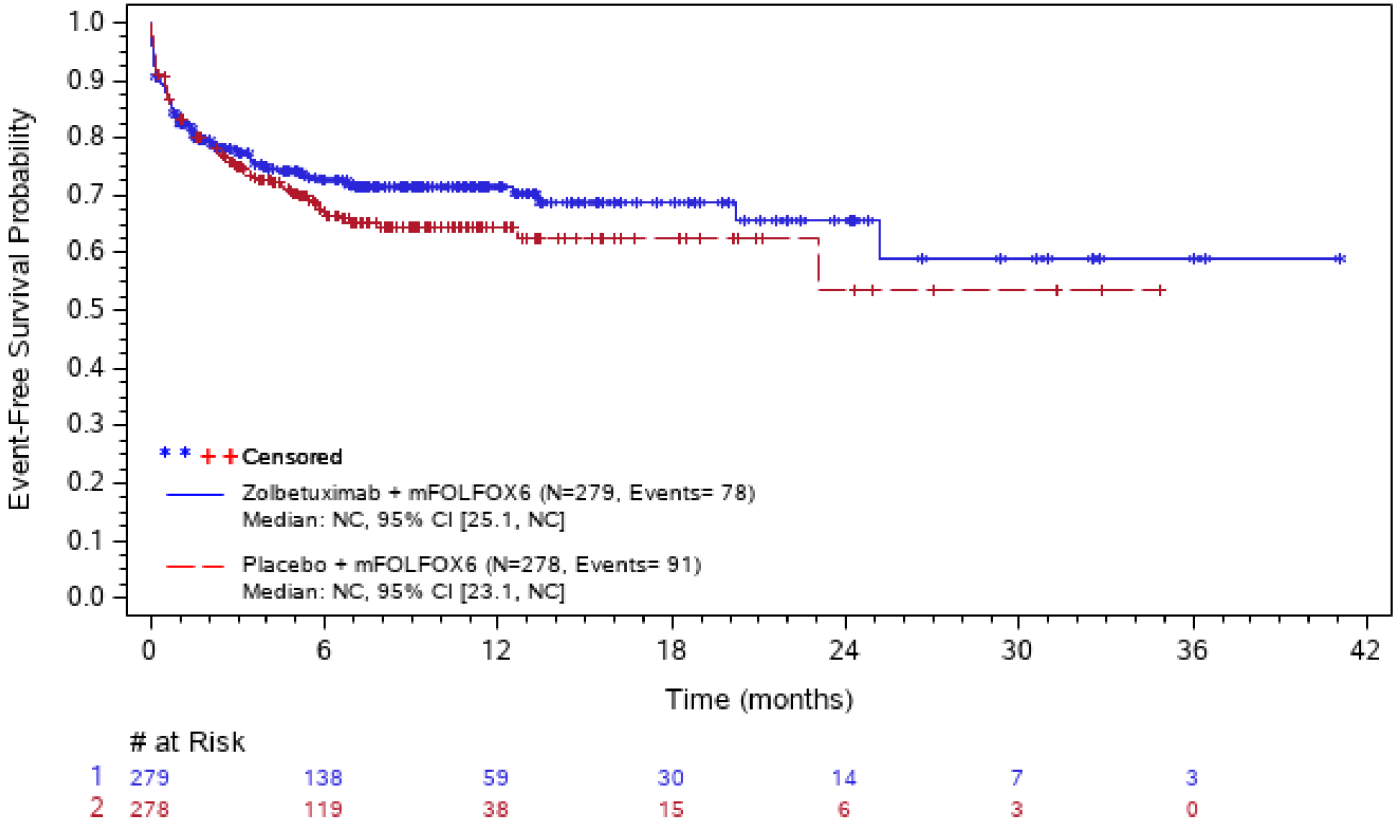
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.42: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Safety Analysis Set



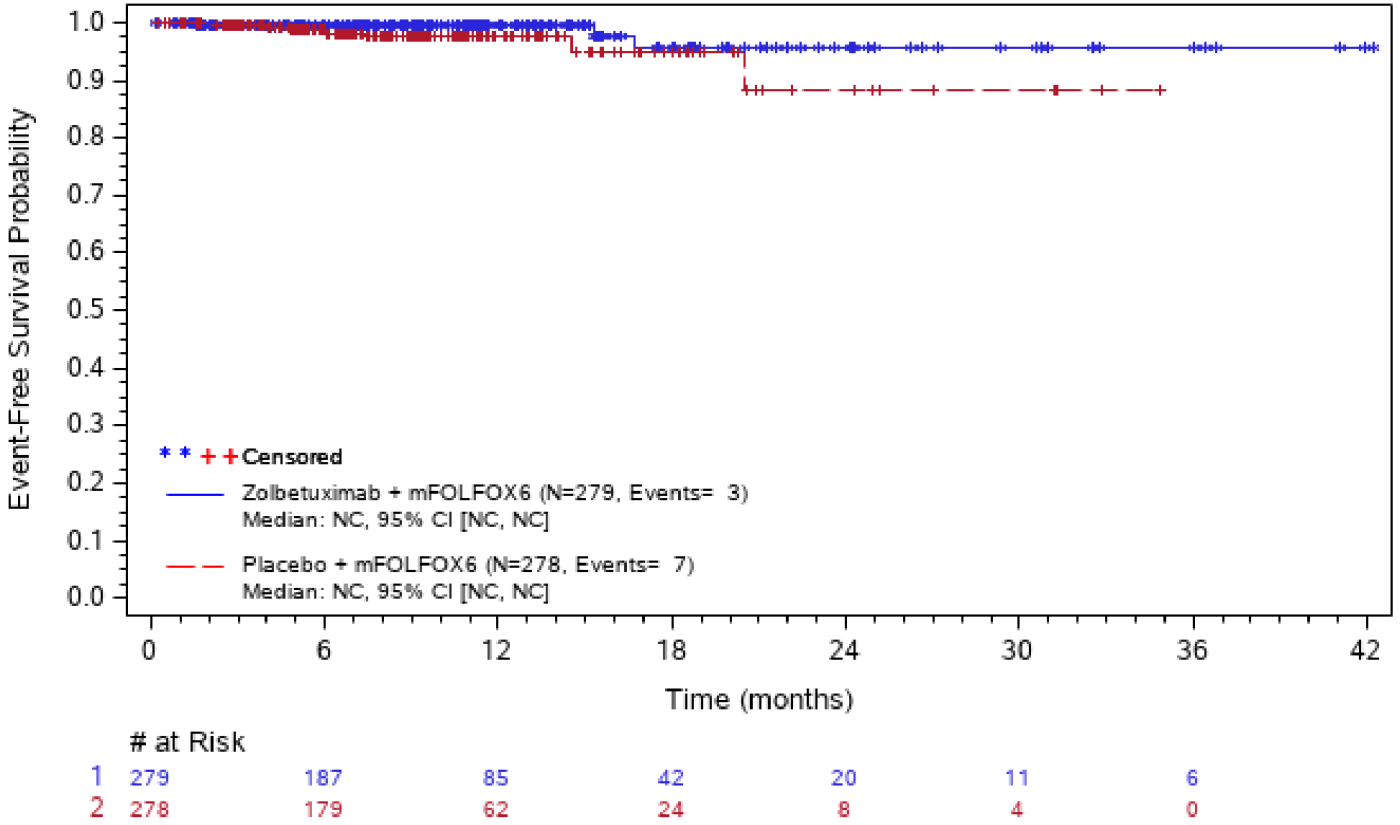
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.43: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Safety Analysis Set



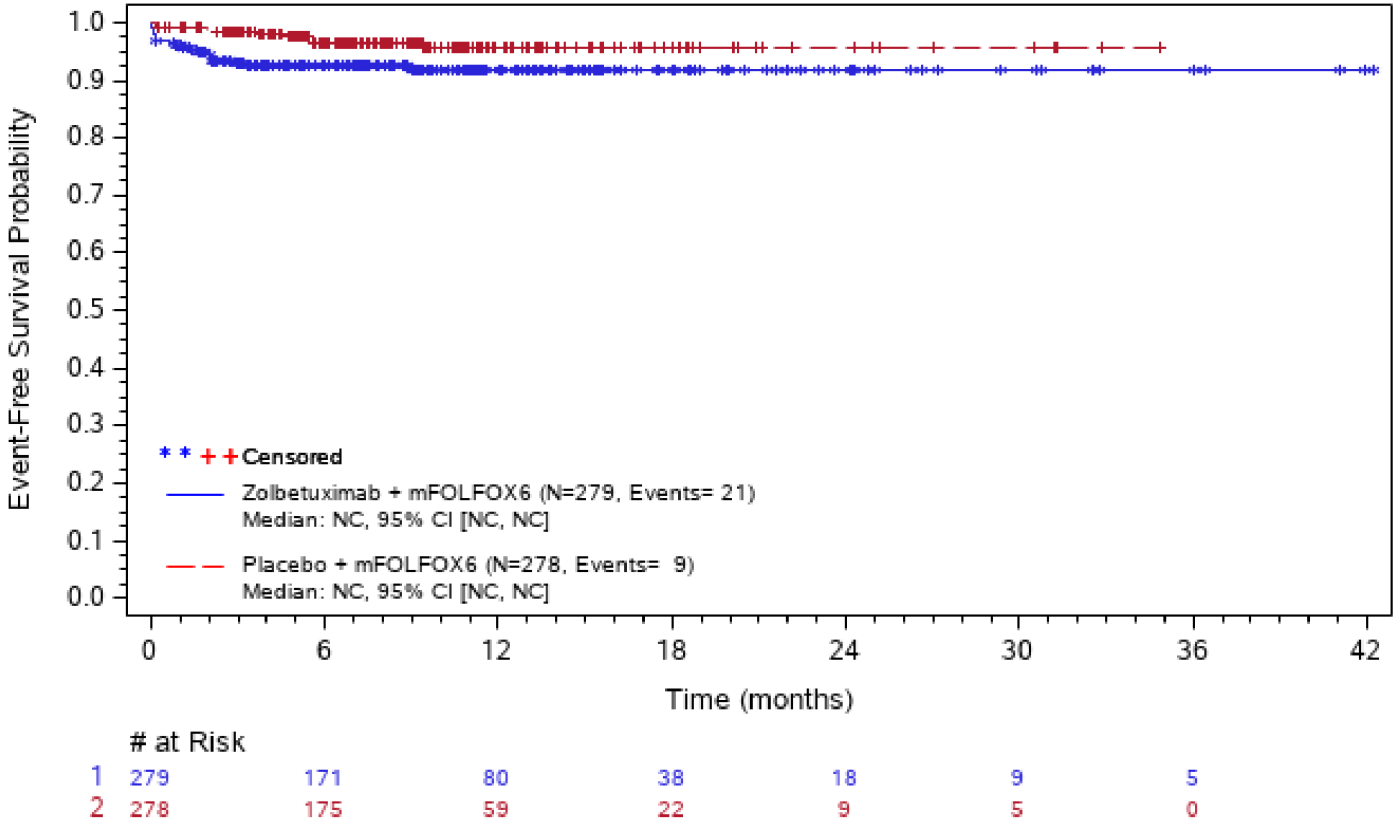
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.44: Kaplan-Meier Plot of Time to first TEAE - General Physical Health Deterioration (PT) - Safety Analysis Set



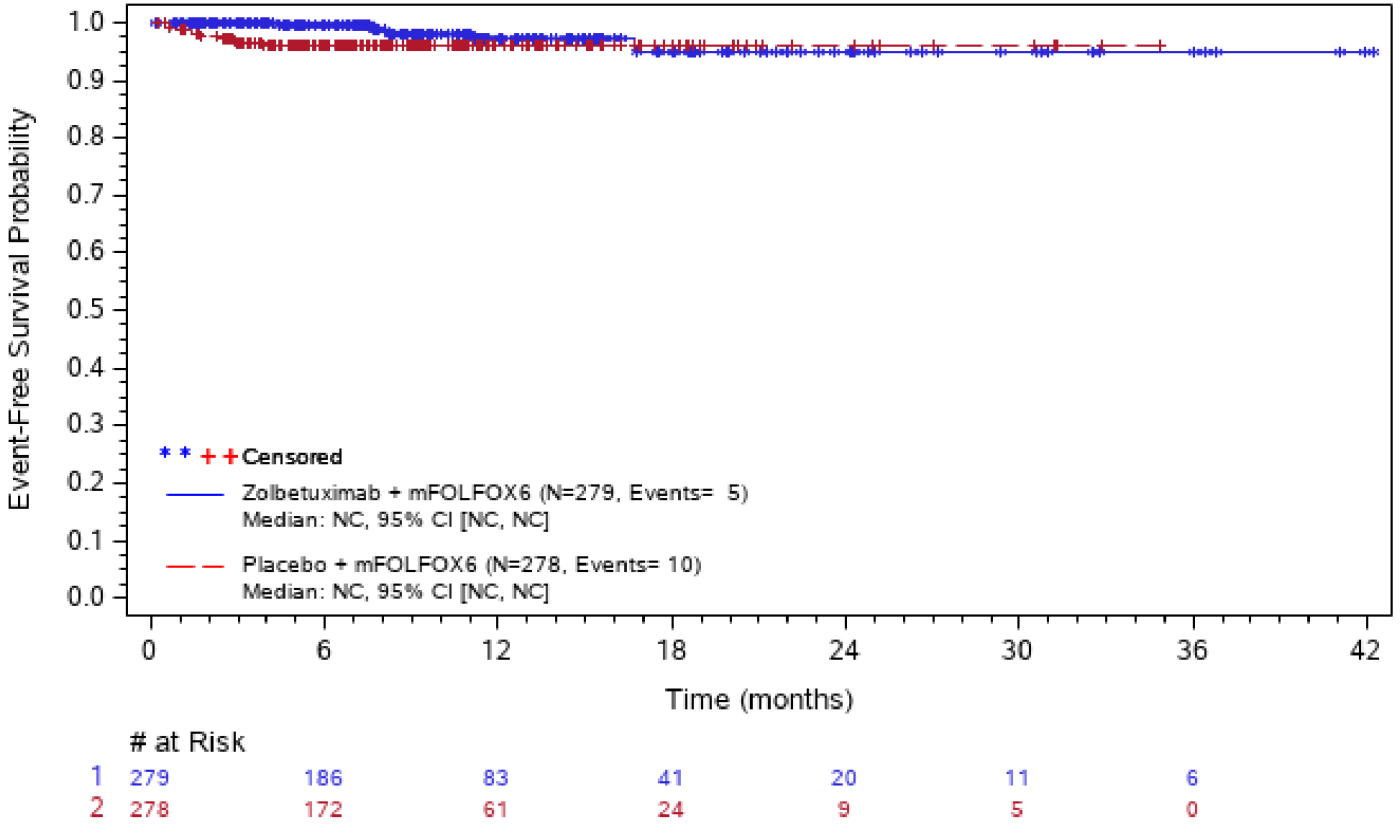
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.45: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Safety Analysis Set



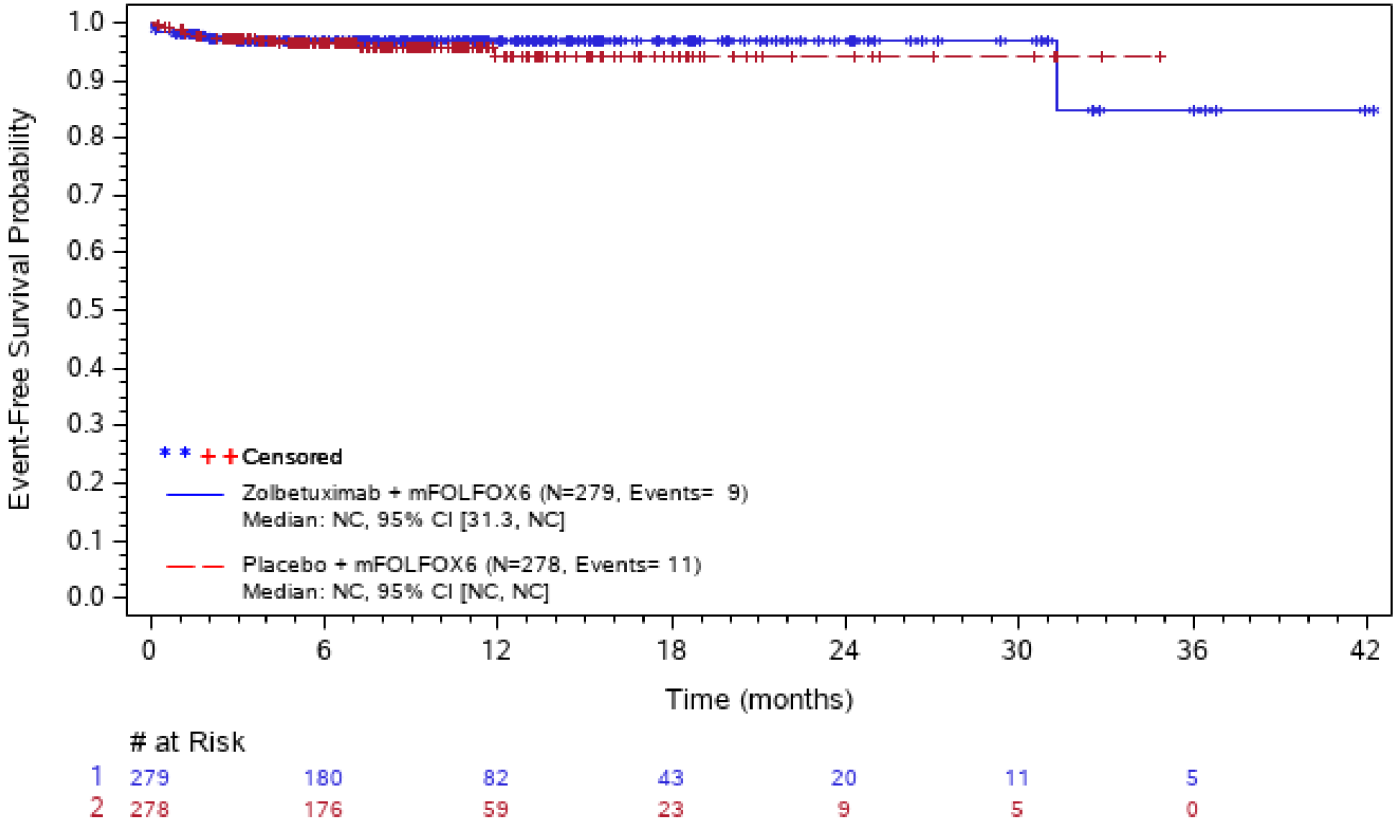
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.46: Kaplan-Meier Plot of Time to first TEAE - Mucosal Inflammation (PT) - Safety Analysis Set



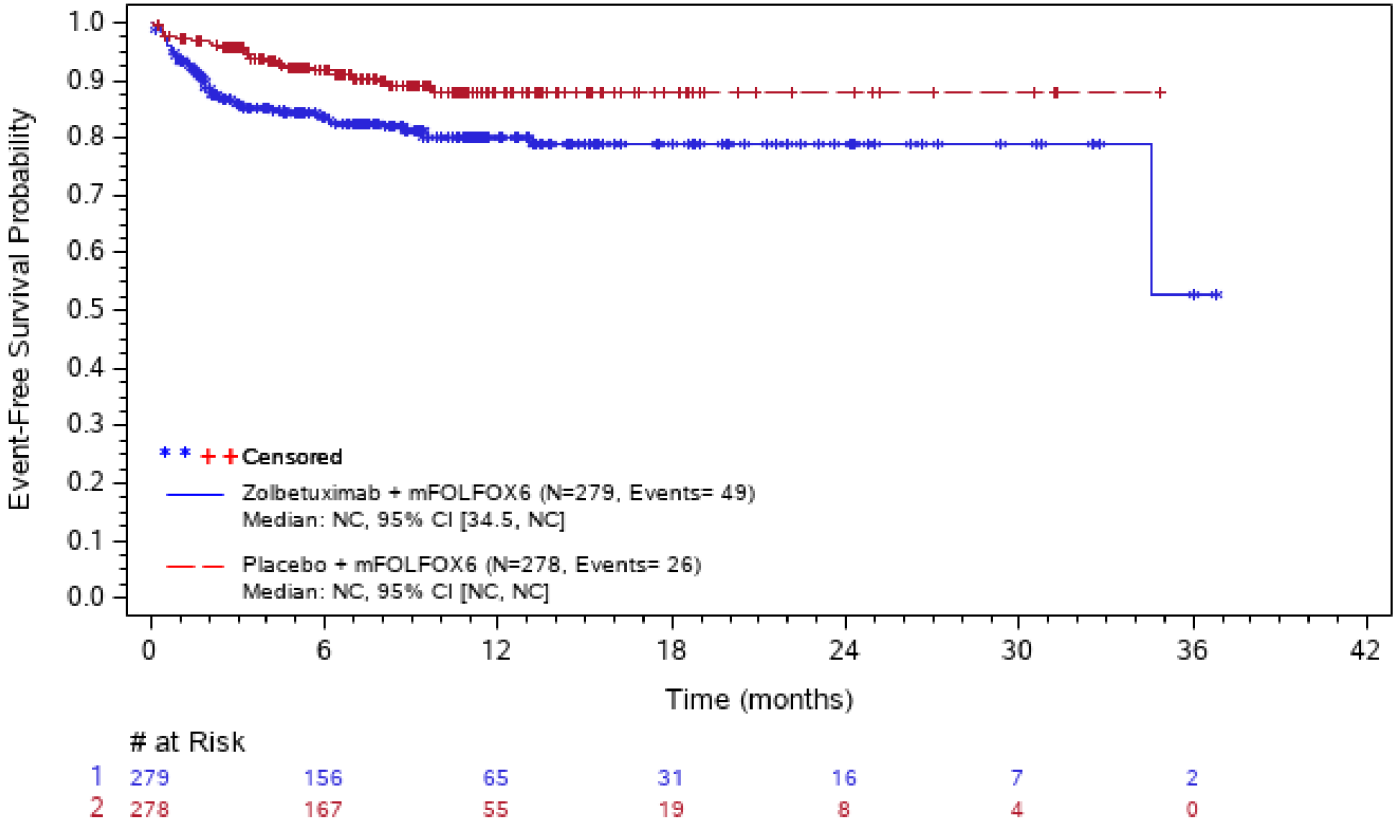
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.47: Kaplan-Meier Plot of Time to first TEAE - Non-Cardiac Chest 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: 09SEP22

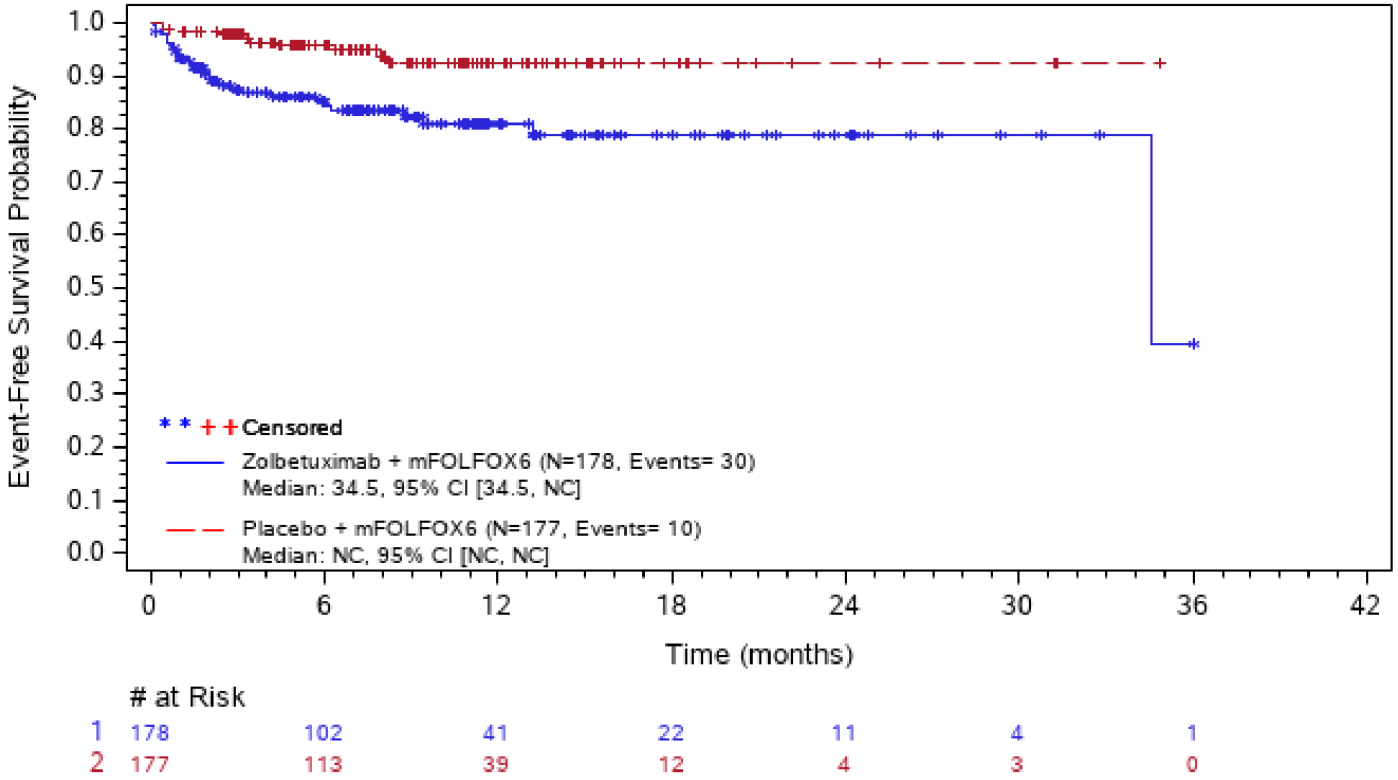
Figure 301.1.2001.48: Kaplan-Meier Plot of Time to first TEAE - Oedema Peripheral (PT) - Safety Analysis Set



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: 09SEP22

Figure 301.1.2001.48.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Oedema Peripheral (PT) - Safety Analysis Set

Age Group 1: <=65 years

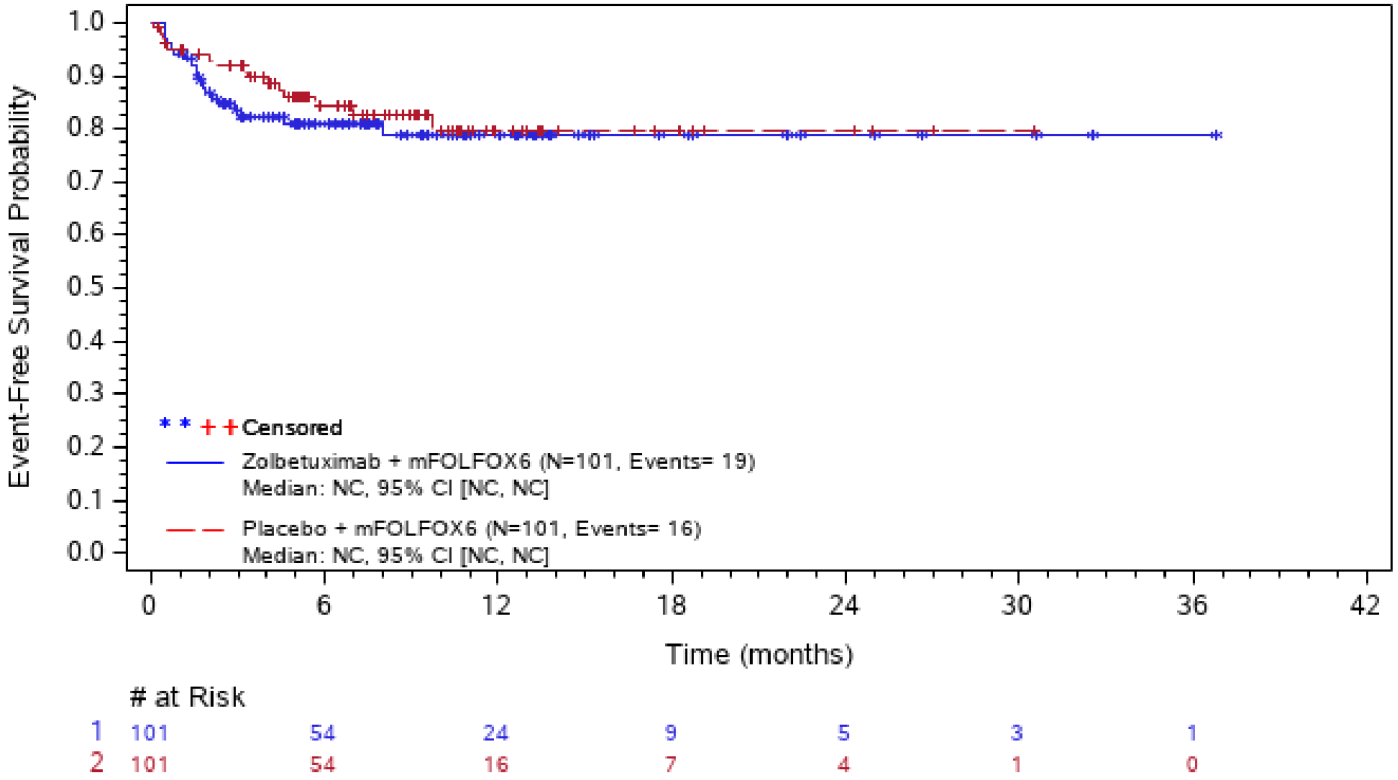


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.48.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Oedema Peripheral (PT) - Safety Analysis Set

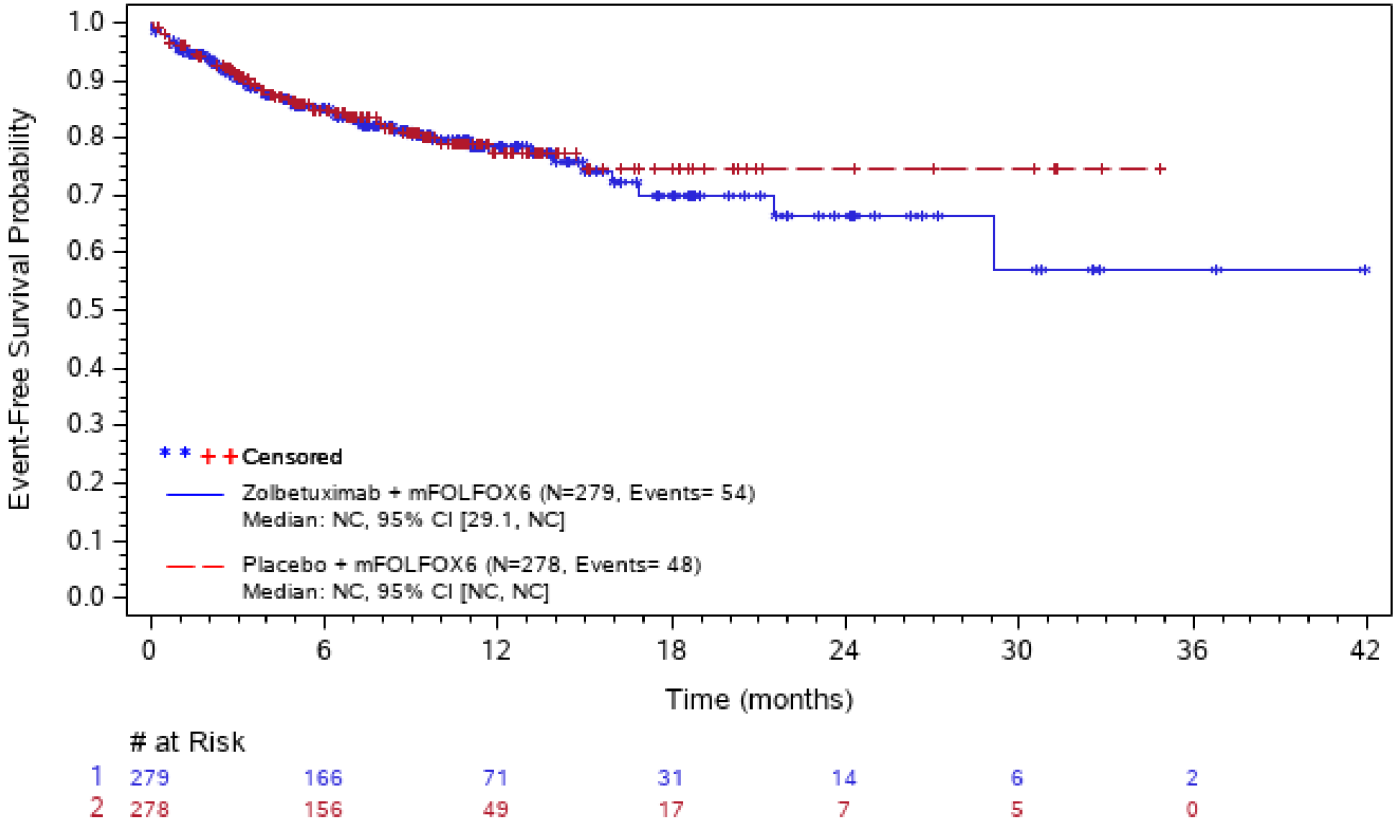
Age Group 1: >65 years



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.

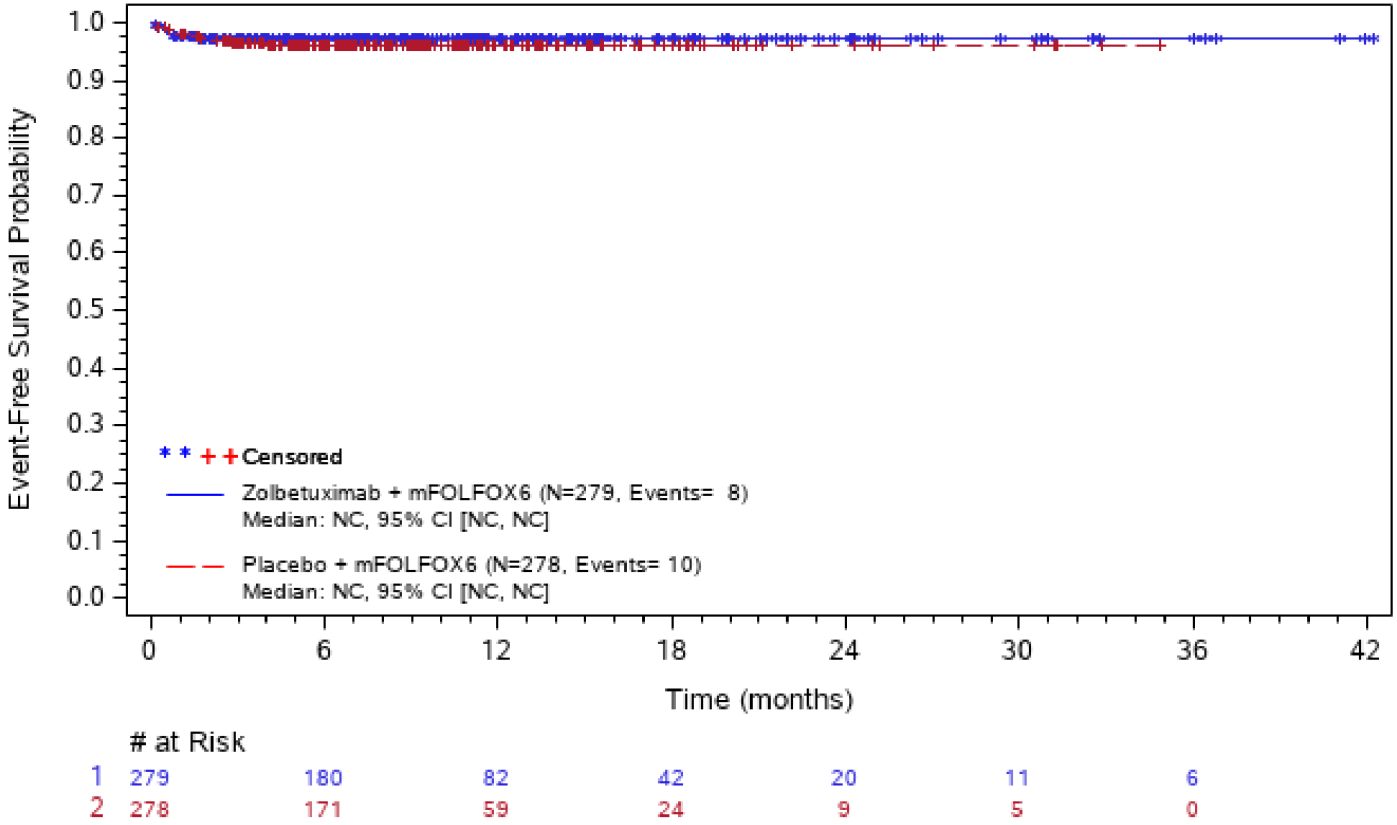
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.49: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Safety Analysis Set



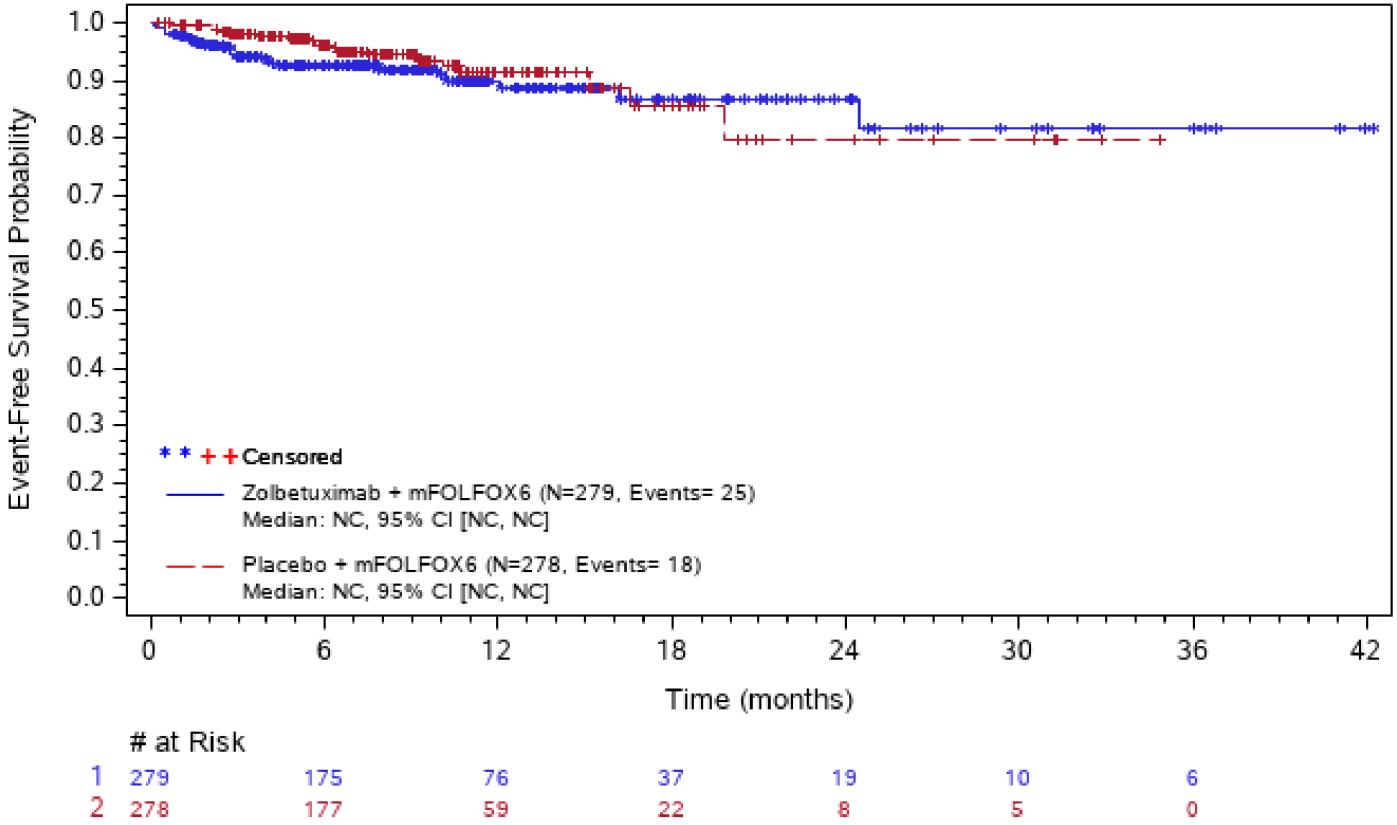
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.50: Kaplan-Meier Plot of Time to first TEAE - Temperature Intolerance (PT) - Safety Analysis Set



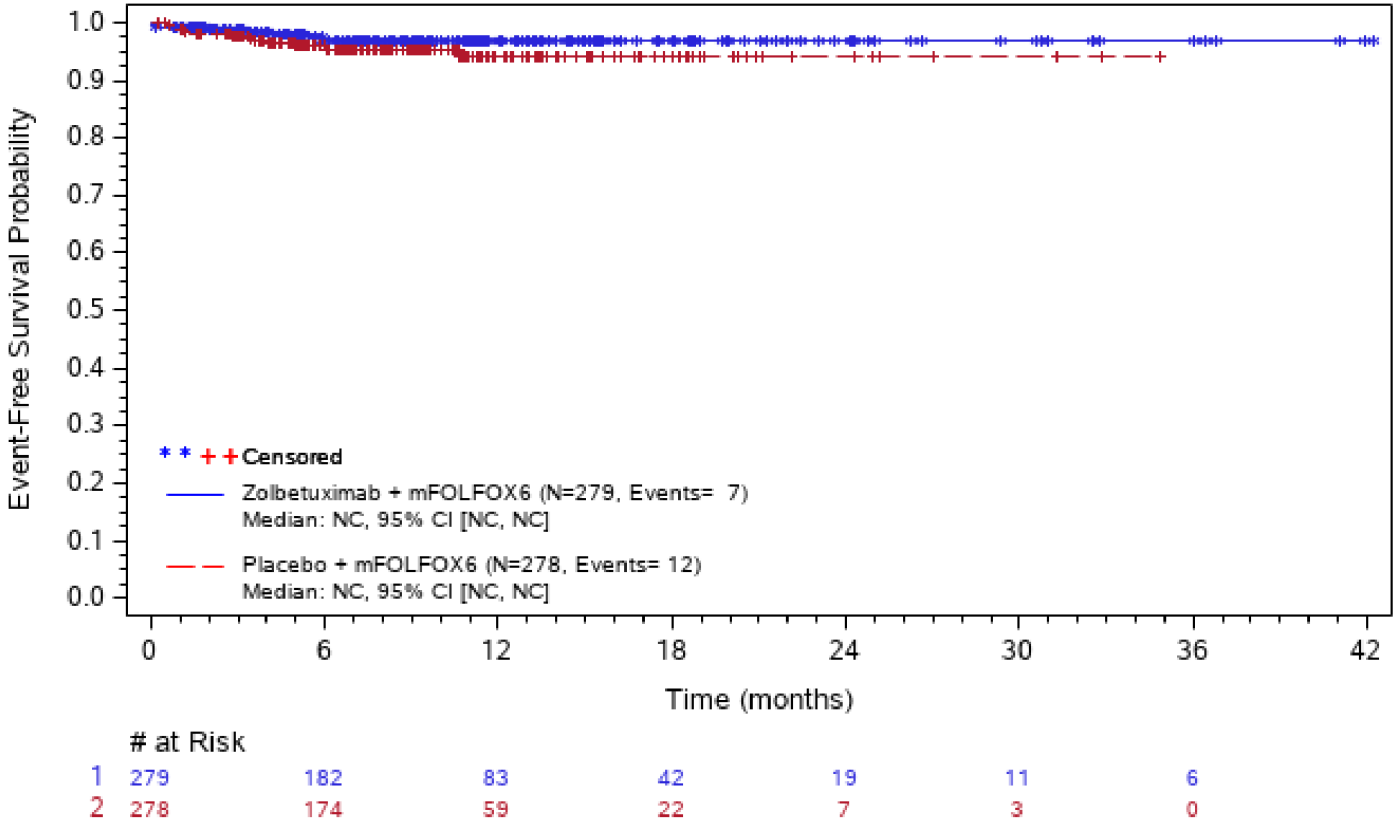
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.51: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



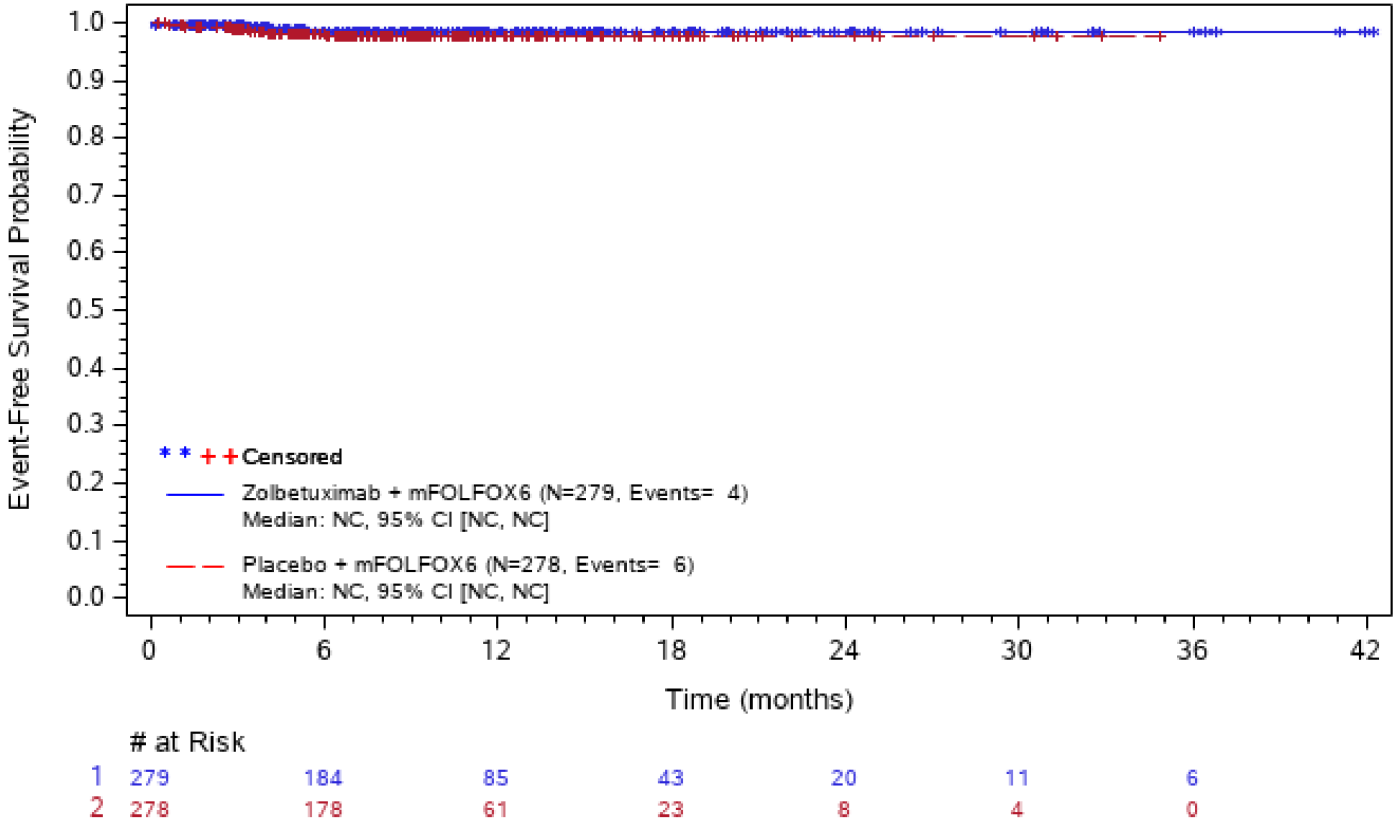
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.52: Kaplan-Meier Plot of Time to first TEAE - Immune System Disorders (SOC) - Safety Analysis Set



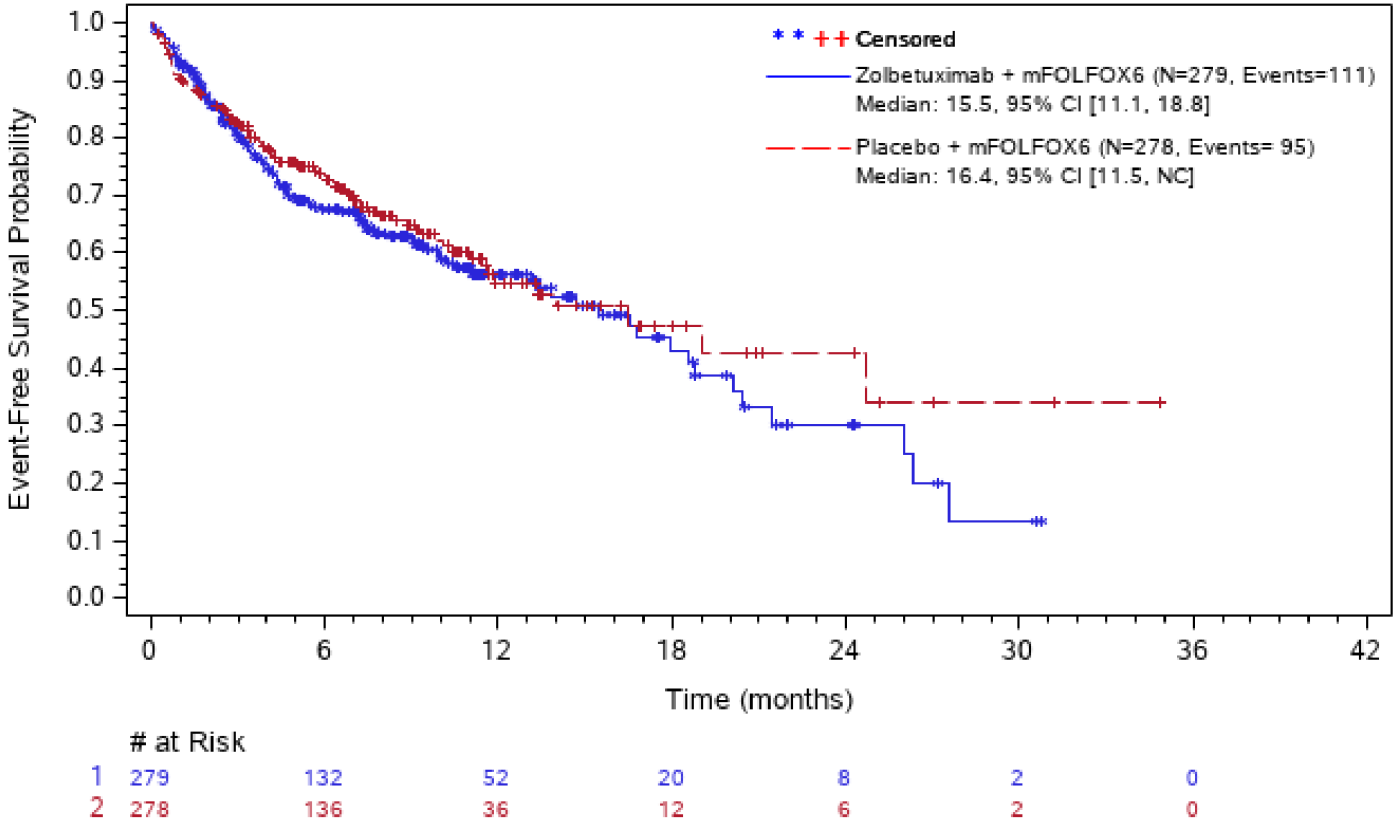
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.53: Kaplan-Meier Plot of Time to first TEAE - Drug Hypersensitivity (PT) - Safety Analysis Set



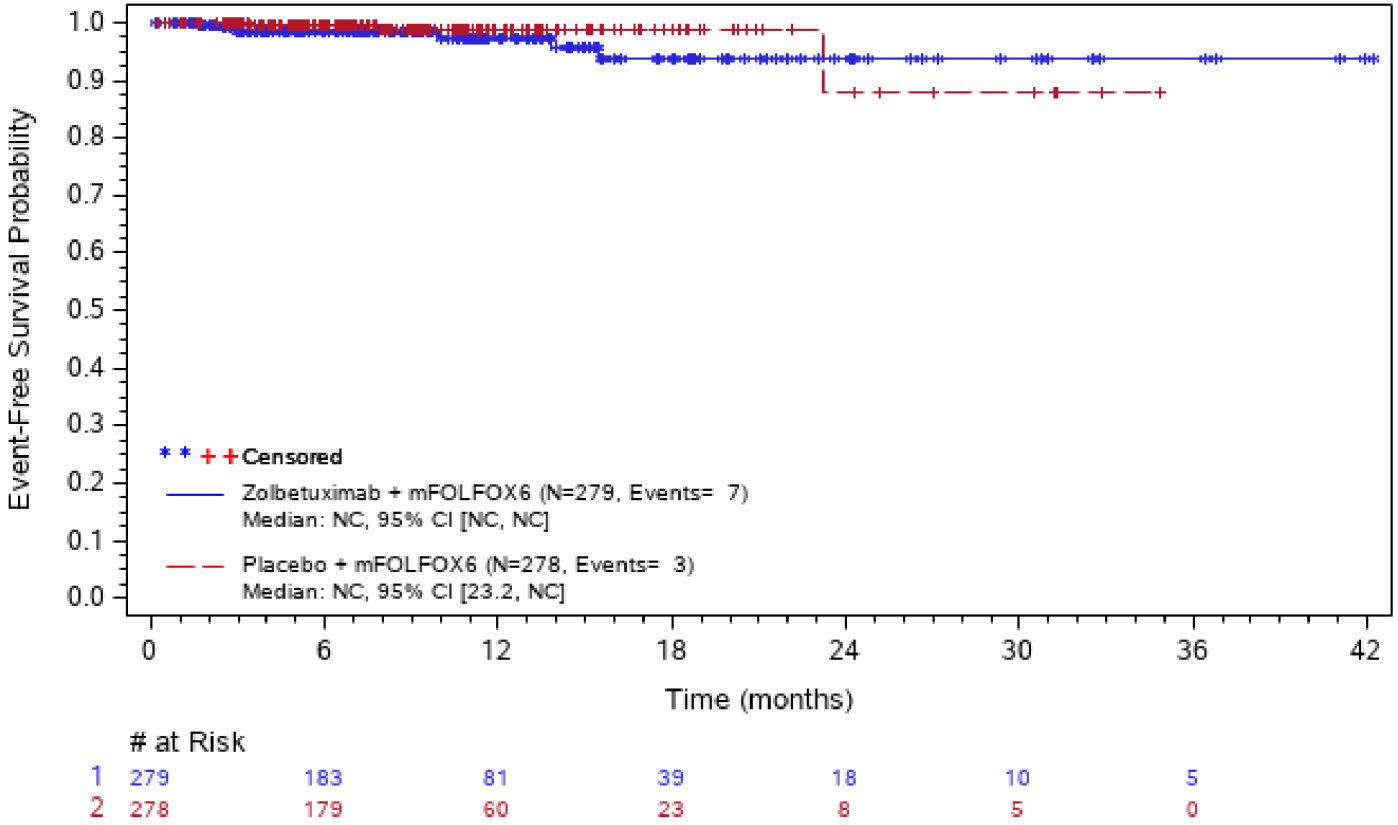
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.54: Kaplan-Meier Plot of Time to first TEAE - Infections And Infestations (SOC) - Safety Analysis Set



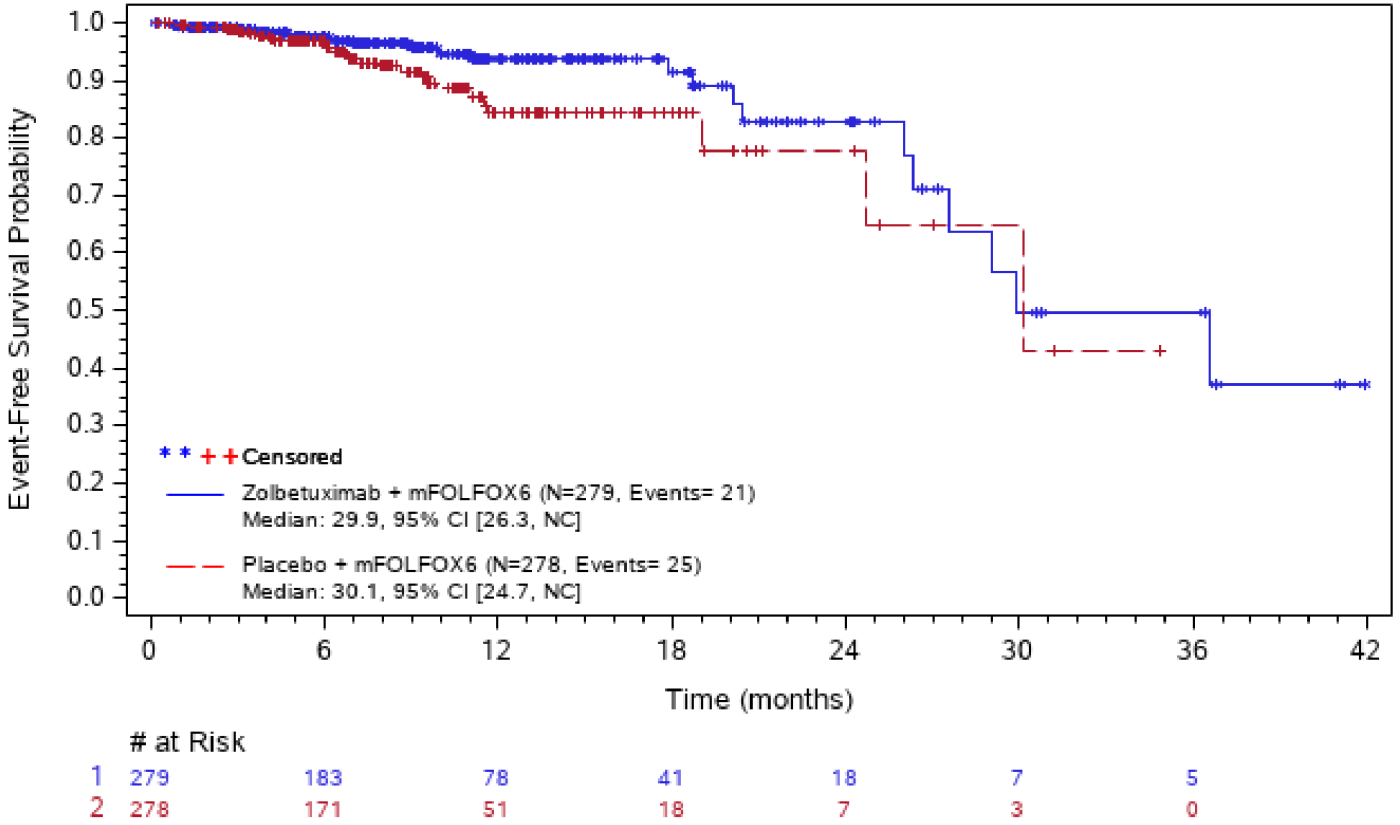
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.55: Kaplan-Meier Plot of Time to first TEAE - Conjunctivitis (PT) - Safety Analysis Set



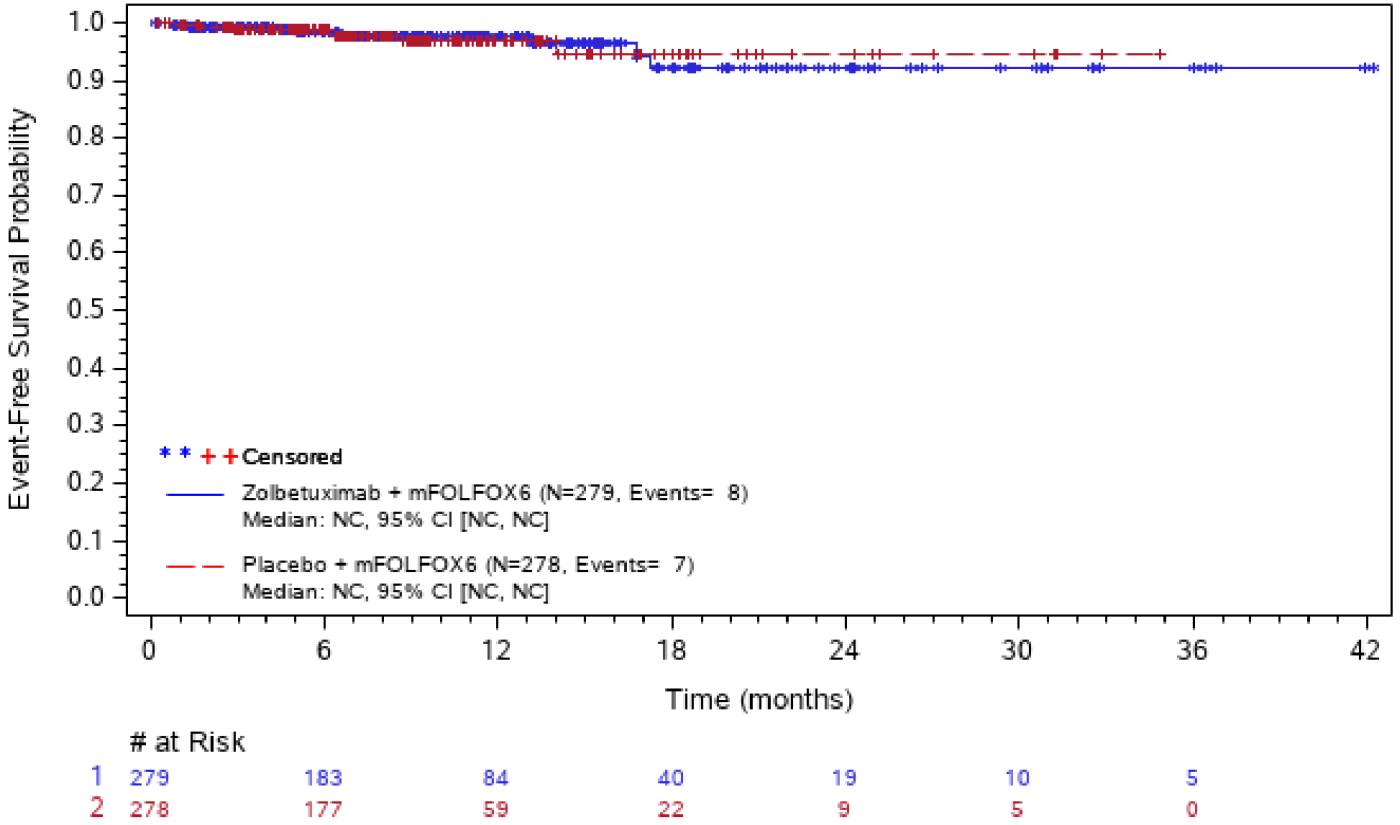
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.56: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set



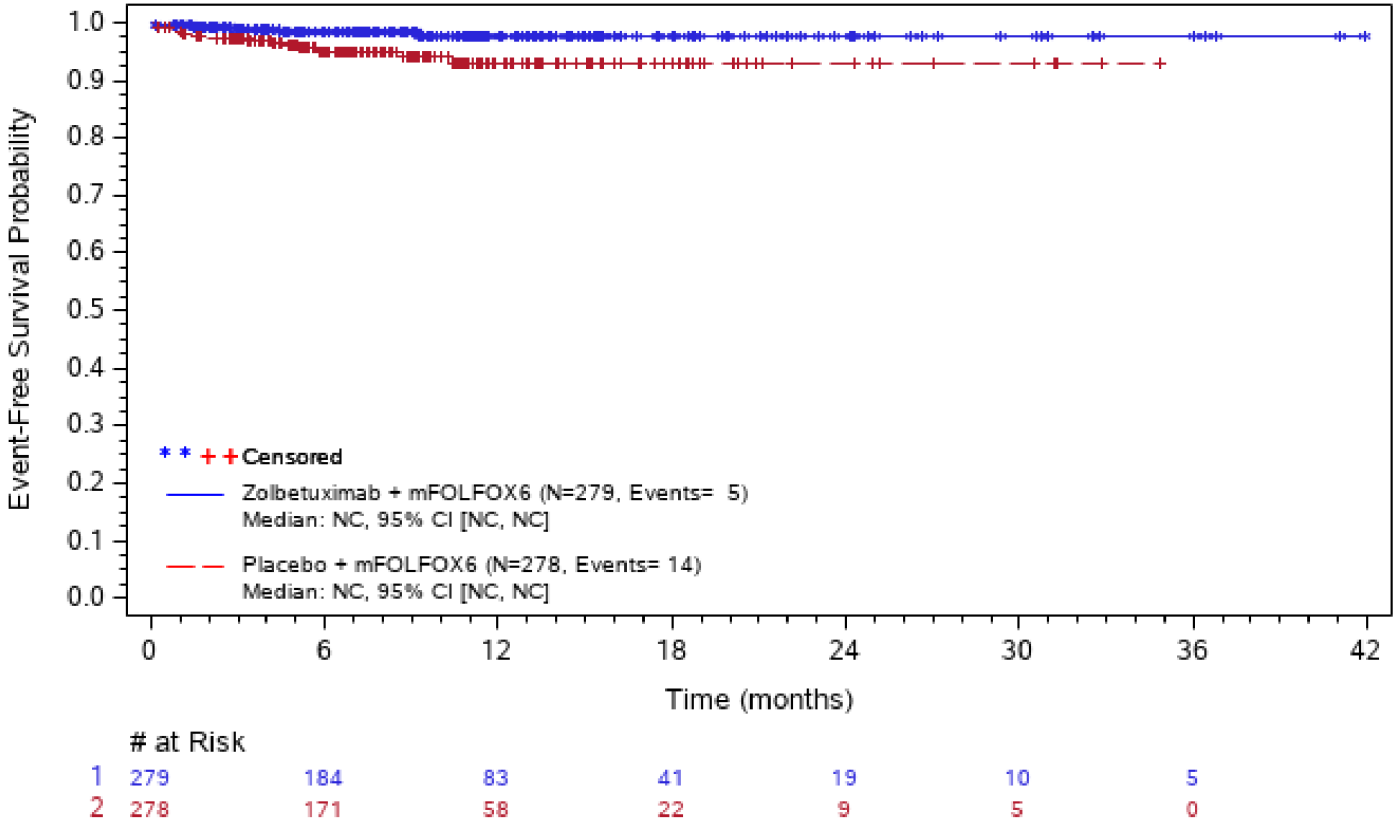
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.57: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set



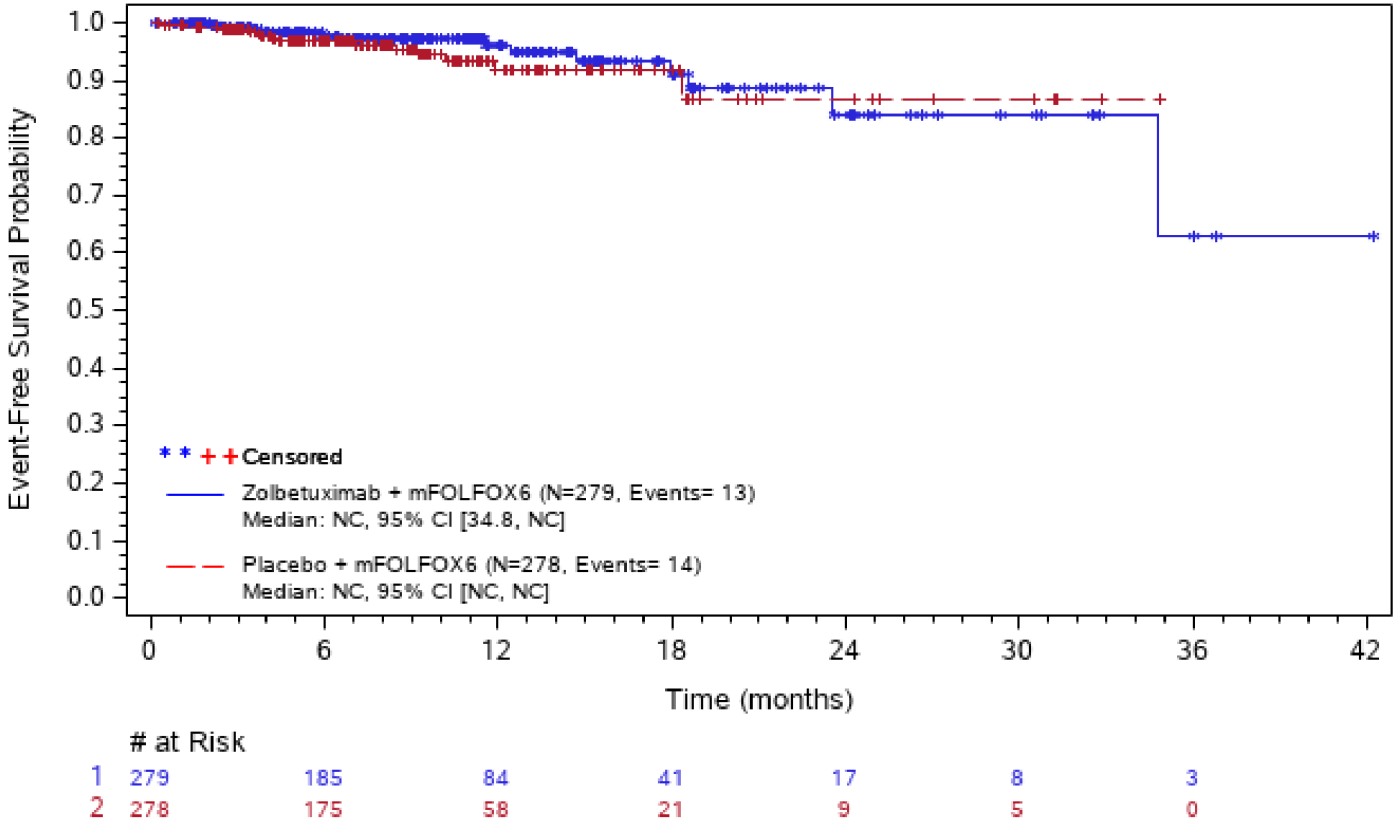
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.58: Kaplan-Meier Plot of Time to first TEAE - Oral Candidiasis (PT) - Safety Analysis Set



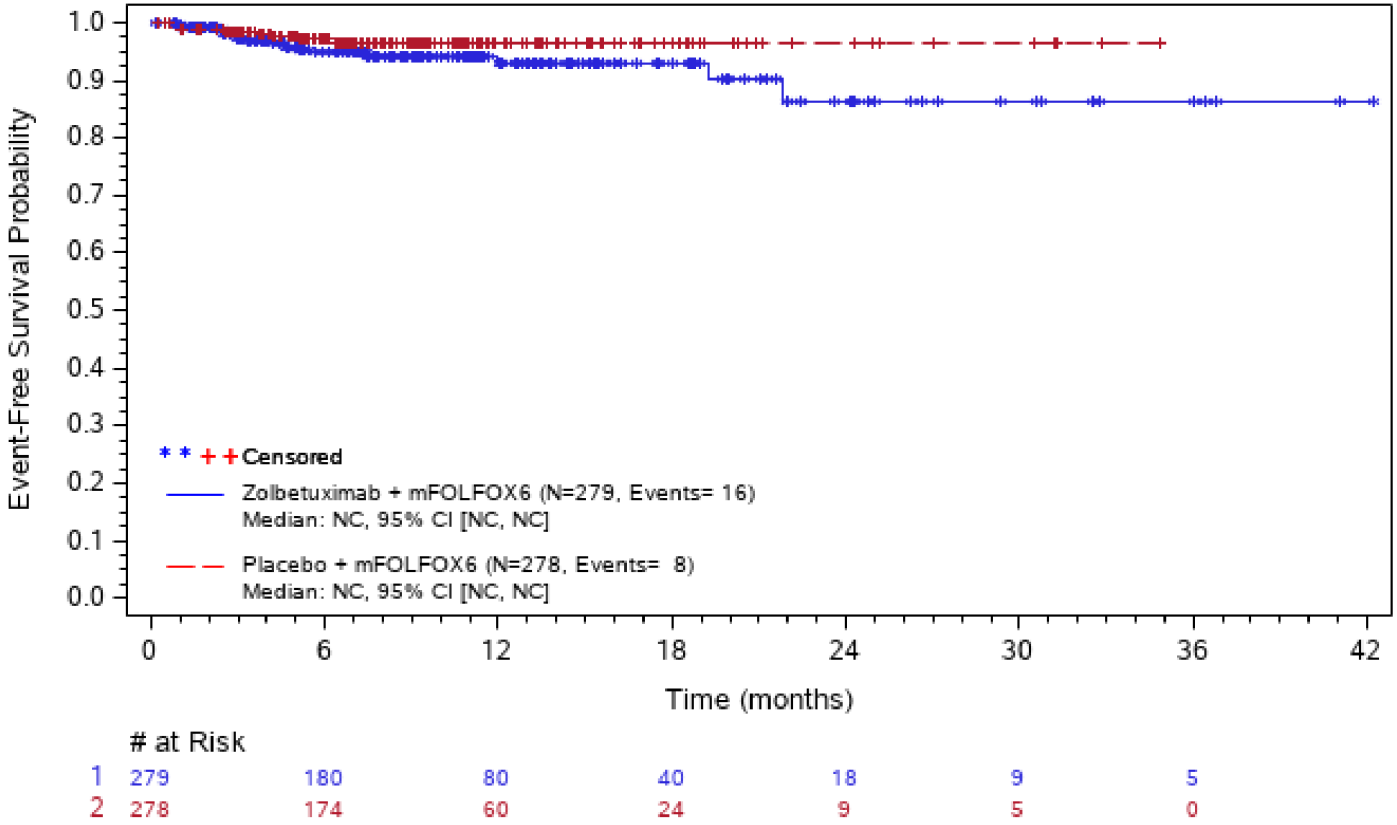
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.59: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Safety Analysis Set



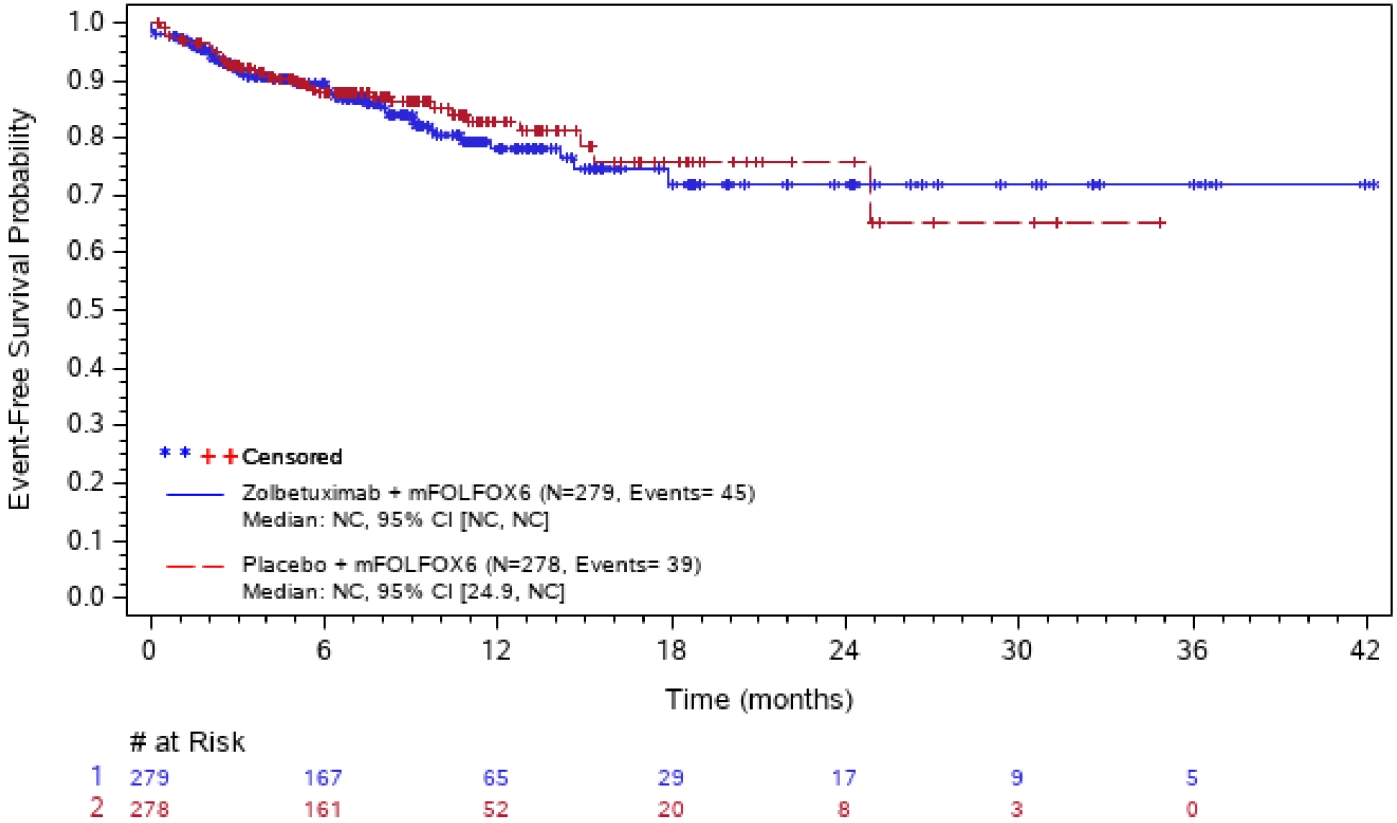
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.60: Kaplan-Meier Plot of Time to first TEAE - Urinary Tract Infection (PT) - Safety Analysis Set



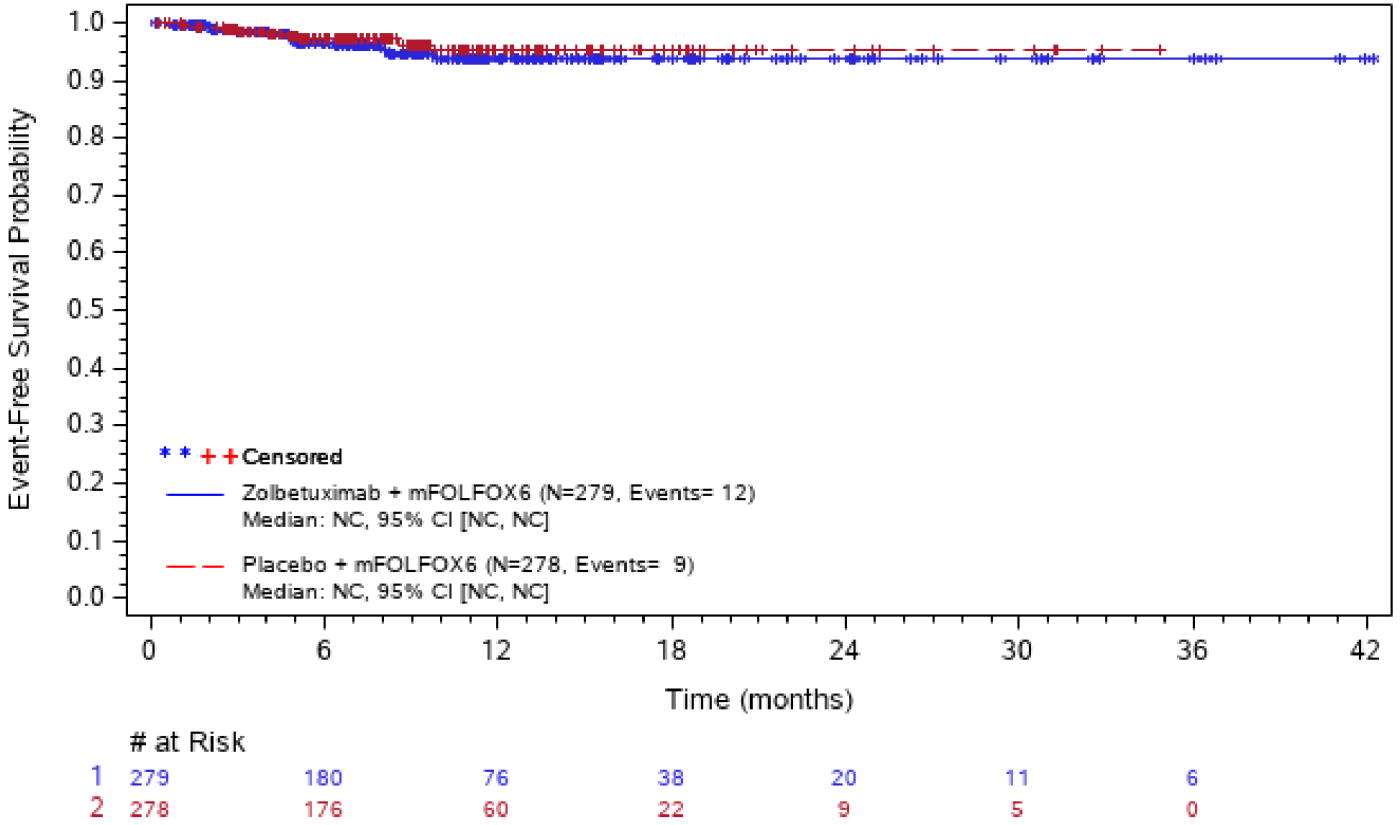
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.61: Kaplan-Meier Plot of Time to first TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



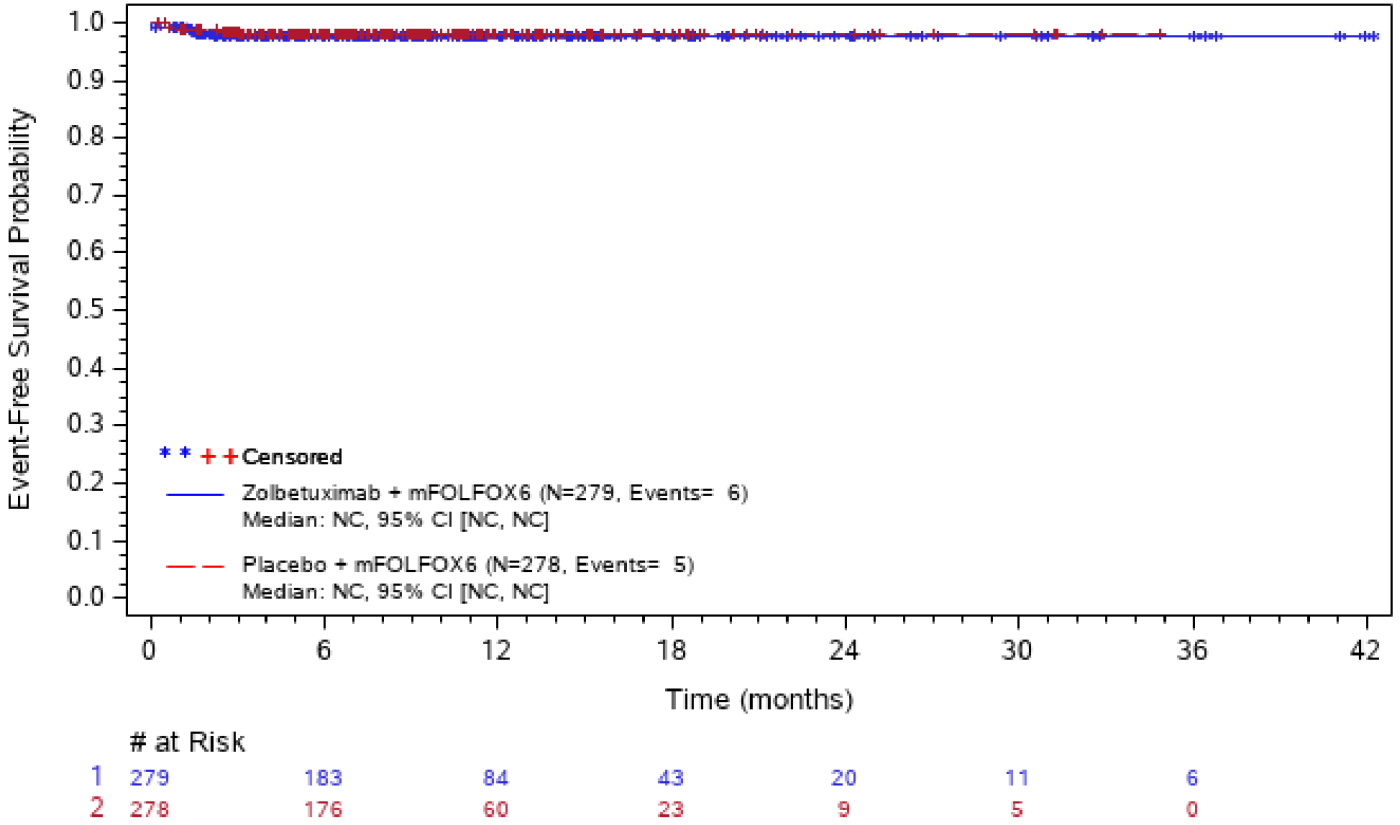
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.62: Kaplan-Meier Plot of Time to first TEAE - Fall (PT) - Safety Analysis Set



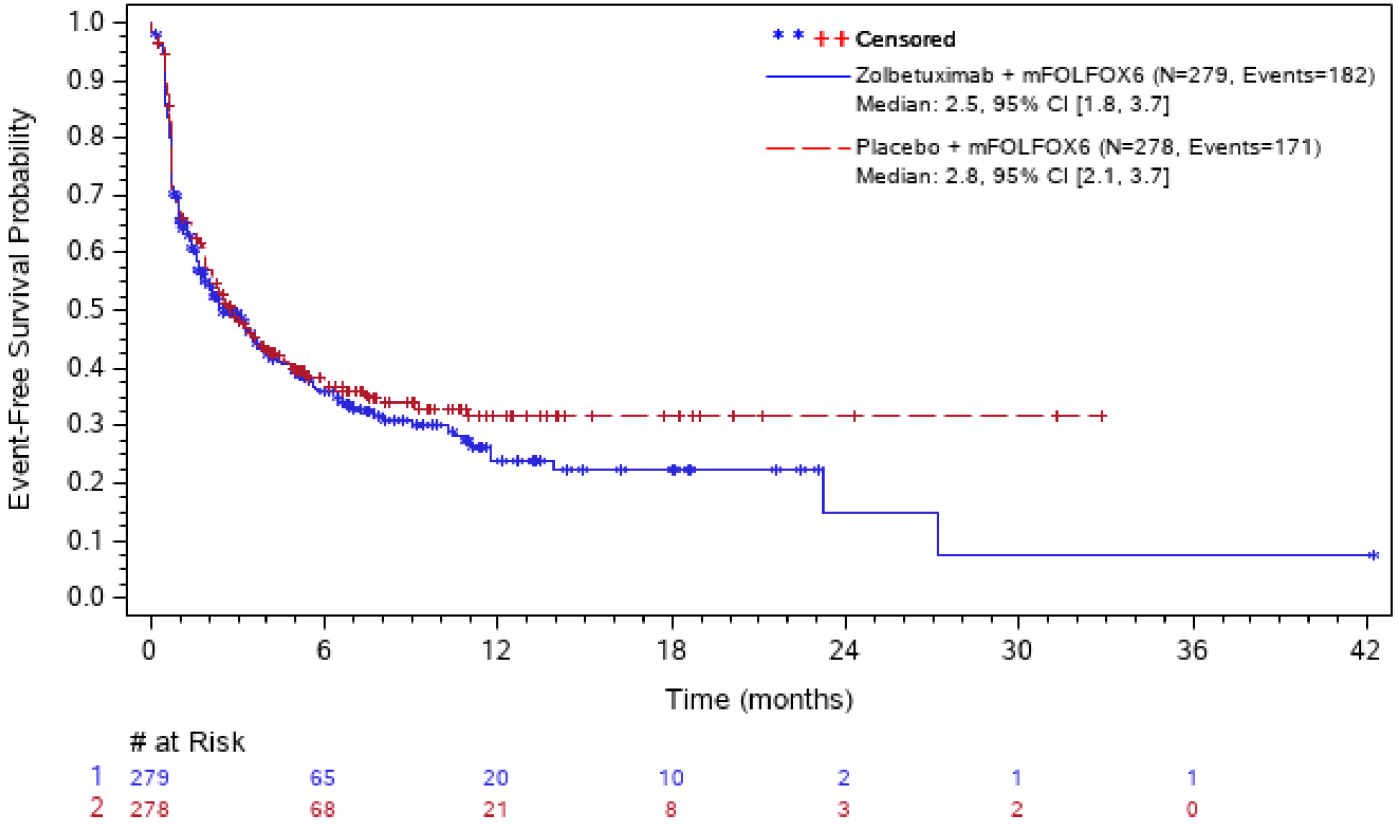
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.63: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (PT) - Safety Analysis Set



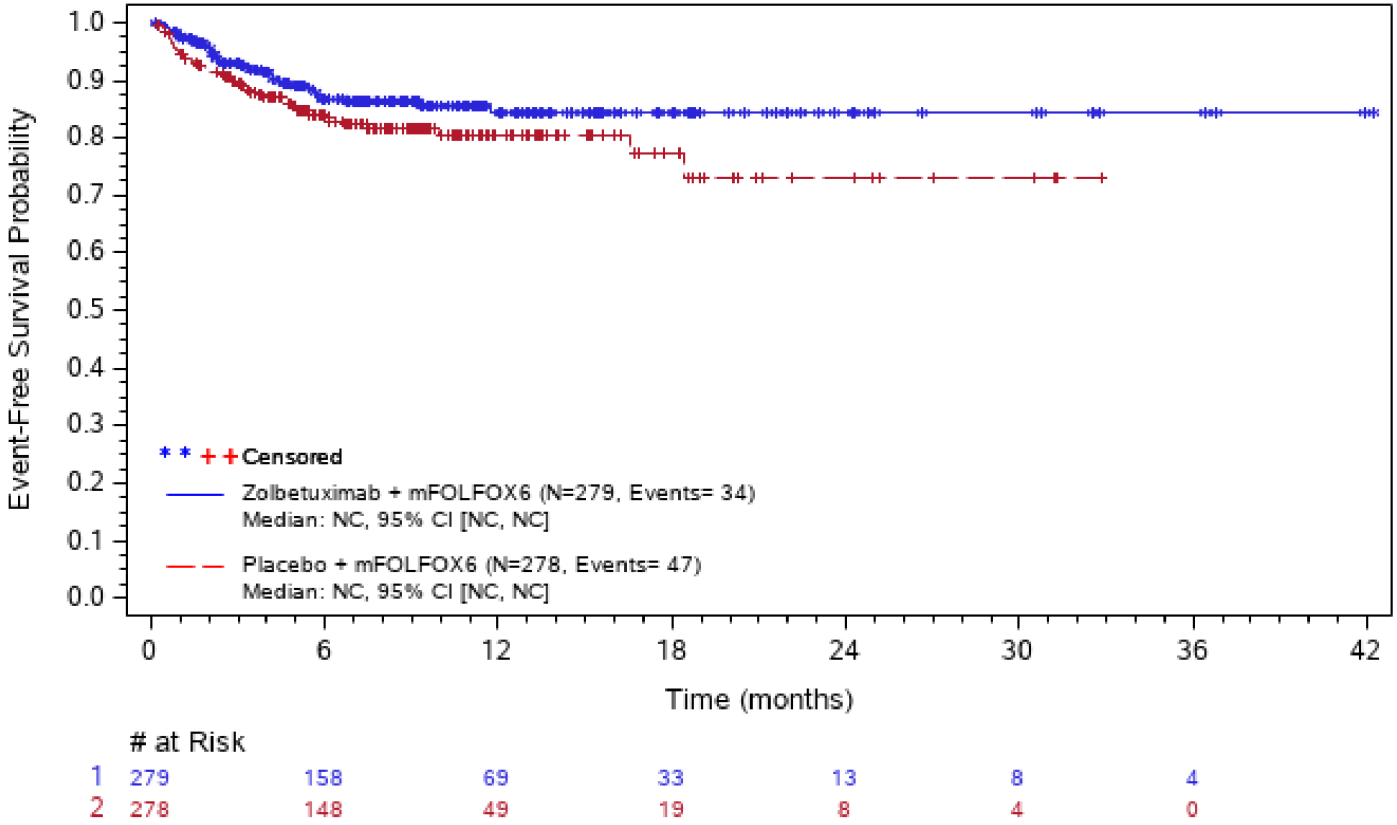
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.64: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Safety Analysis Set



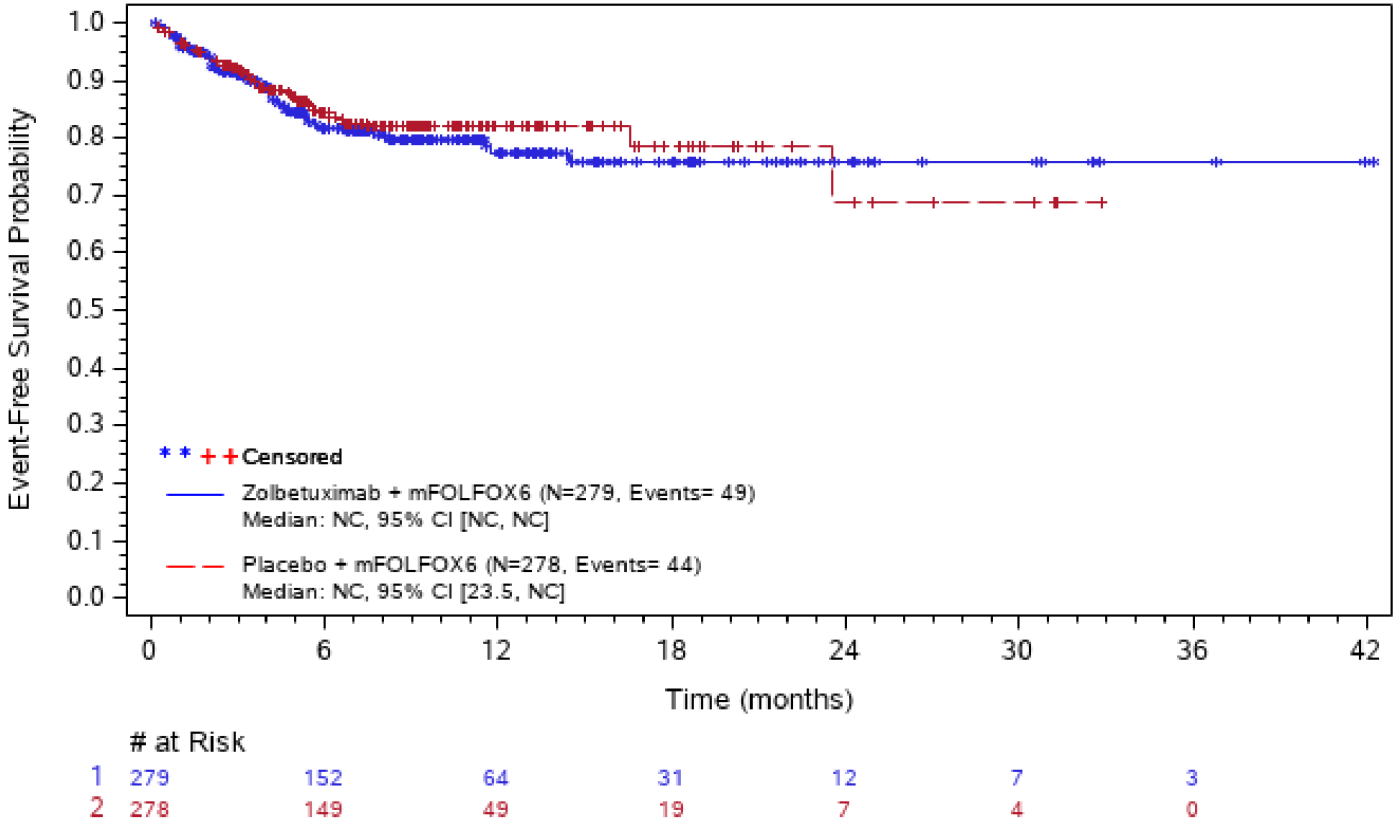
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.65: Kaplan-Meier Plot of Time to first TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set



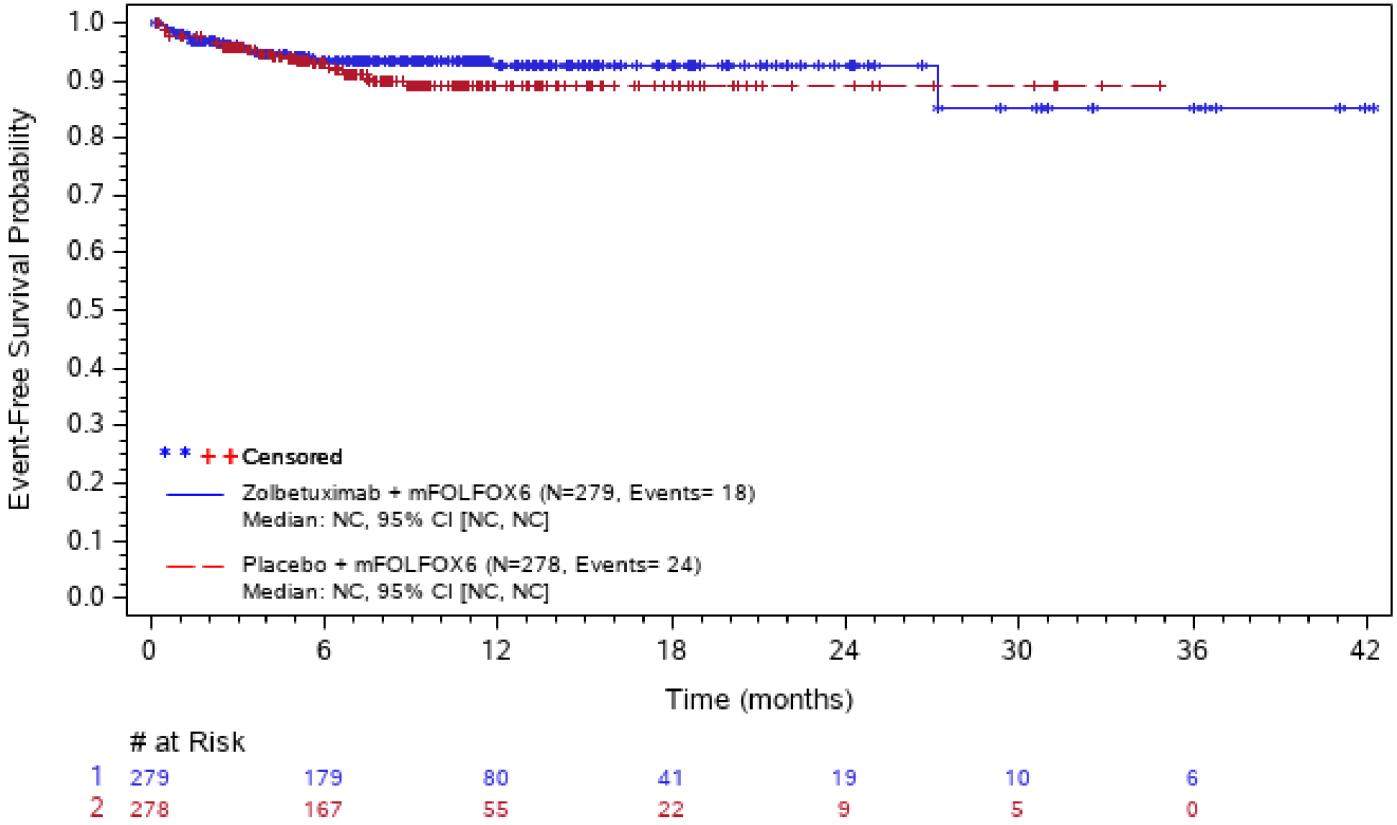
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.66: Kaplan-Meier Plot of Time to first TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



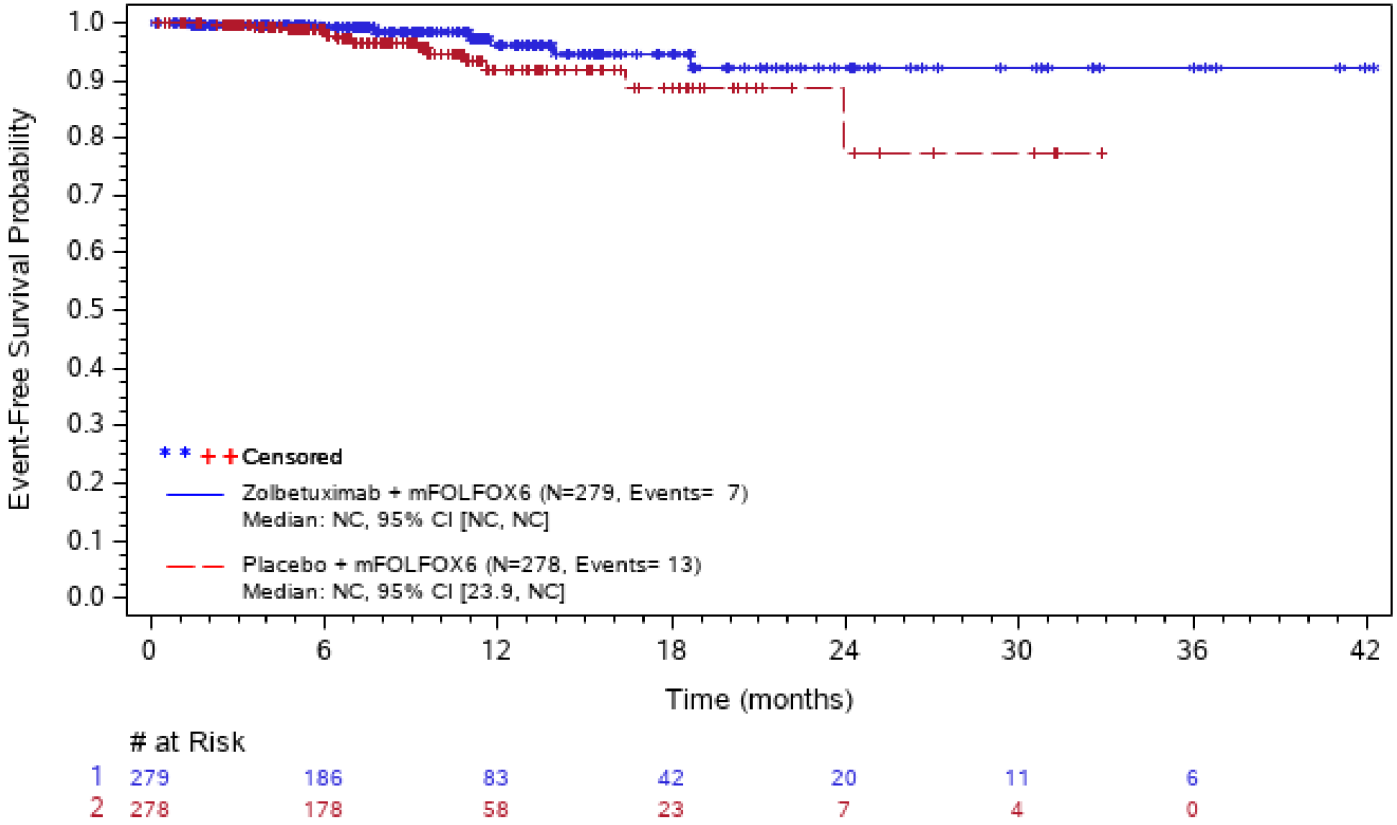
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.67: Kaplan-Meier Plot of Time to first TEAE - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set



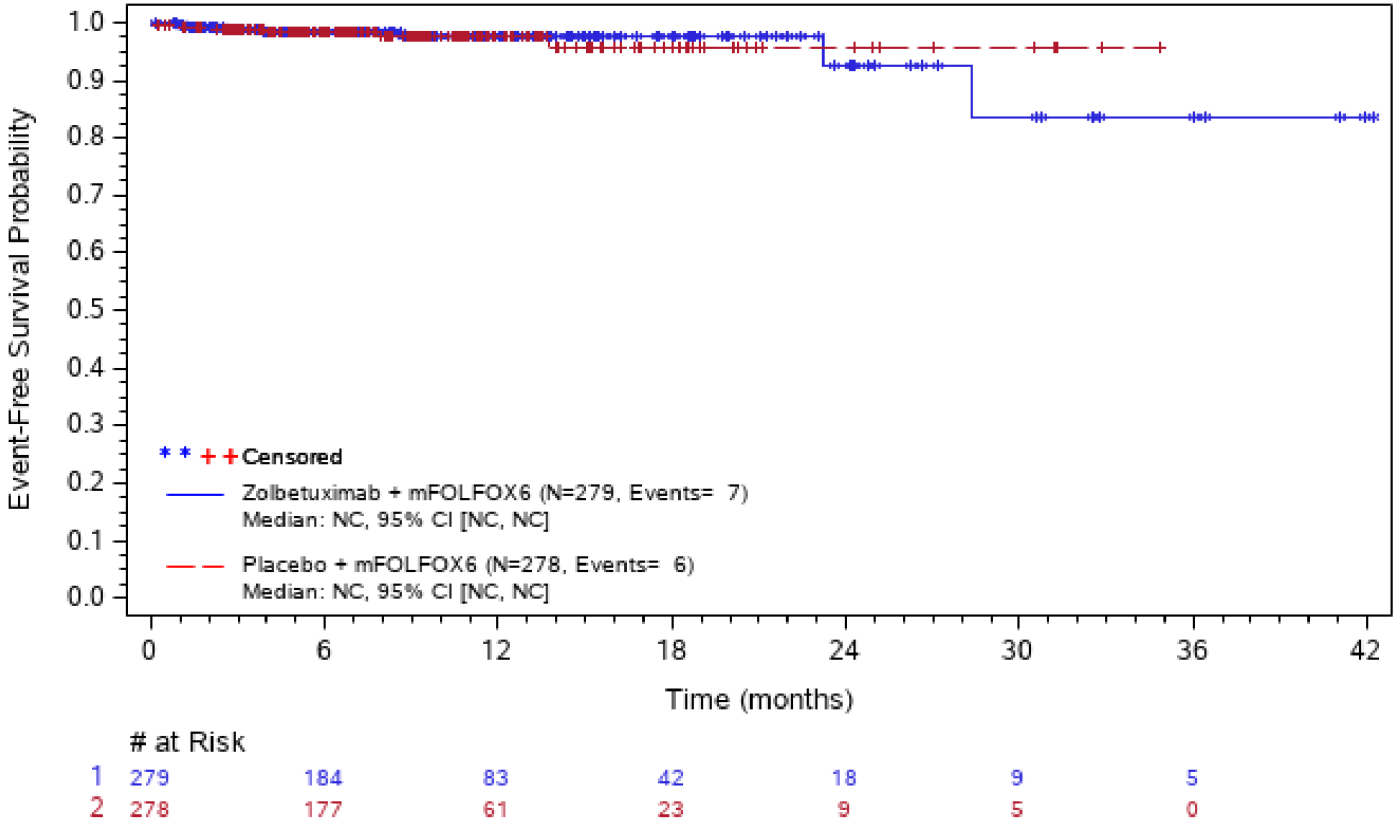
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.68: Kaplan-Meier Plot of Time to first TEAE - Blood Bilirubin Increased (PT) - Safety Analysis Set



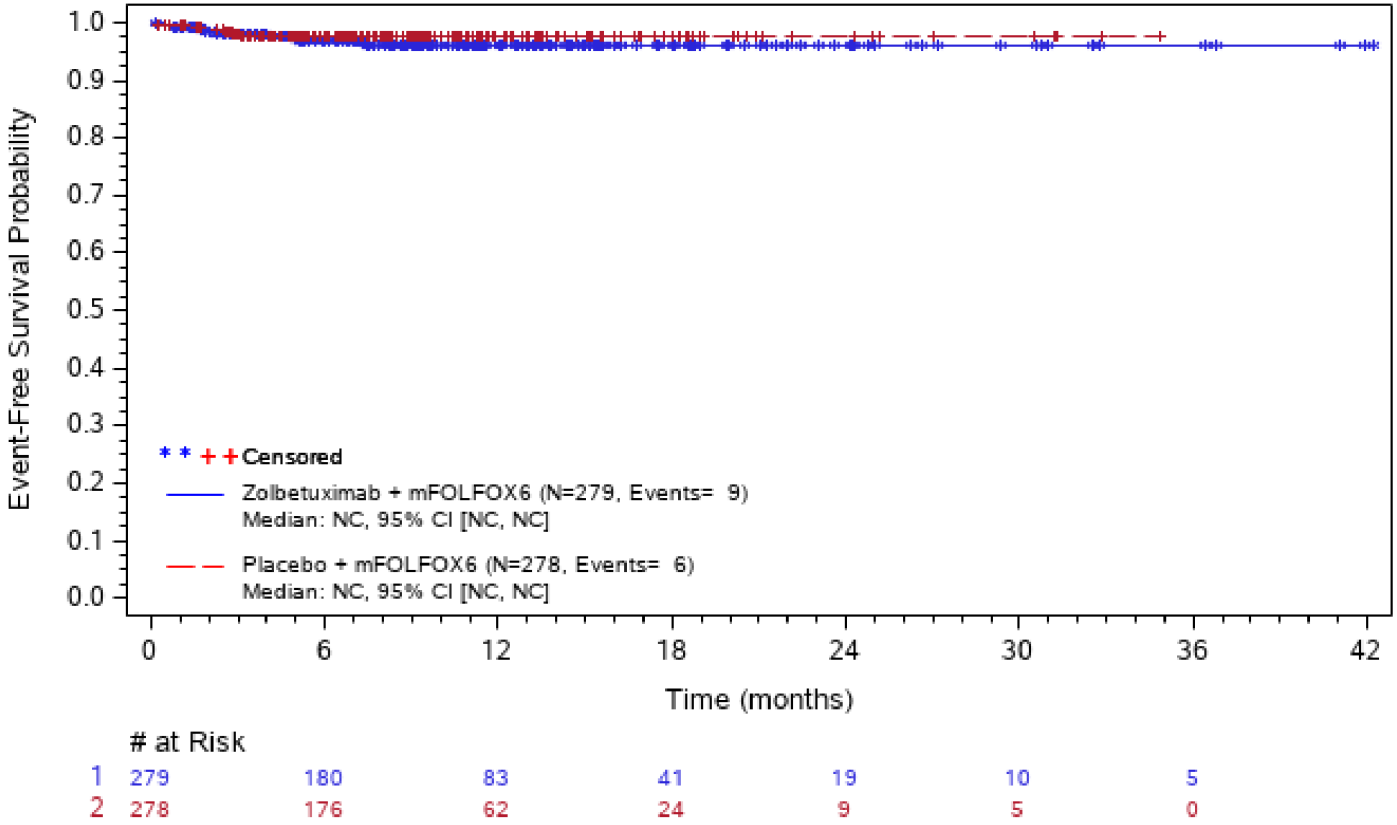
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.69: Kaplan-Meier Plot of Time to first TEAE - Blood Creatinine Increased (PT) - Safety Analysis Set



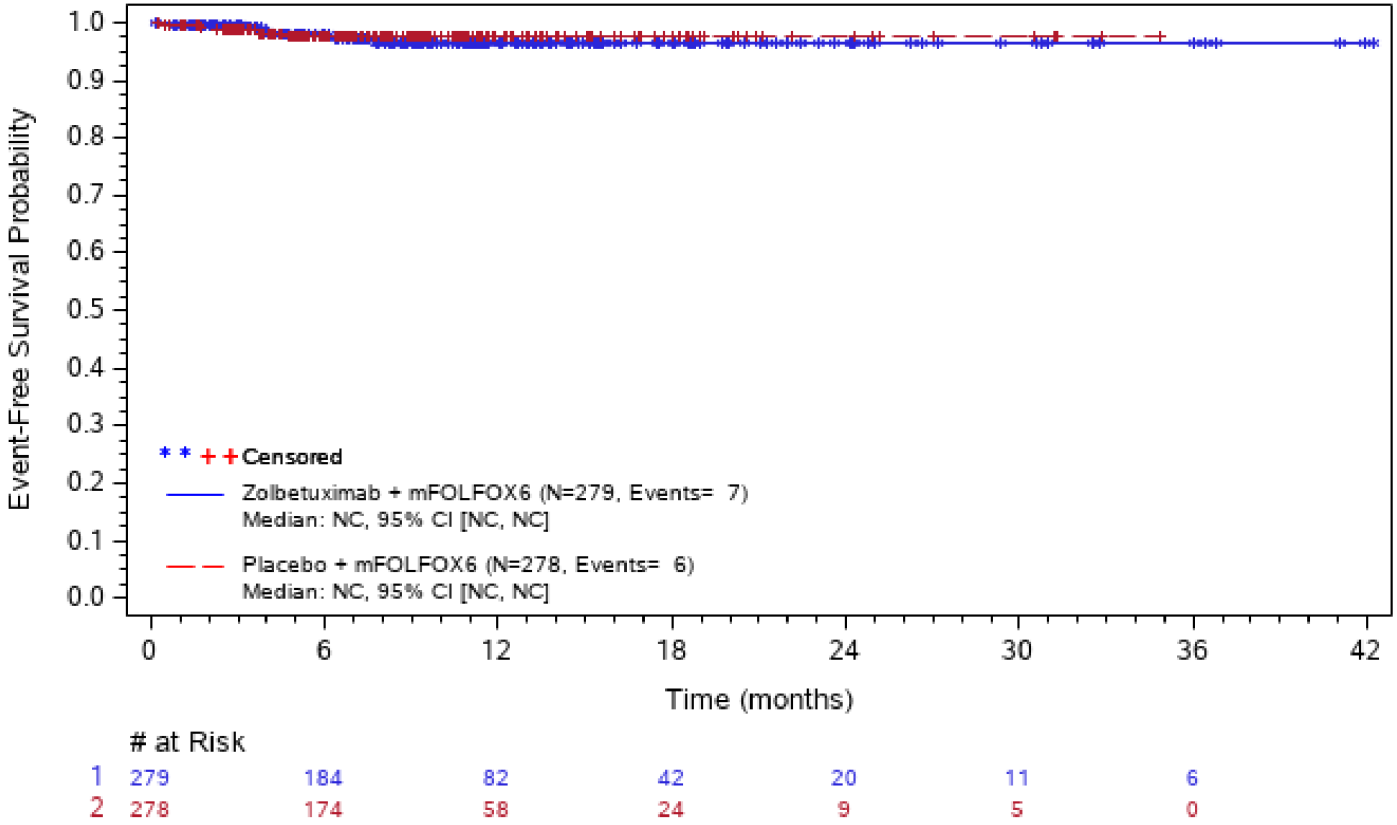
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.70: Kaplan-Meier Plot of Time to first TEAE - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set



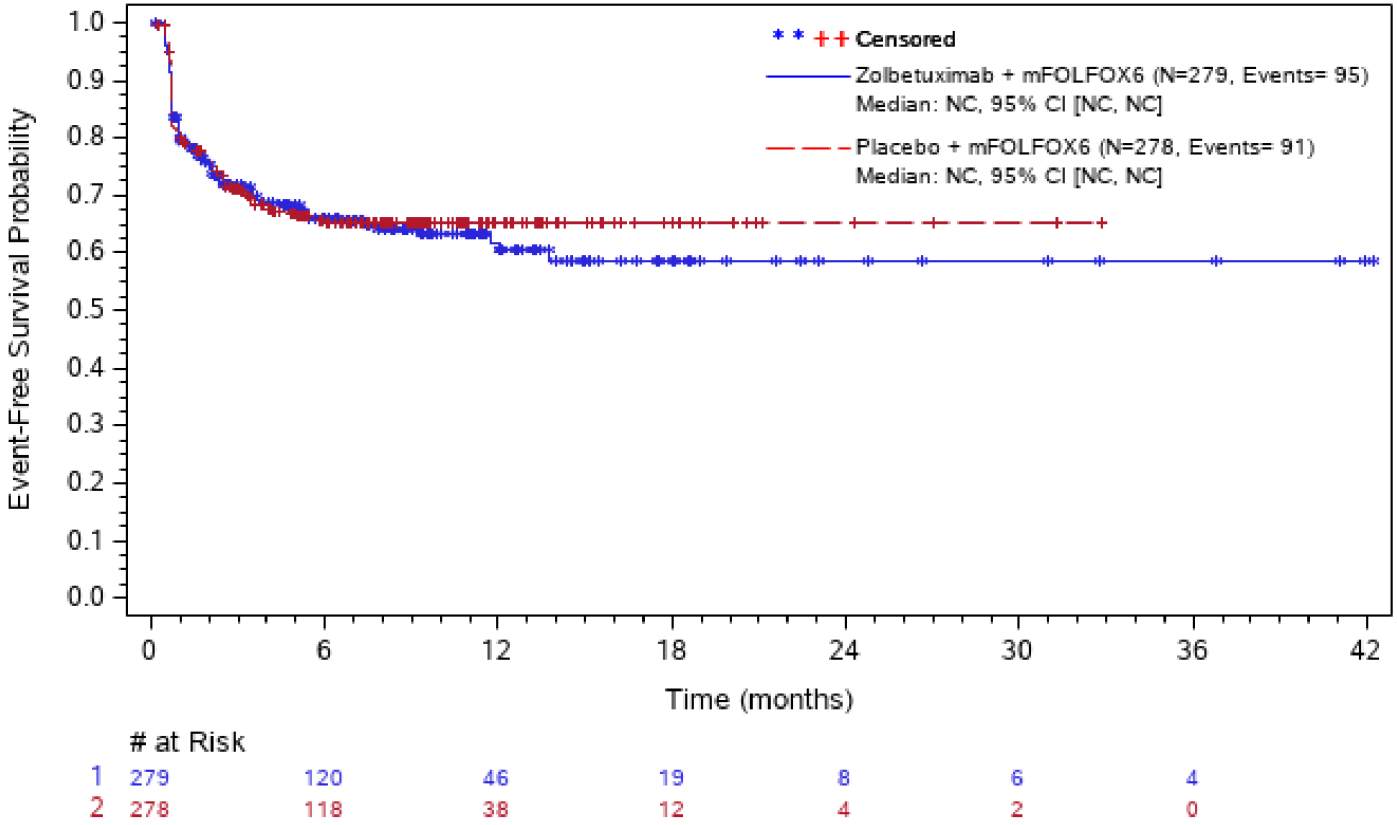
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.71: Kaplan-Meier Plot of Time to first TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



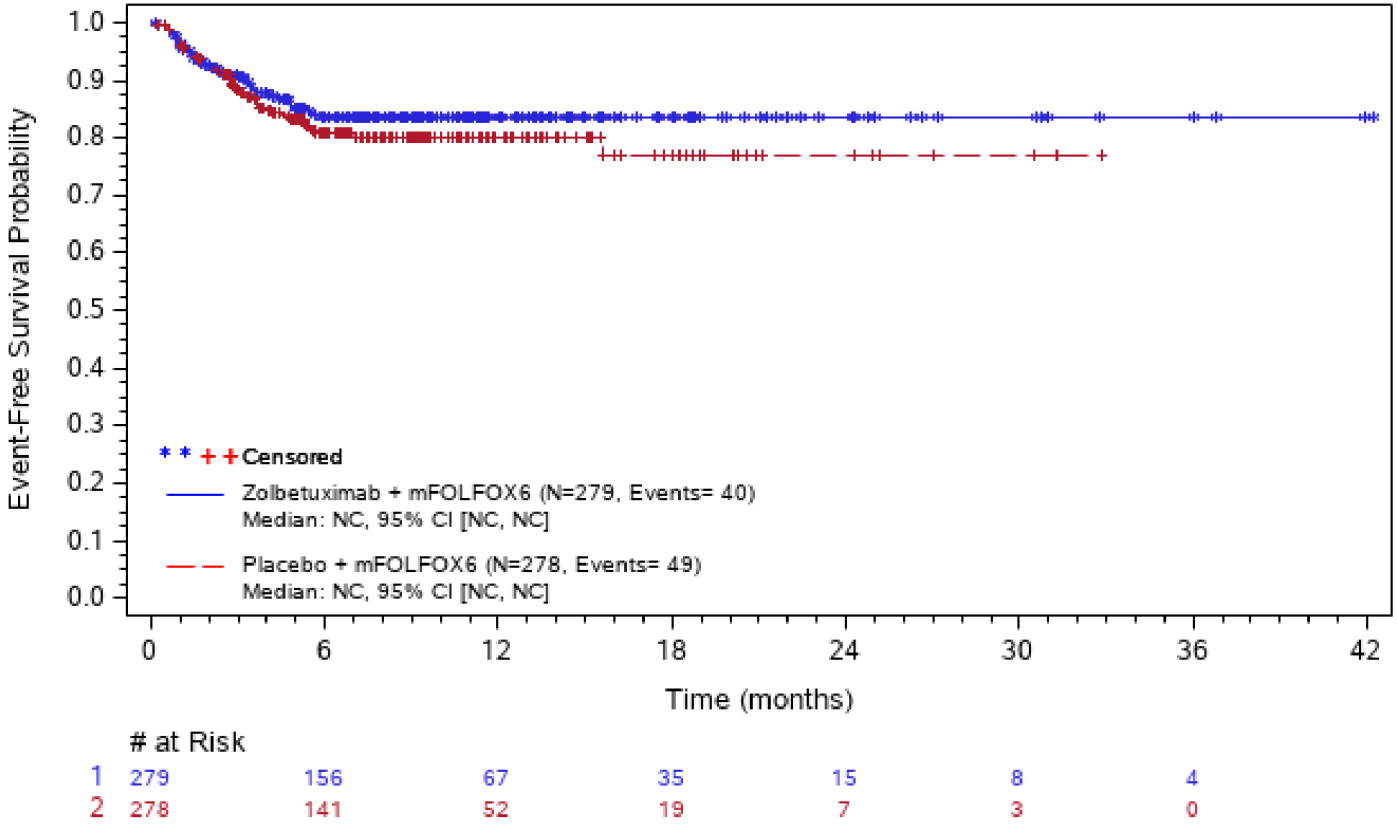
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.72: Kaplan-Meier Plot of Time to first TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



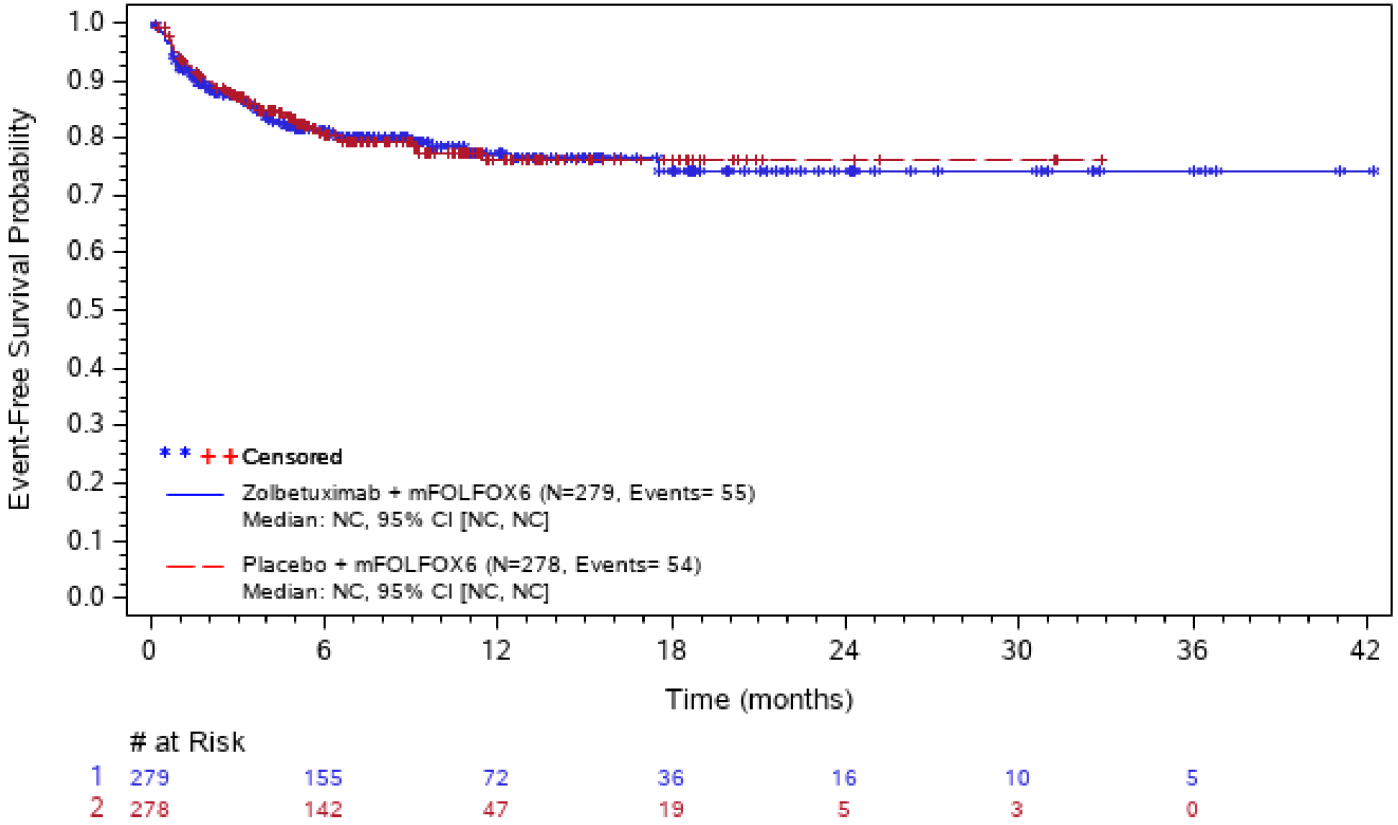
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.73: Kaplan-Meier Plot of Time to first TEAE - Platelet Count Decreased (PT) - Safety Analysis Set



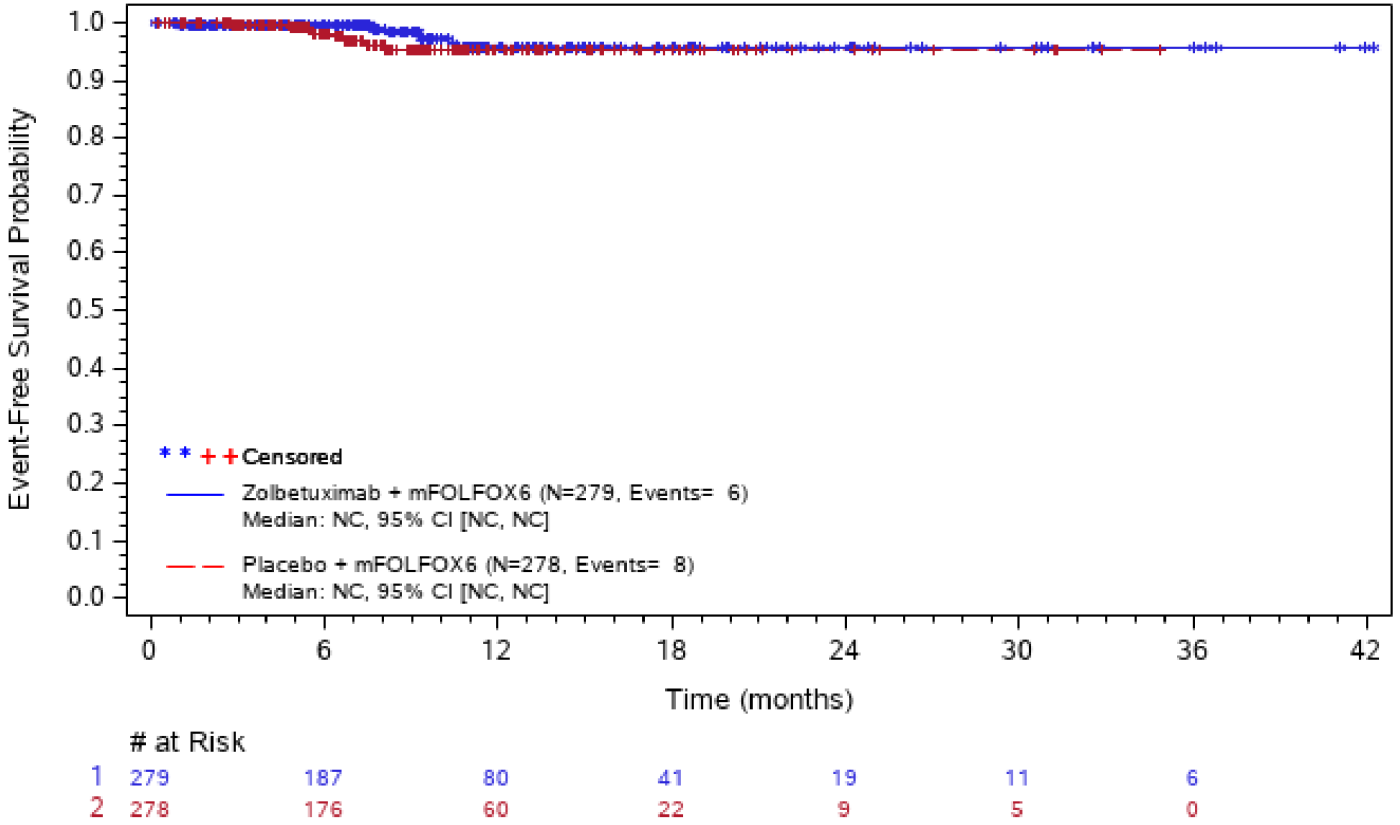
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.74: Kaplan-Meier Plot of Time to first TEAE - Weight Decreased (PT) - Safety Analysis Set



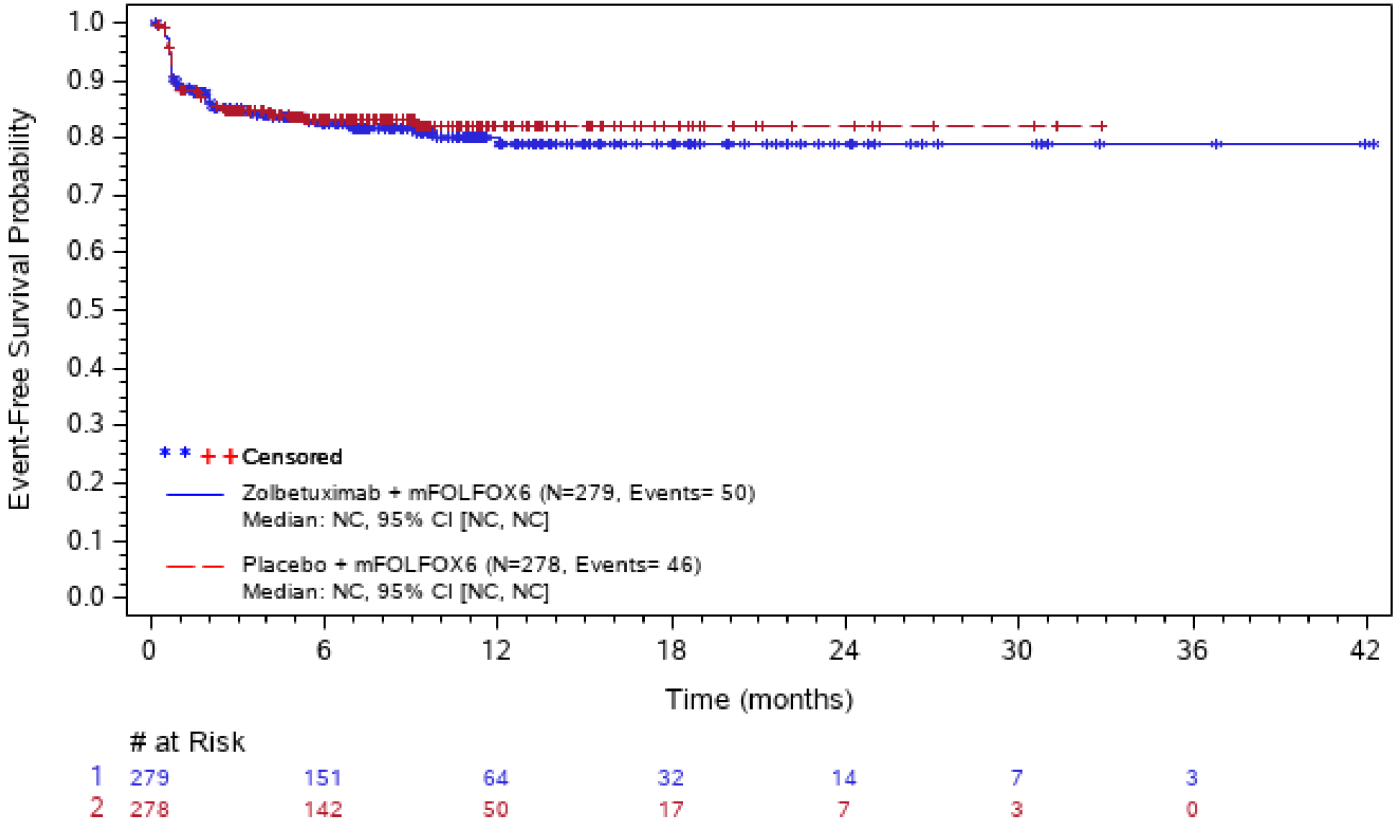
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.75: Kaplan-Meier Plot of Time to first TEAE - Weight Increased (PT) - Safety Analysis Set



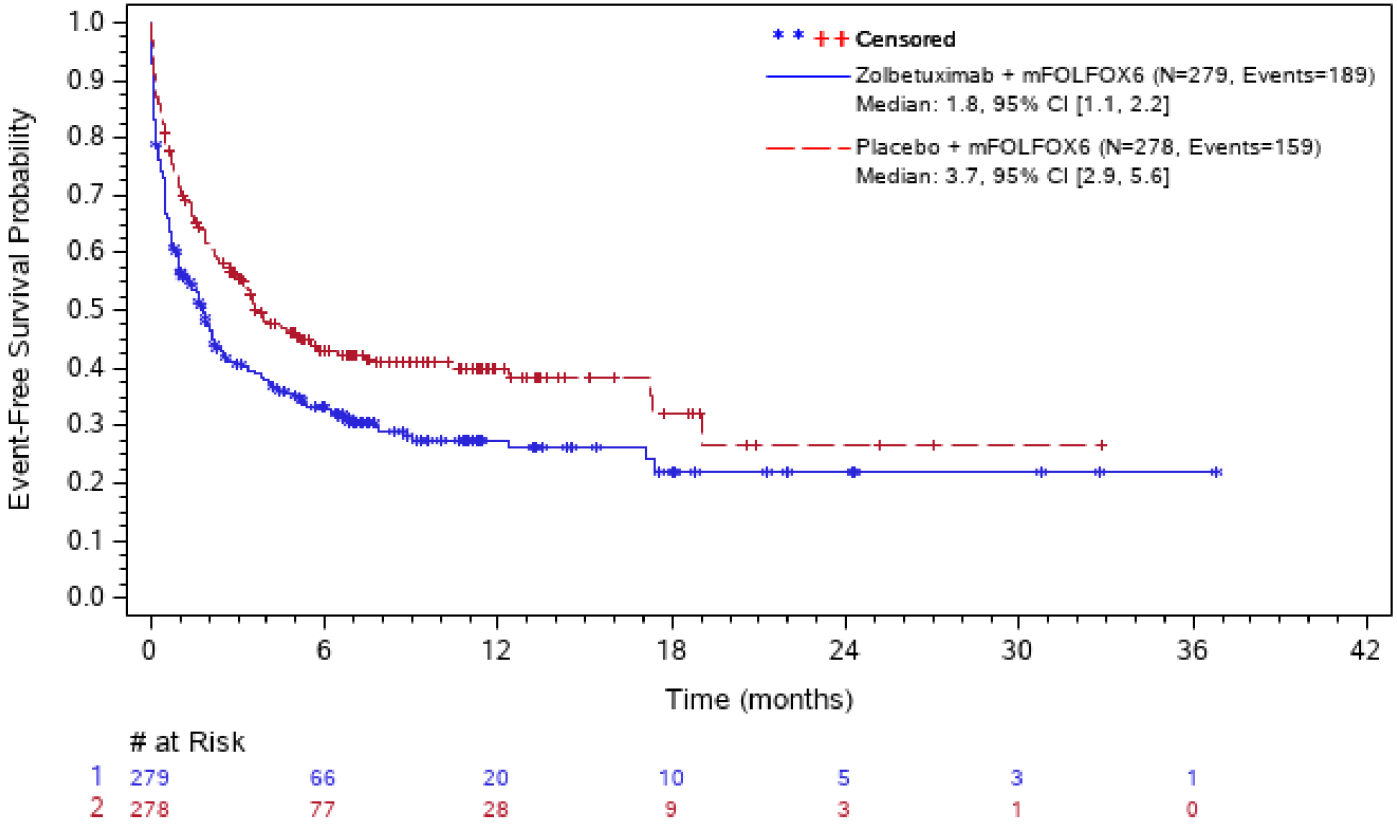
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.76: Kaplan-Meier Plot of Time to first TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set



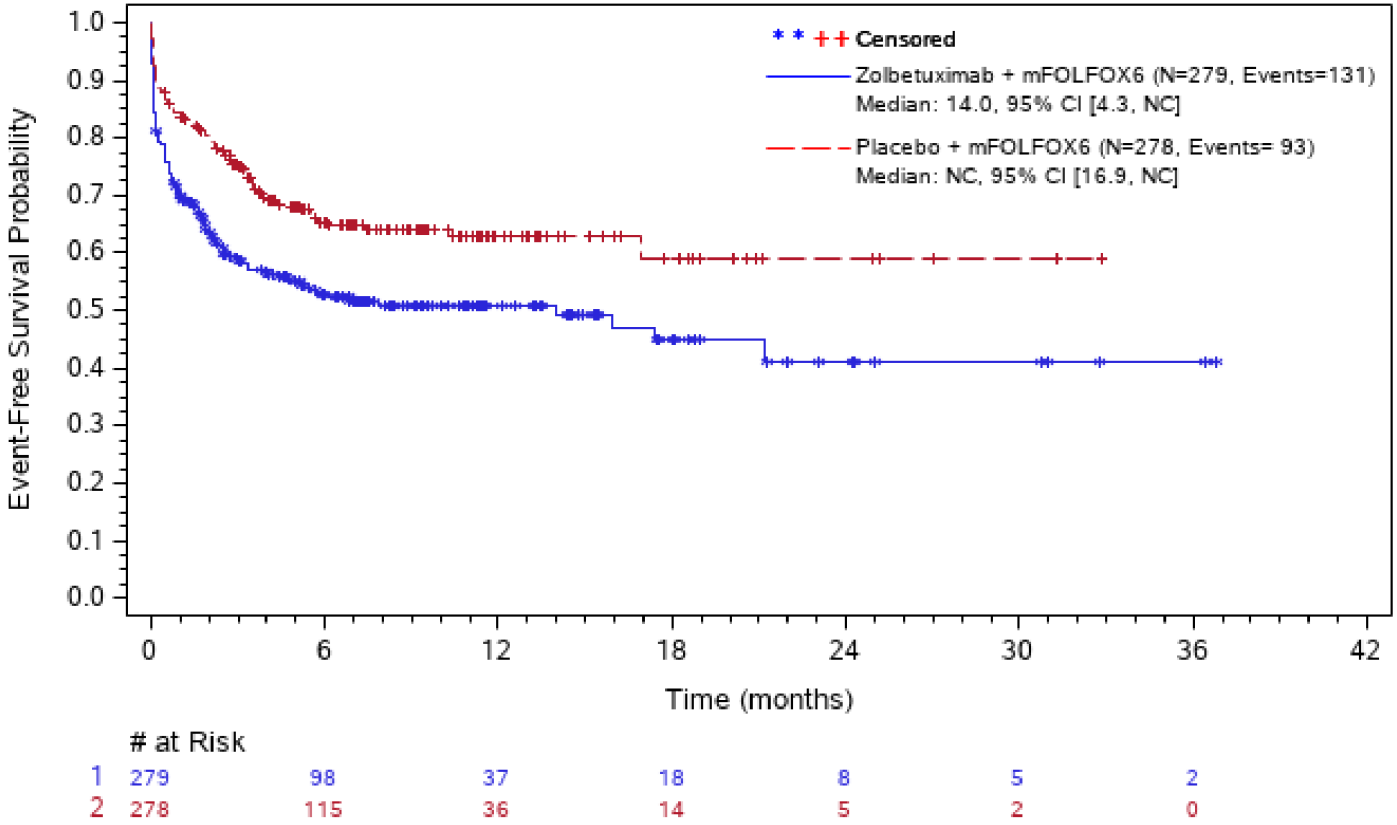
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.77: Kaplan-Meier Plot of Time to first TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



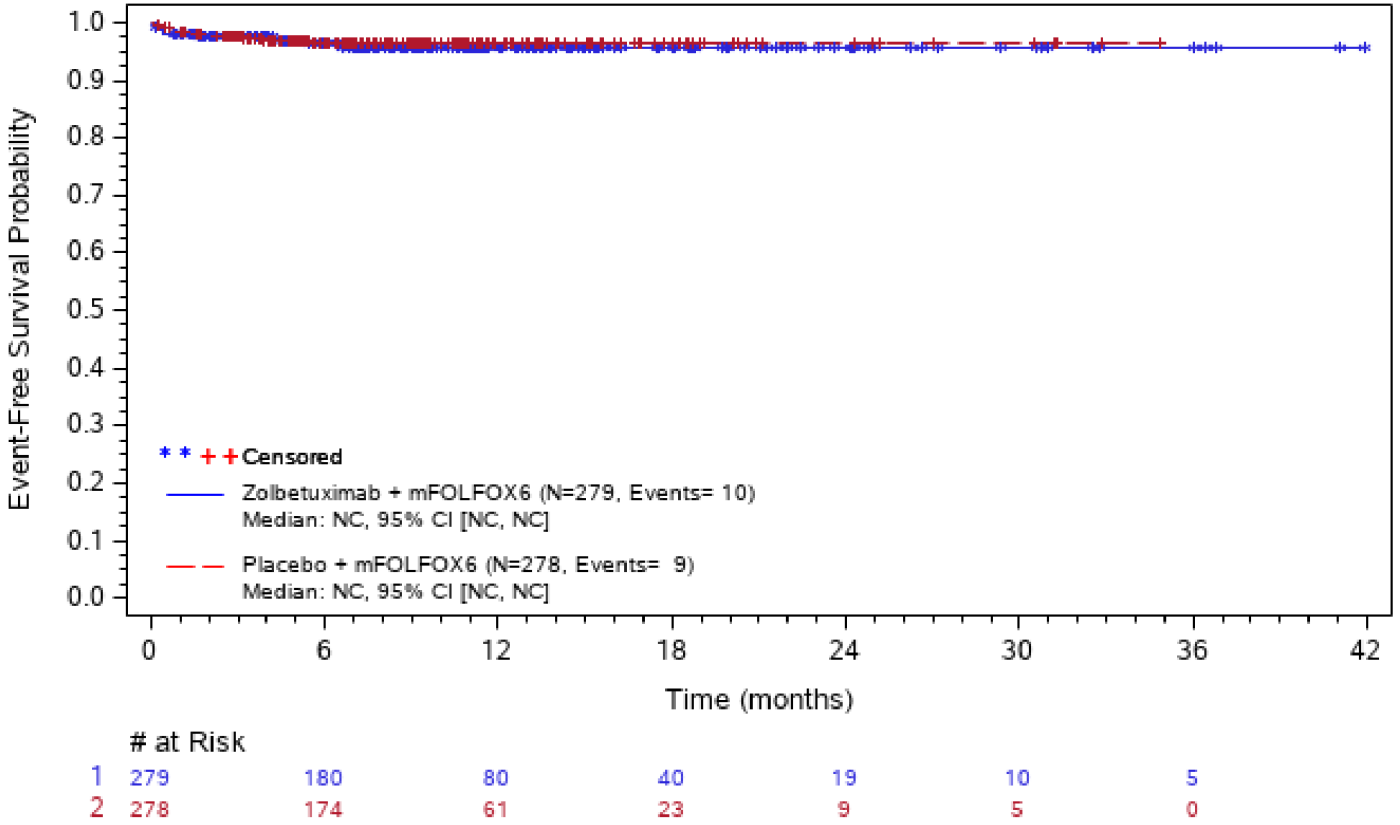
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.78: Kaplan-Meier Plot of Time to first TEAE - Decreased Appetite (PT) - Safety Analysis Set



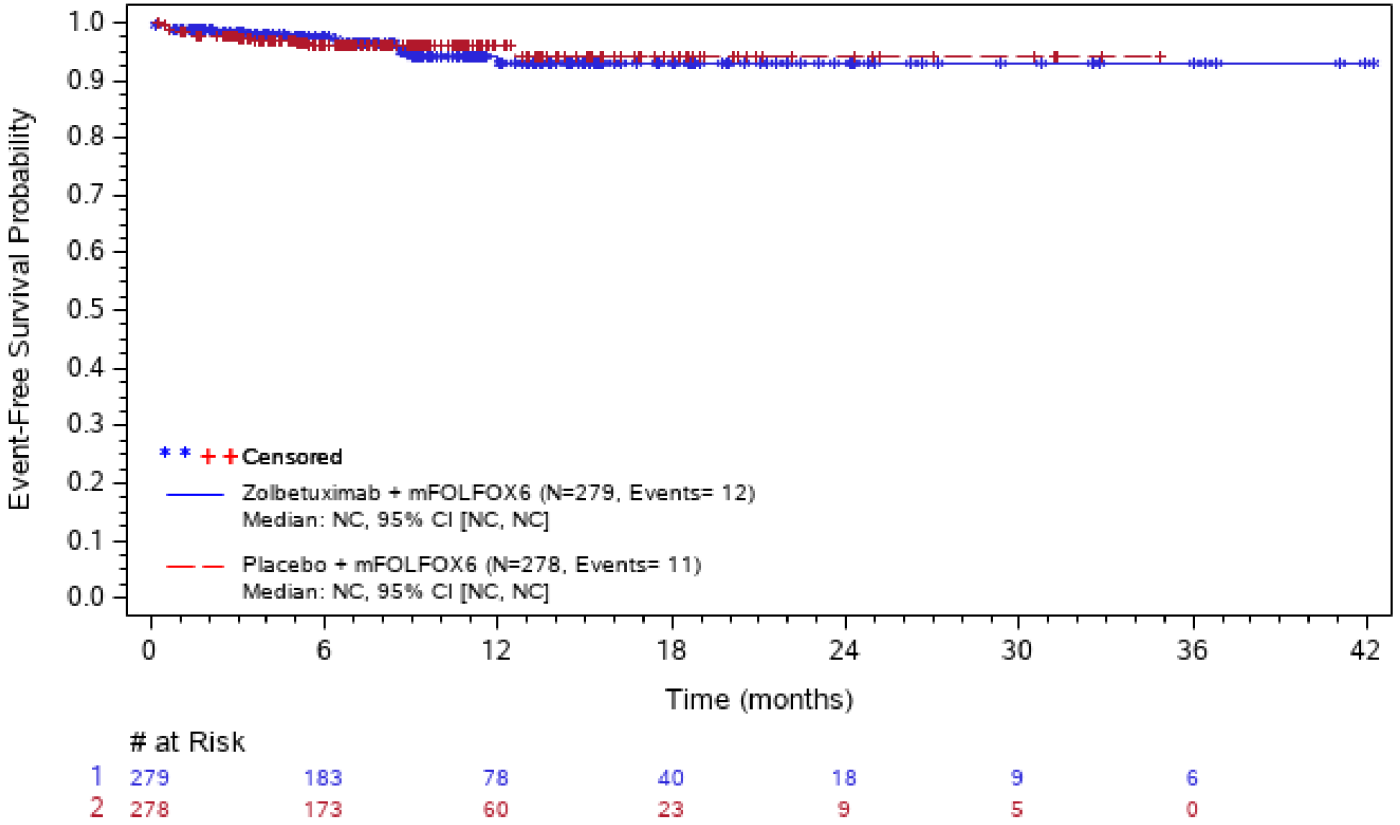
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.79: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Safety Analysis Set



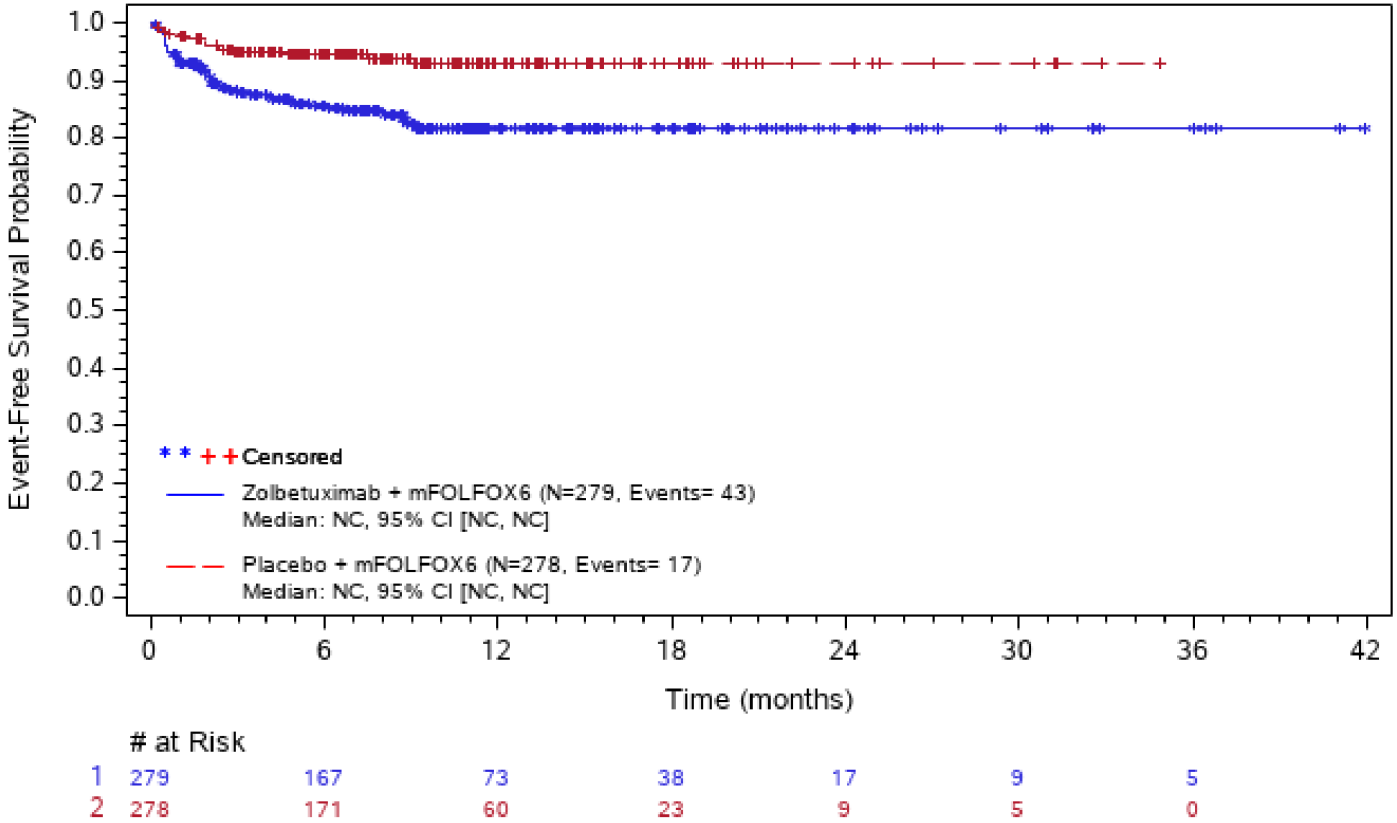
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.80: Kaplan-Meier Plot of Time to first TEAE - Hyperglycaemia (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: 09SEP22

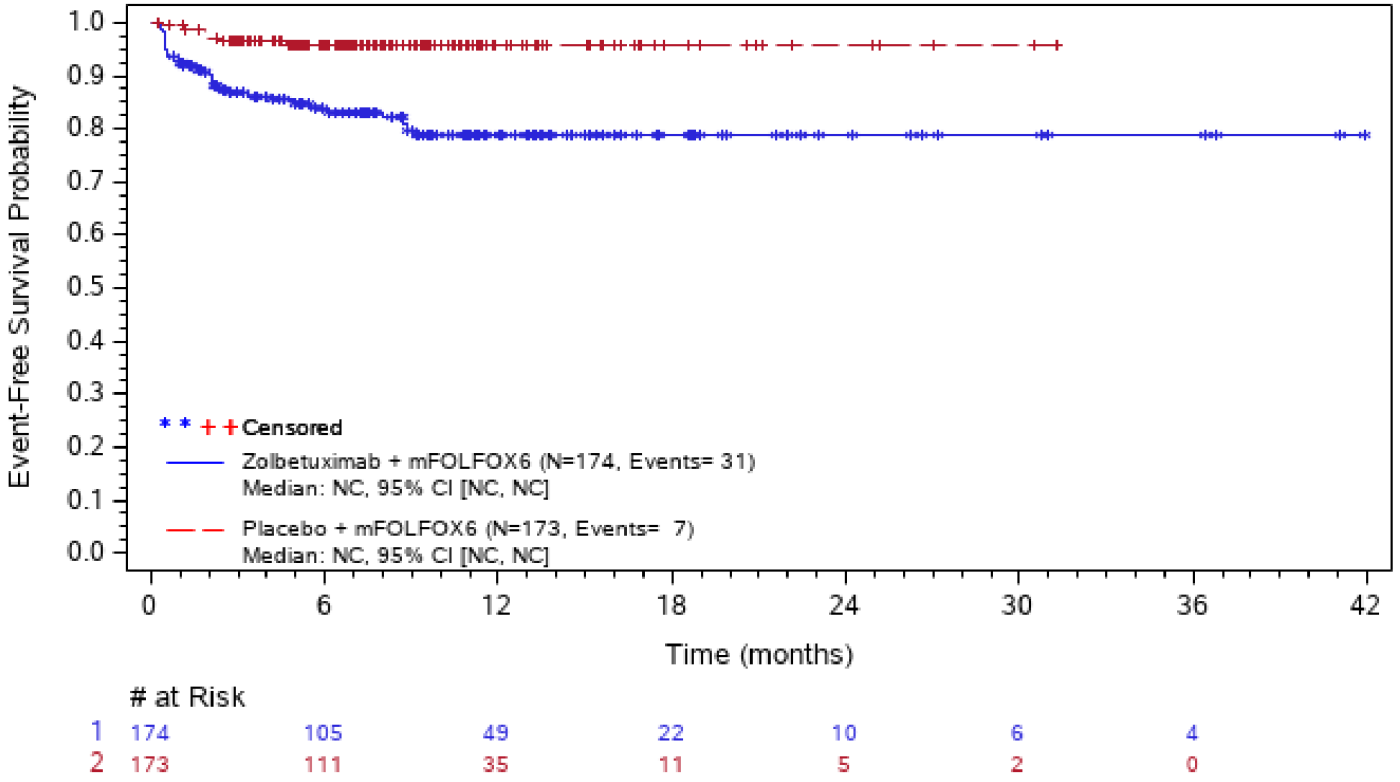
Figure 301.1.2001.81: Kaplan-Meier Plot of Time to first TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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: 09SEP22

Figure 301.1.2001.81.2: Kaplan-Meier Plot of Time to first TEAE by Sex - Hypoalbuminaemia (PT) - Safety Analysis Set

Sex: Male

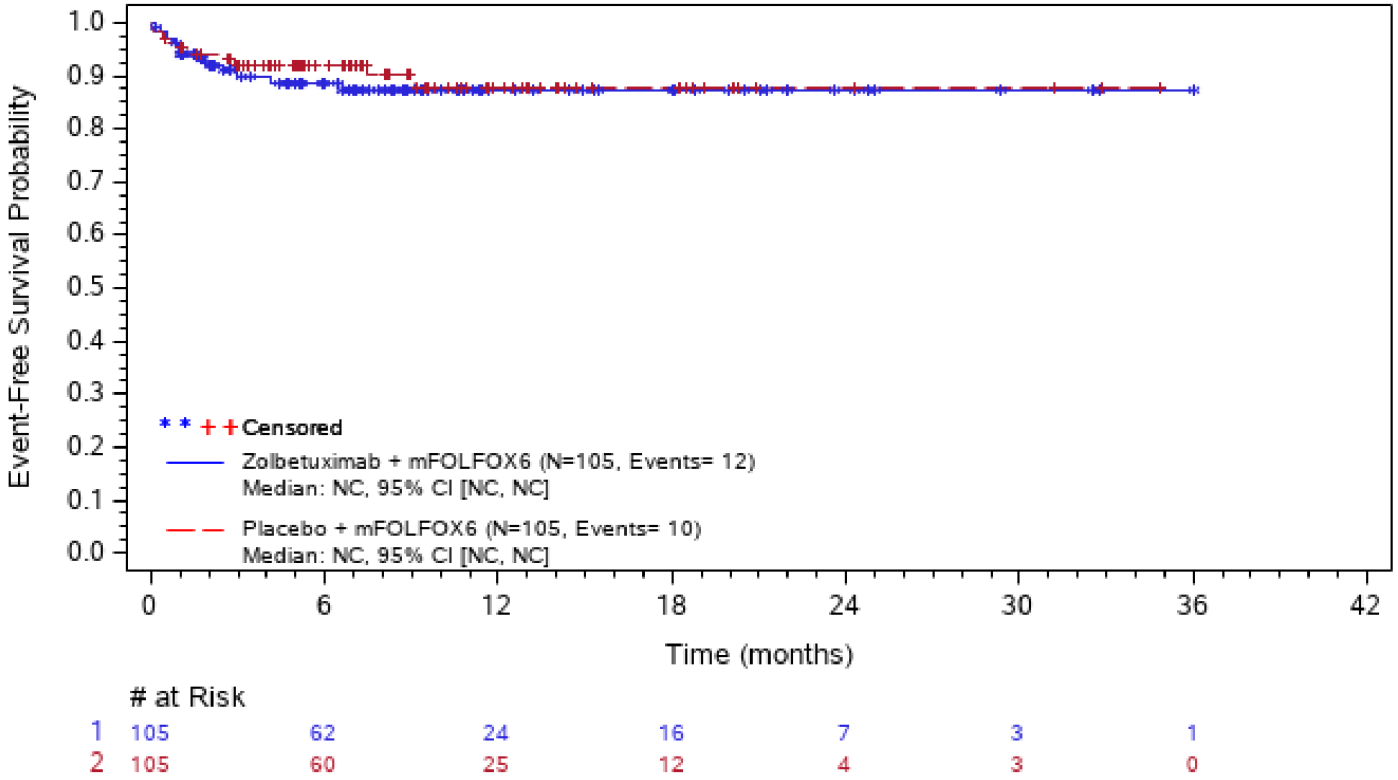


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.81.2: Kaplan-Meier Plot of Time to first TEAE by Sex - Hypoalbuminaemia (PT) - Safety Analysis Set

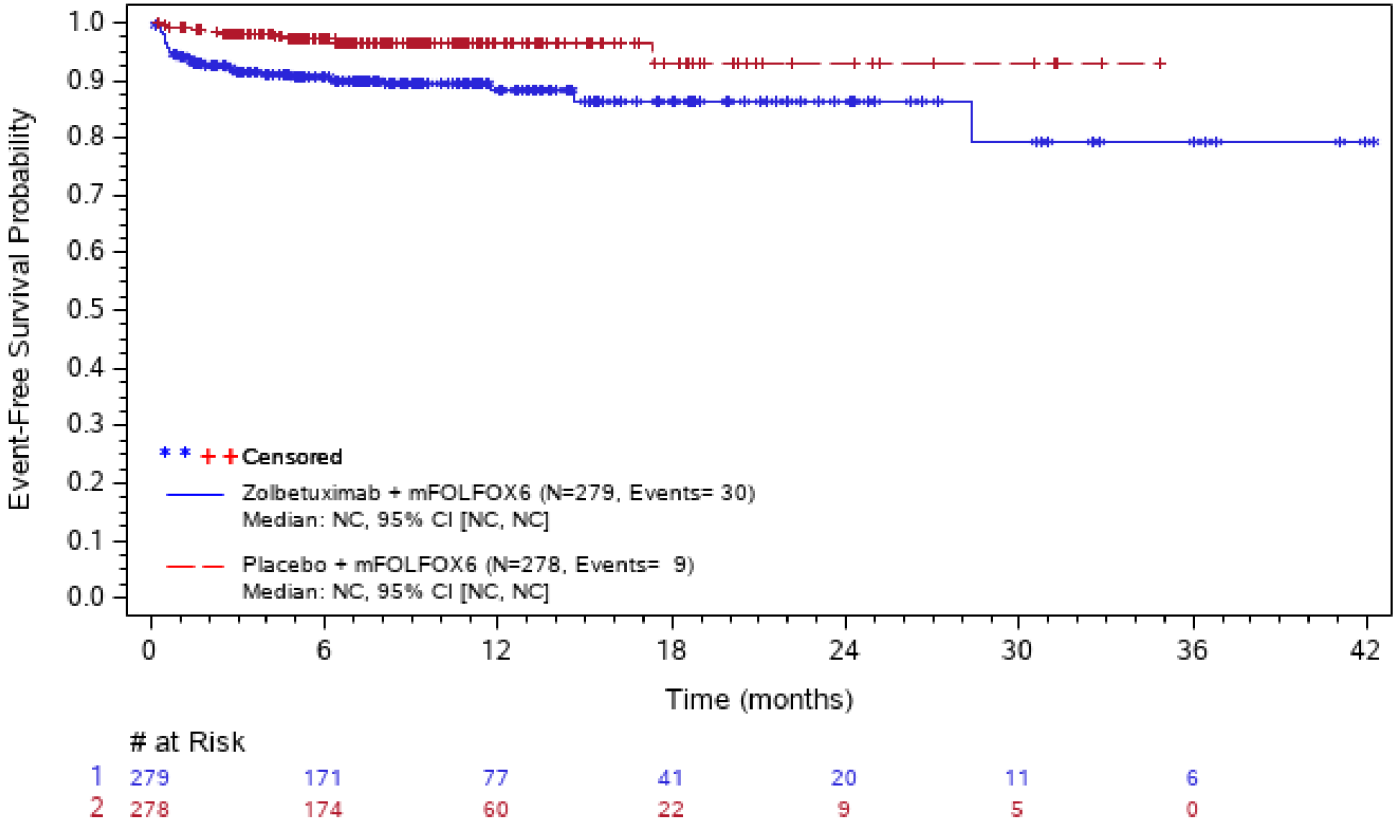
Sex: Female



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.

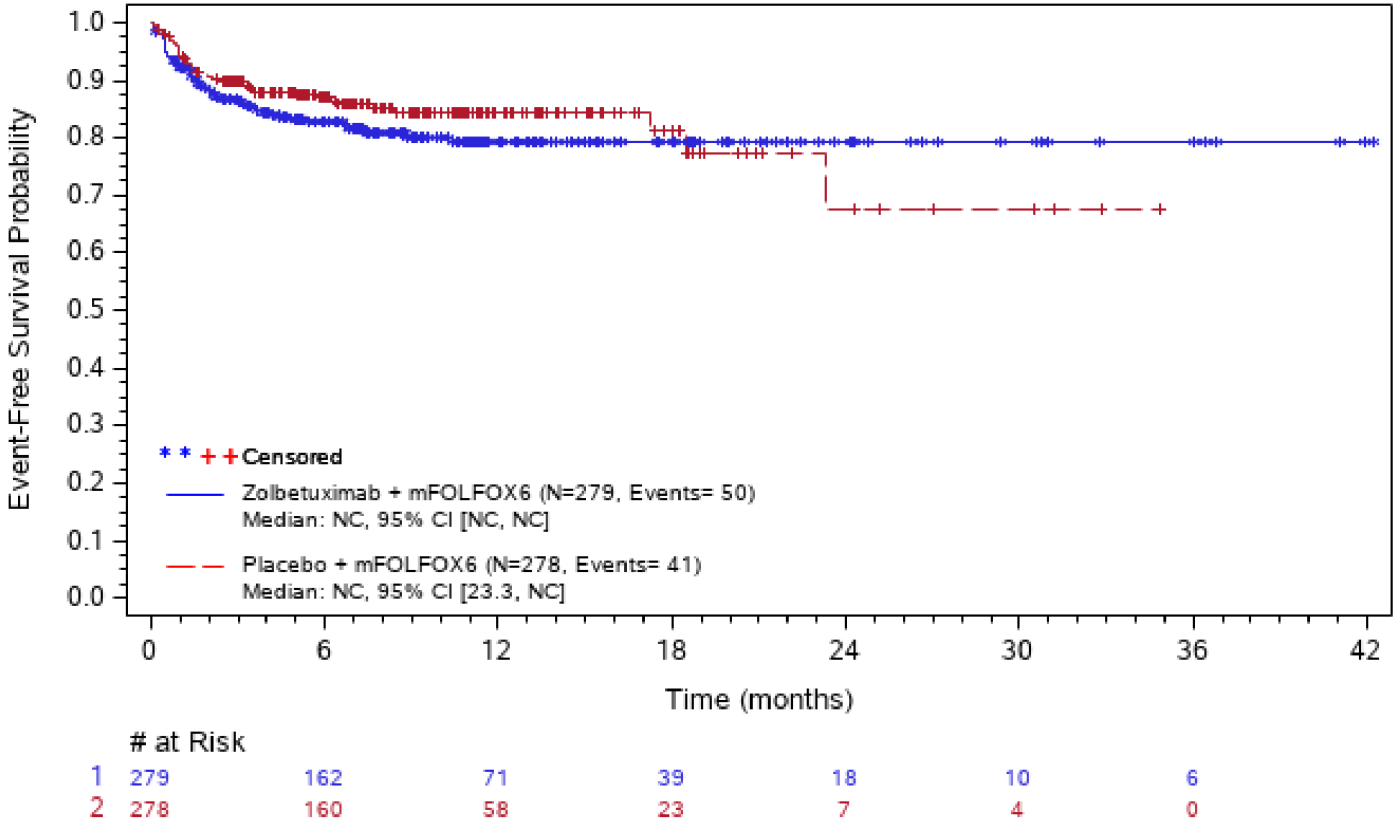
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.82: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Safety Analysis Set



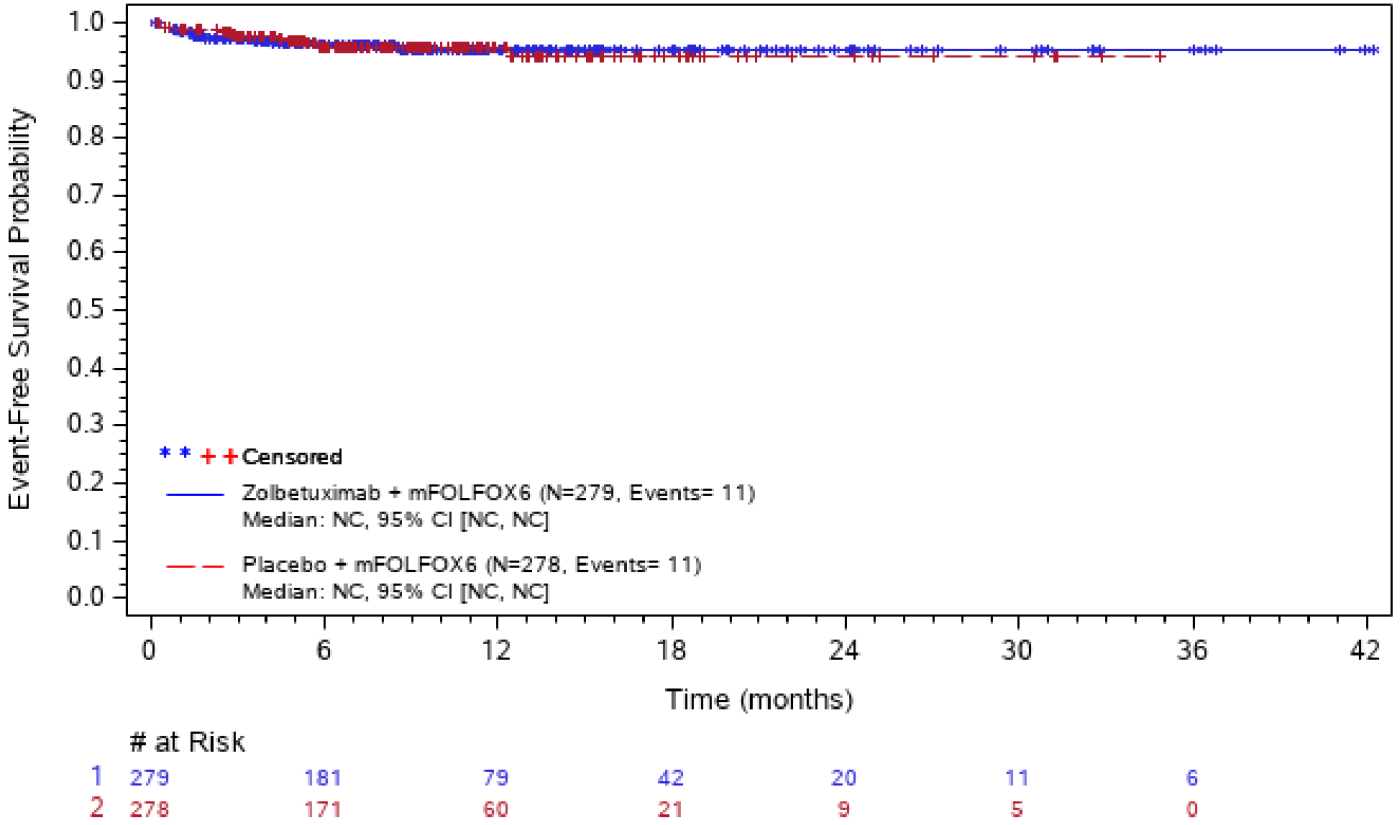
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.83: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Safety Analysis Set



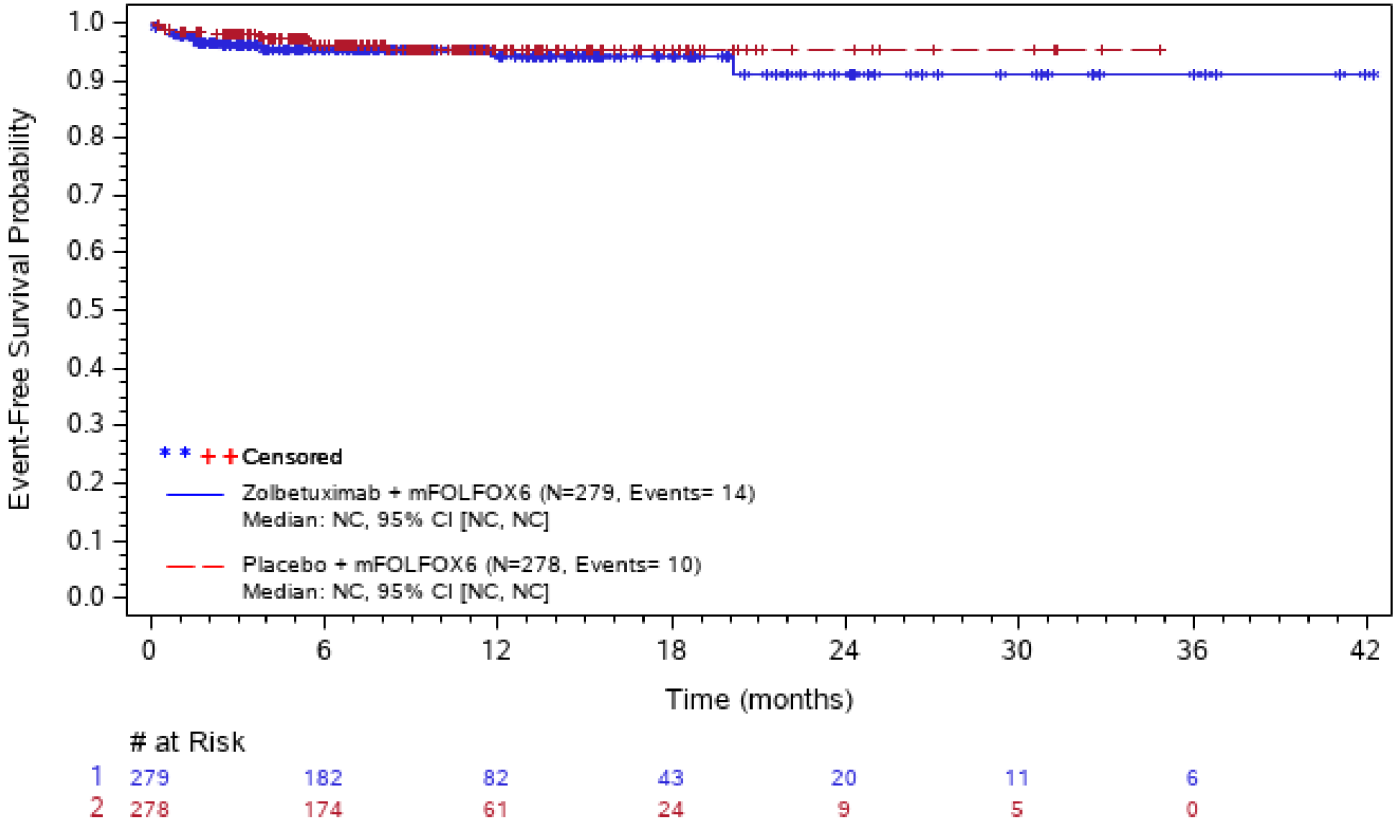
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.84: Kaplan-Meier Plot of Time to first TEAE - Hypomagnesaemia (PT) - Safety Analysis Set



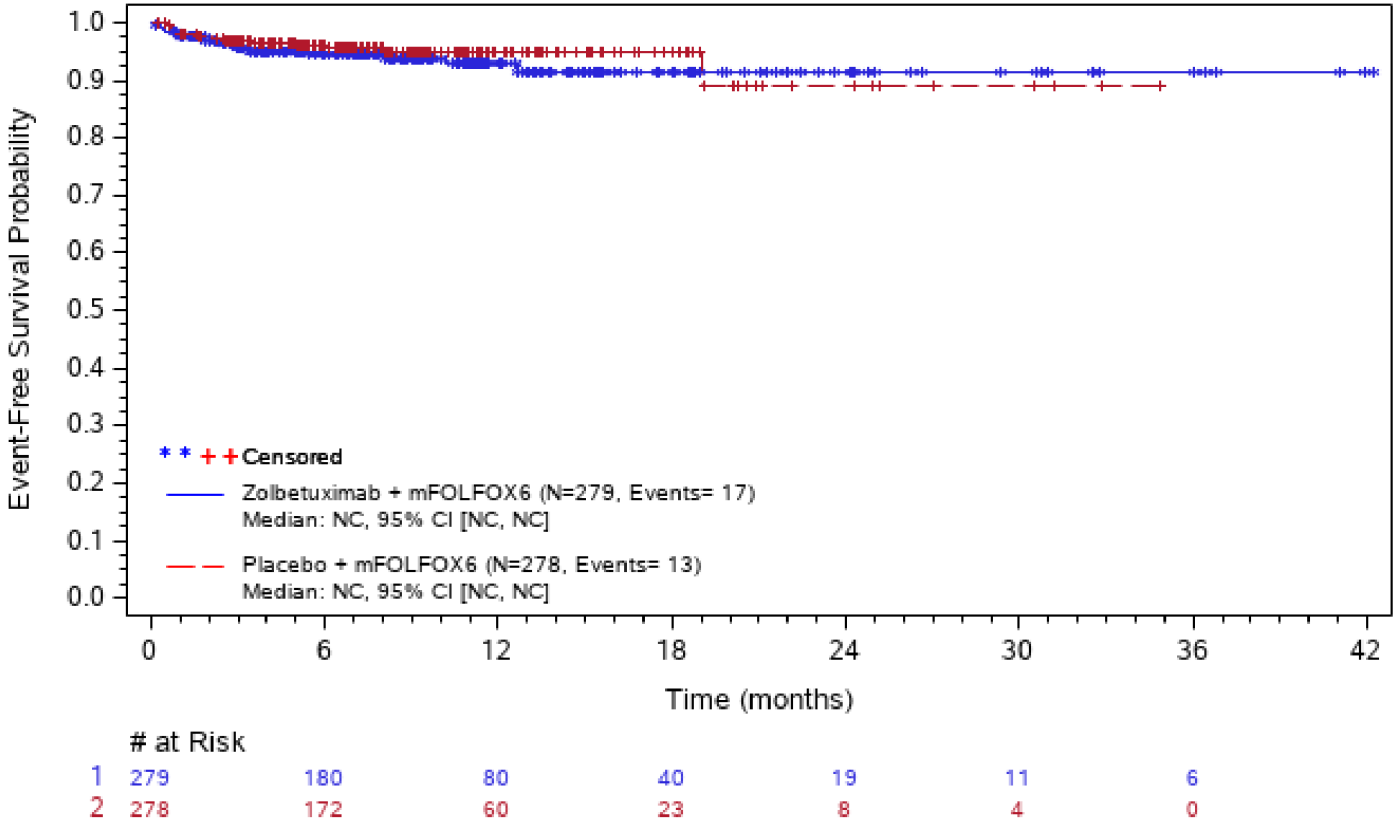
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.85: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Safety Analysis Set



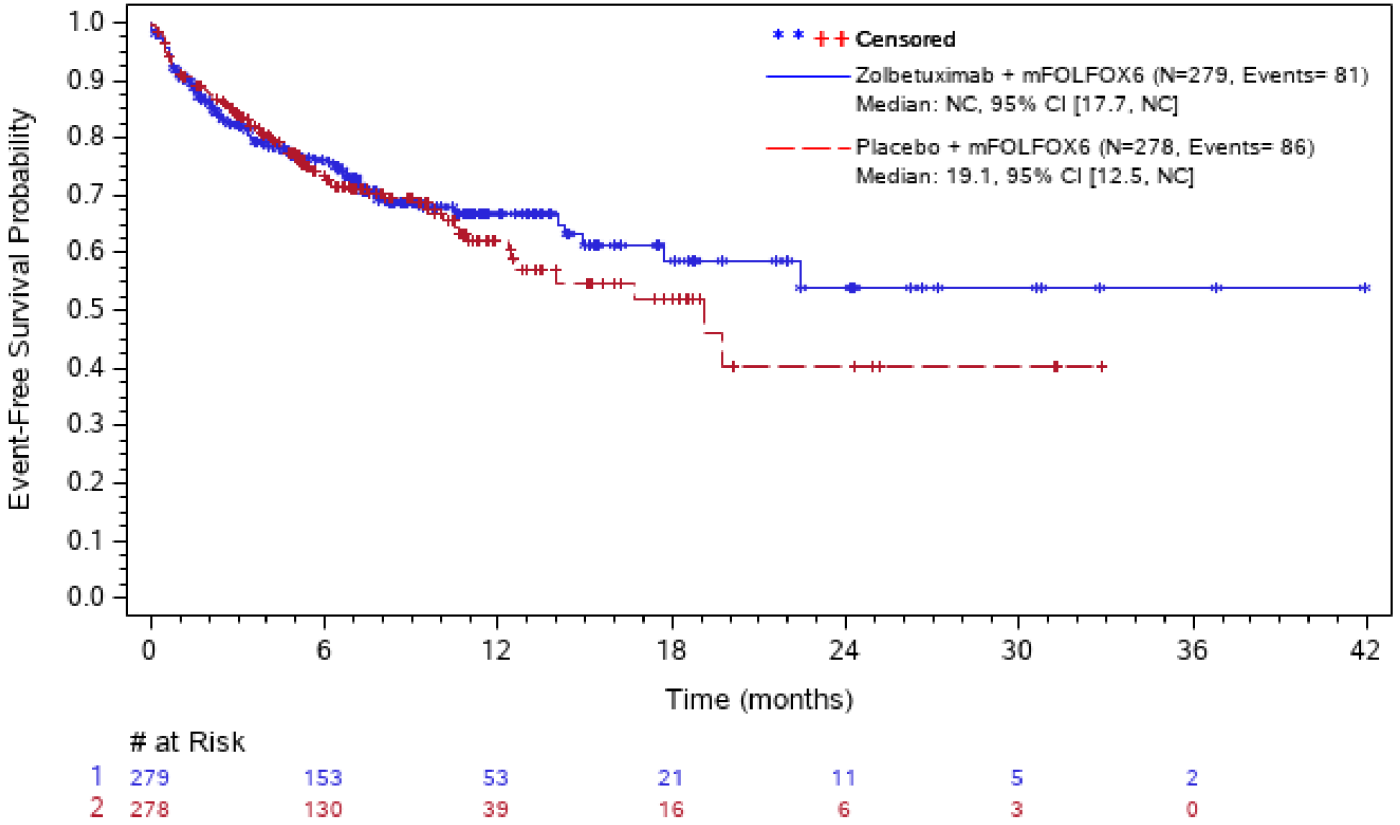
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.86: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Safety Analysis Set



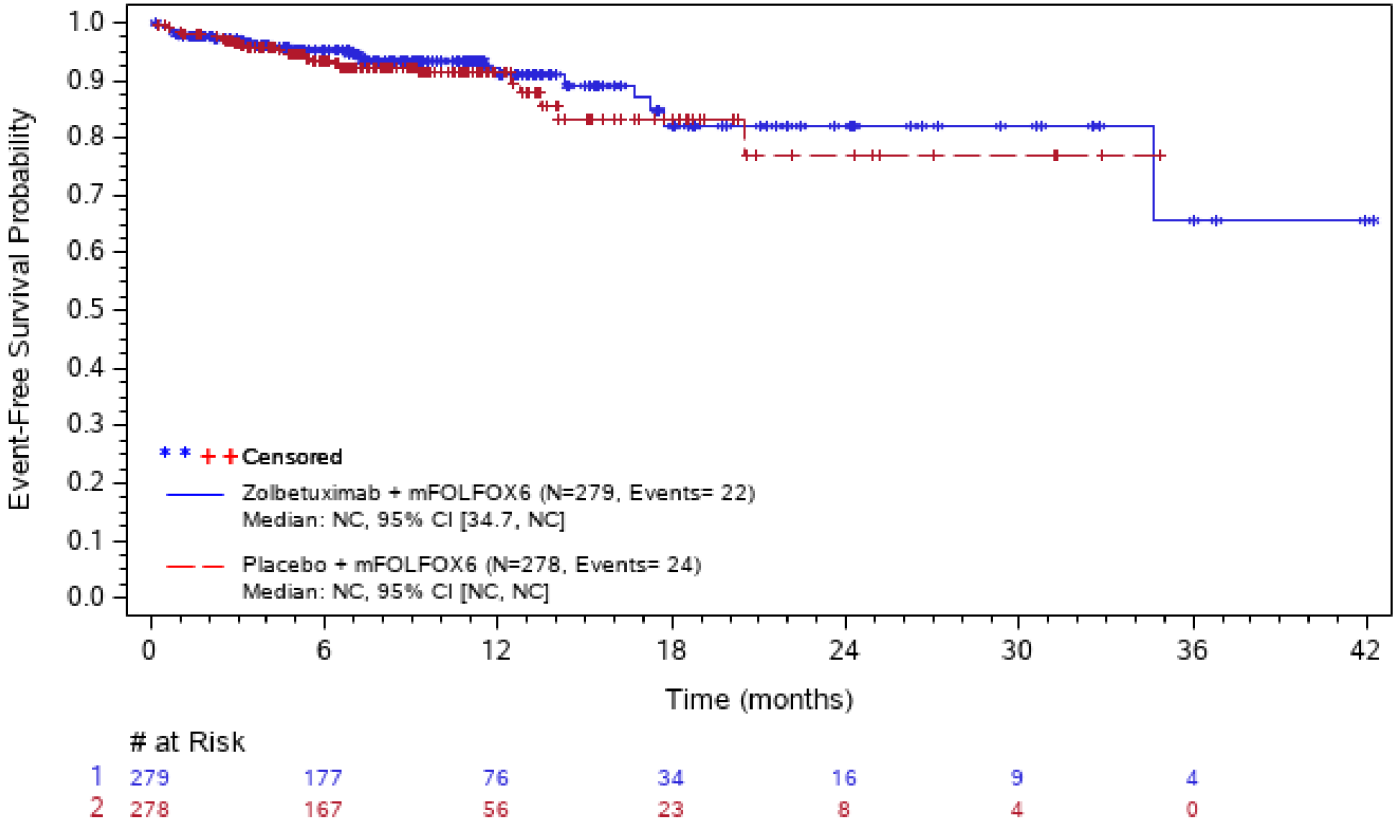
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.87: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set



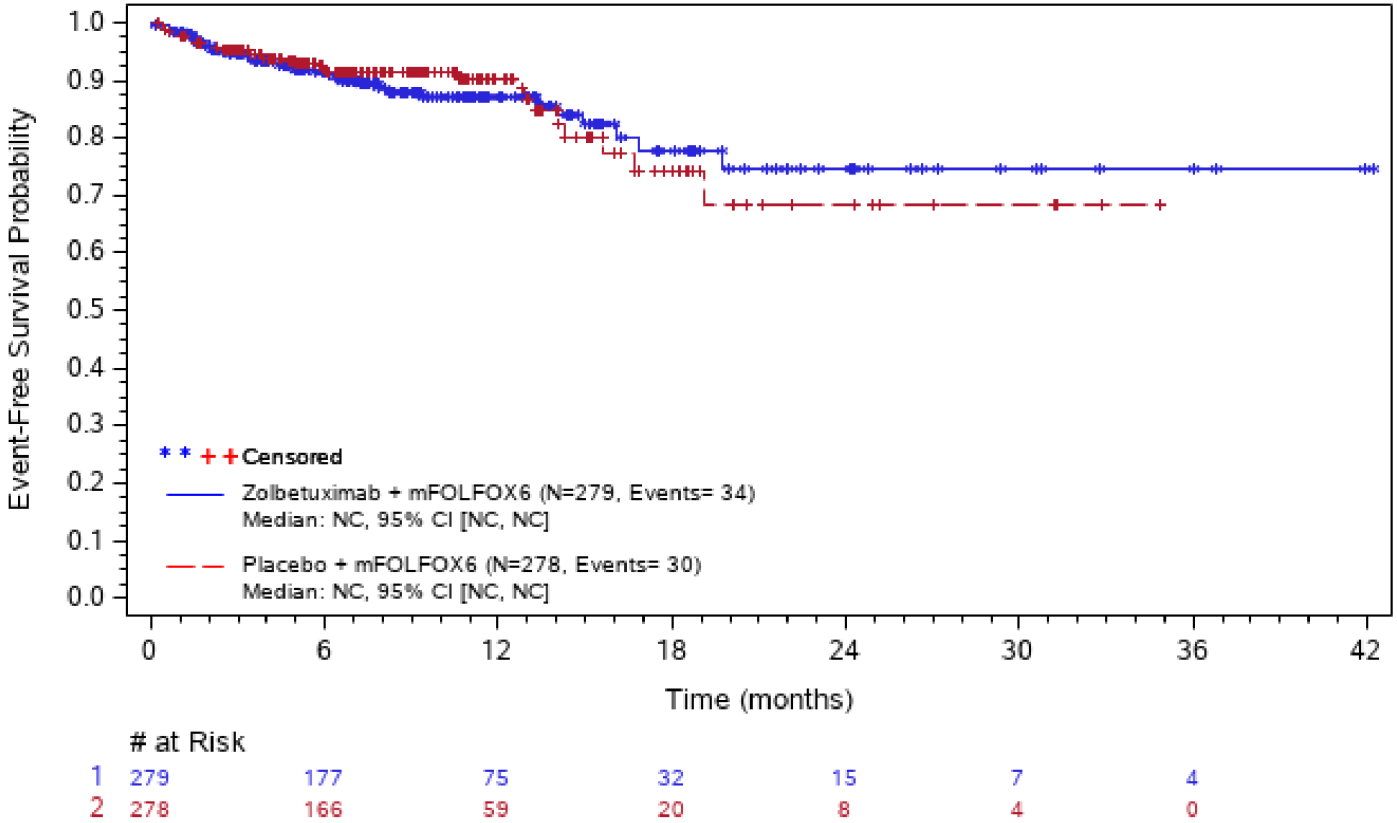
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.88: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Safety Analysis Set



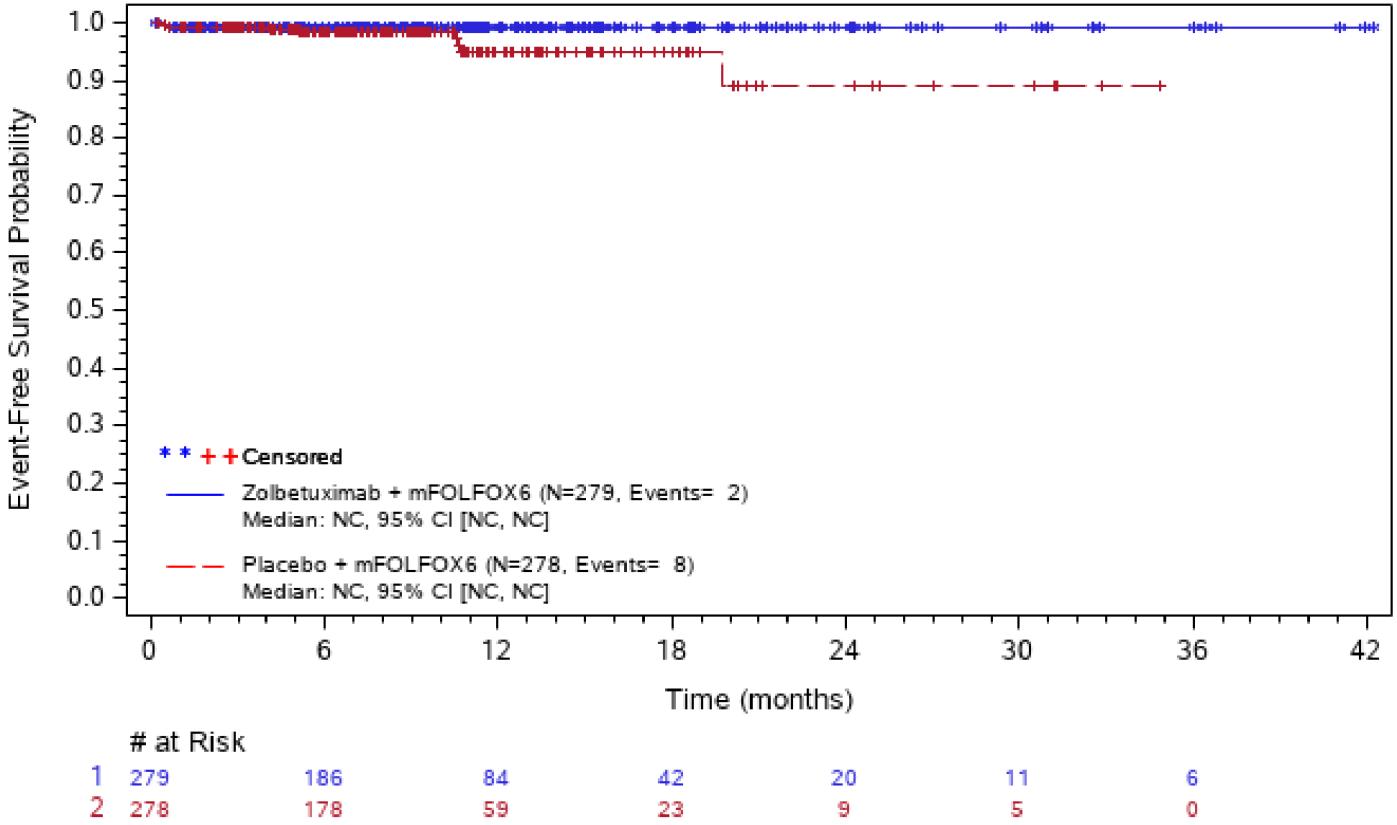
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.89: Kaplan-Meier Plot of Time to first TEAE - Back Pain (PT) - Safety Analysis Set



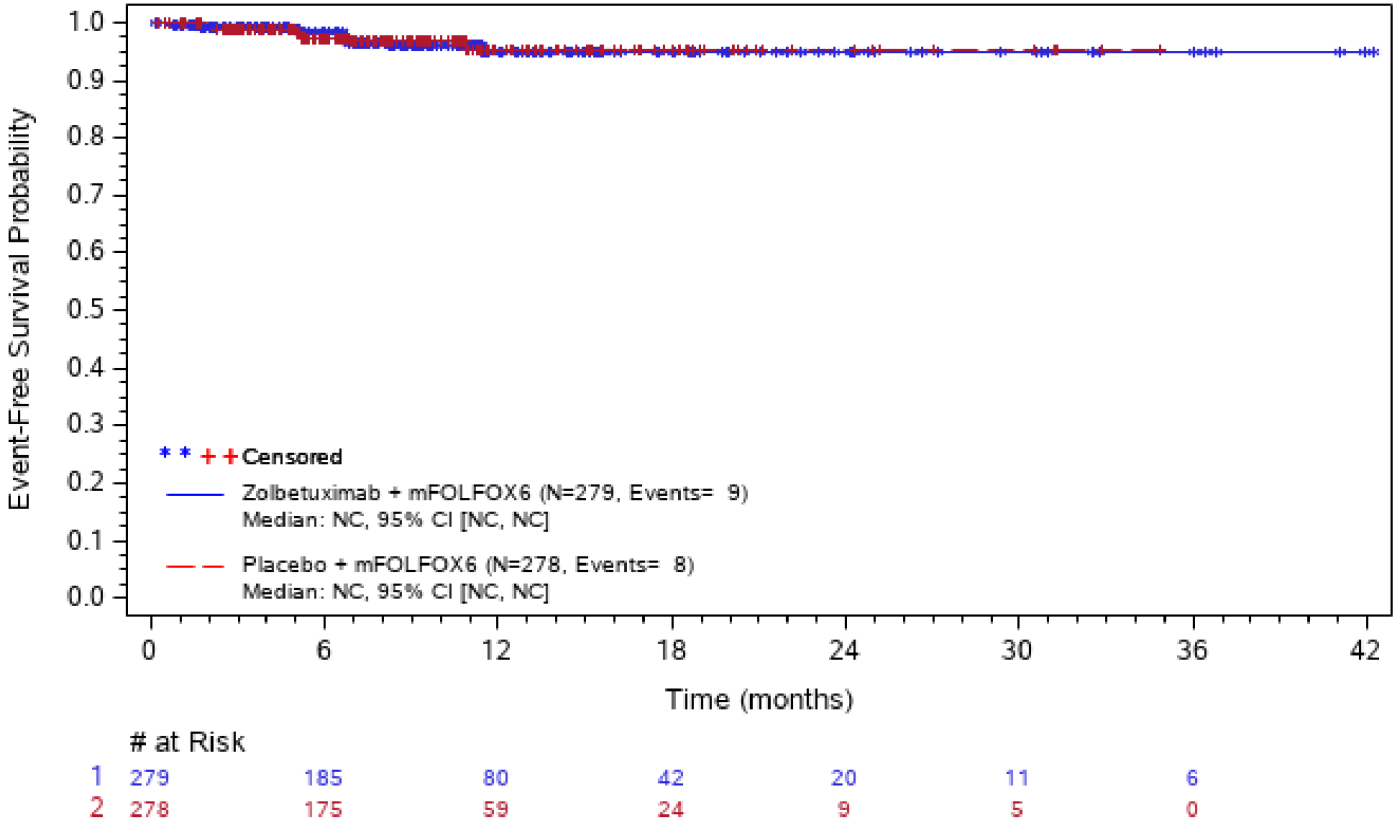
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.90: Kaplan-Meier Plot of Time to first TEAE - Flank Pain (PT) - Safety Analysis Set



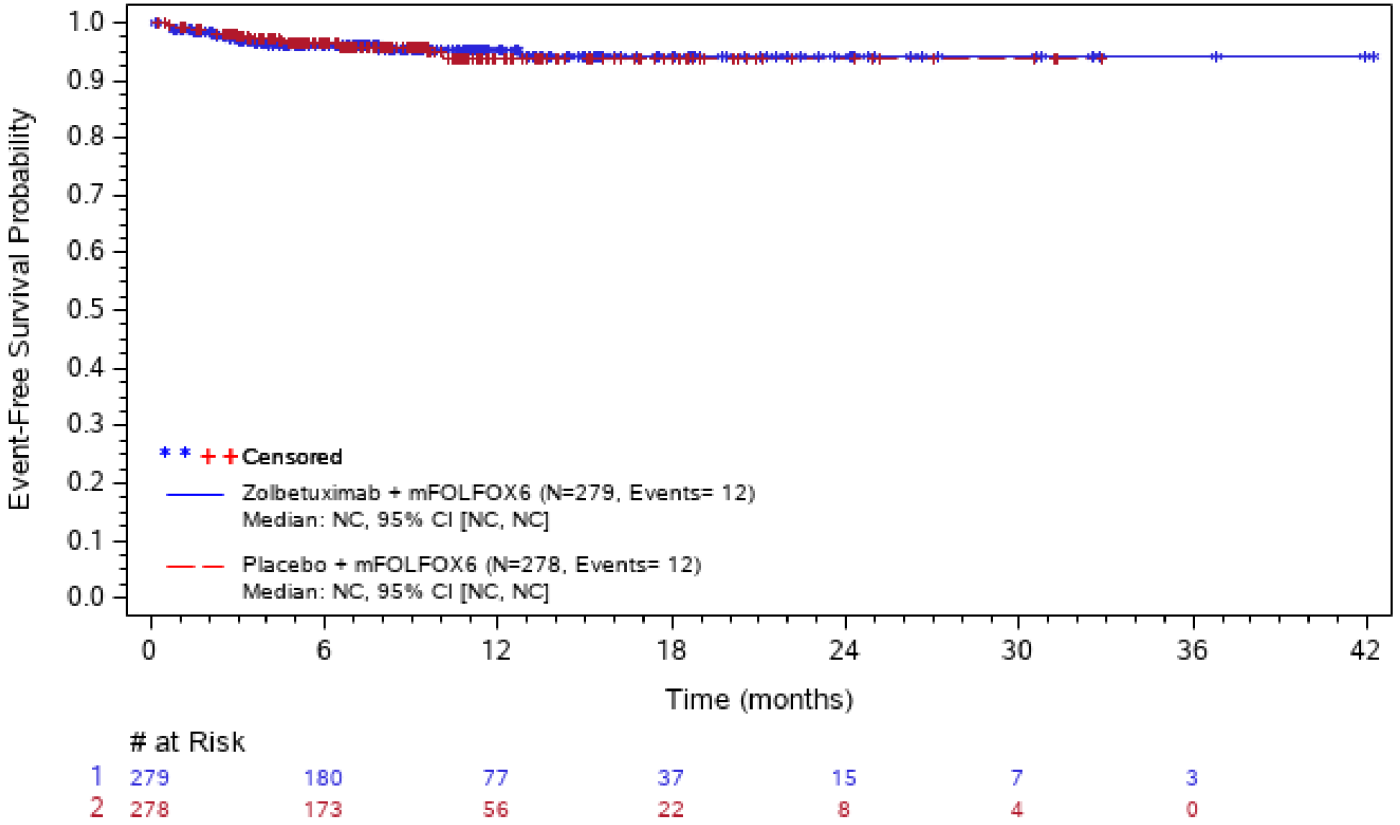
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.91: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal Chest Pain (PT) - Safety Analysis Set



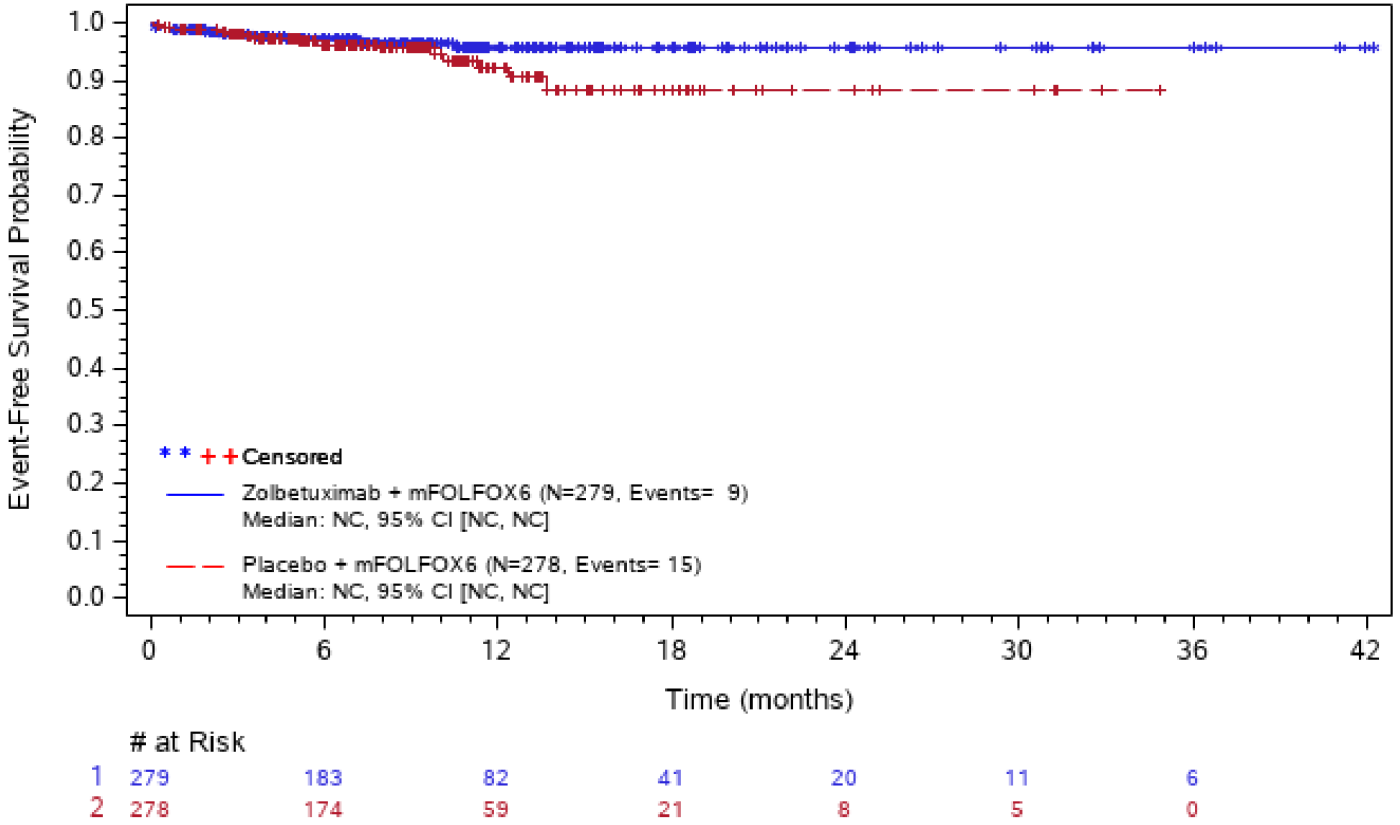
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.92: Kaplan-Meier Plot of Time to first TEAE - Myalgia (PT) - Safety Analysis Set



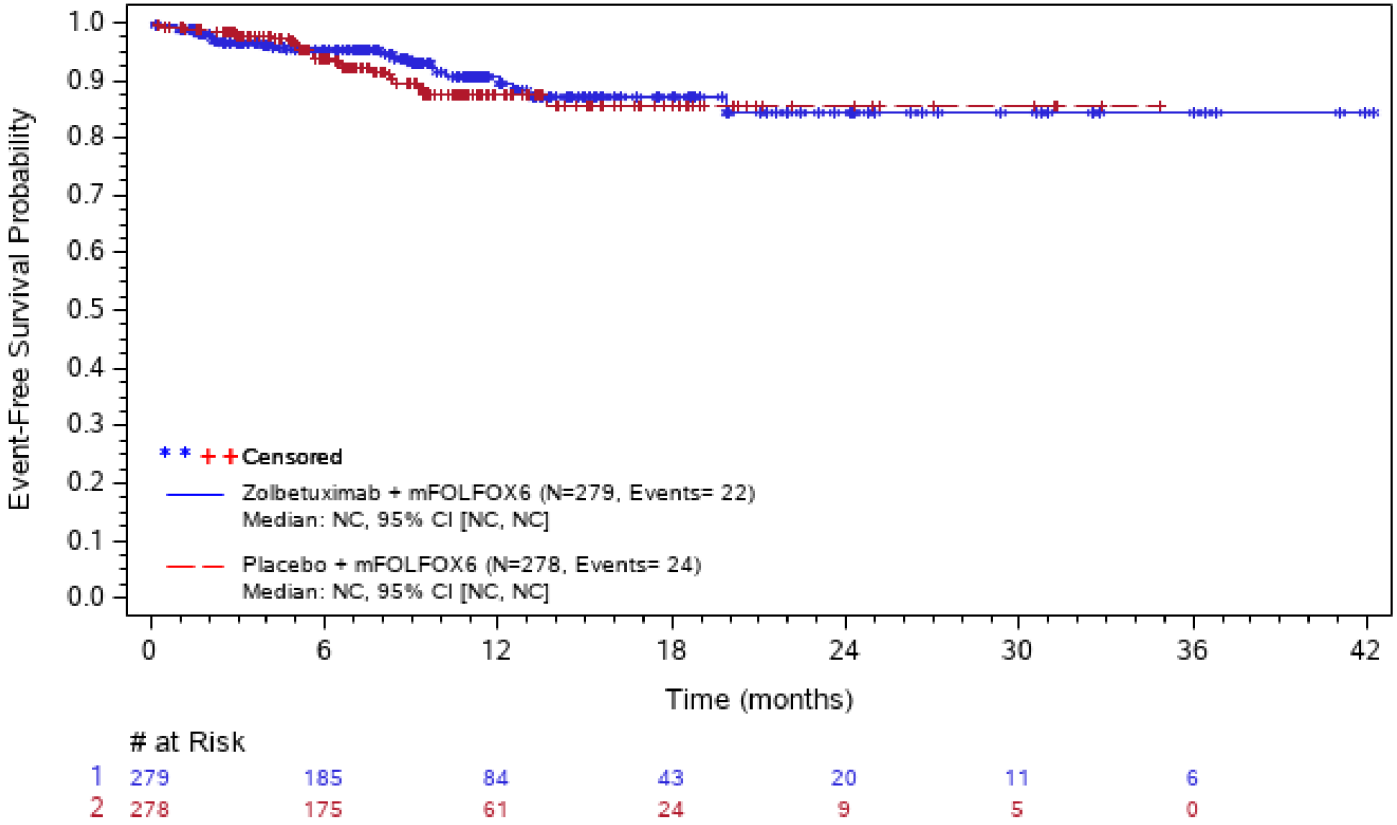
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.93: Kaplan-Meier Plot of Time to first TEAE - Pain In Extremity (PT) - Safety Analysis Set



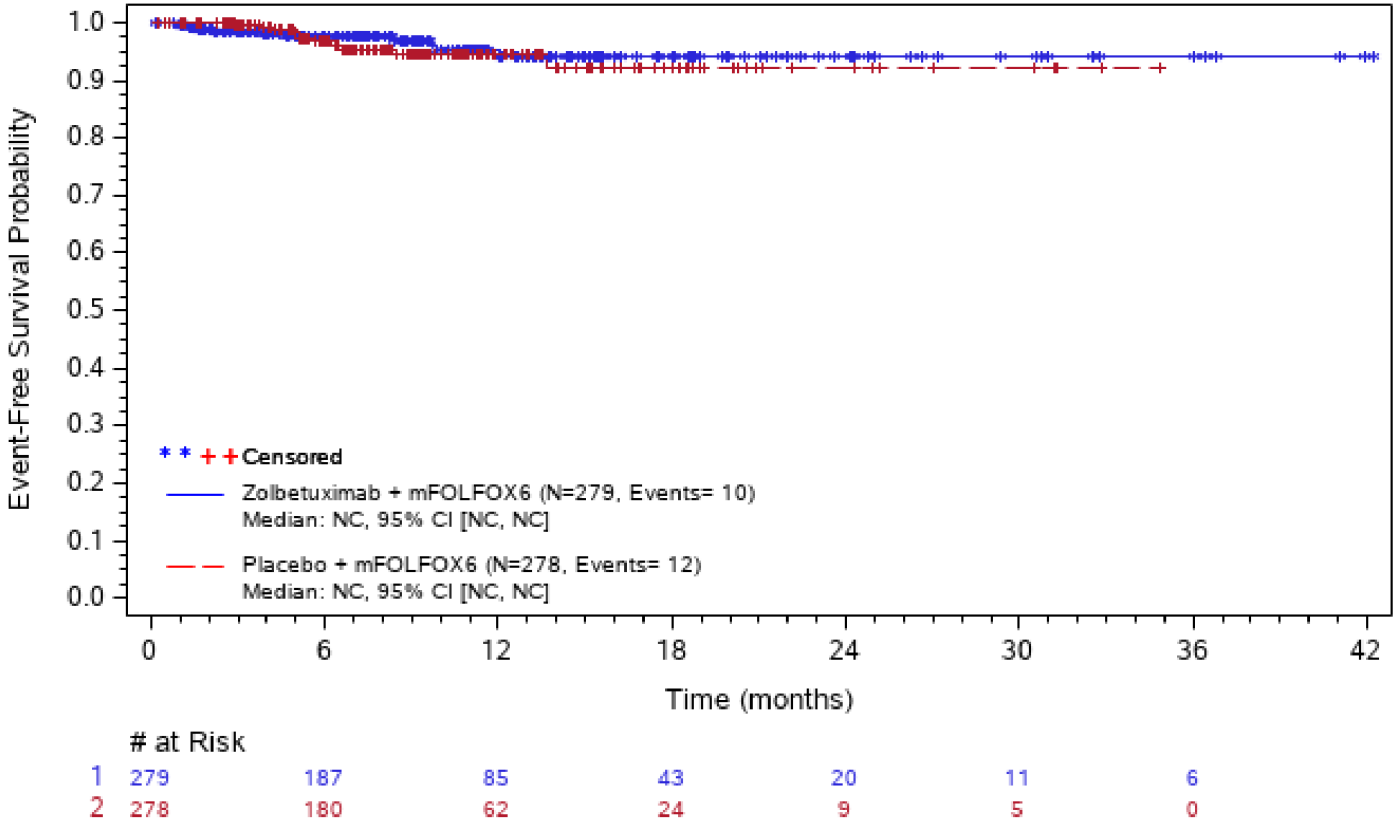
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.94: Kaplan-Meier Plot of Time to first TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



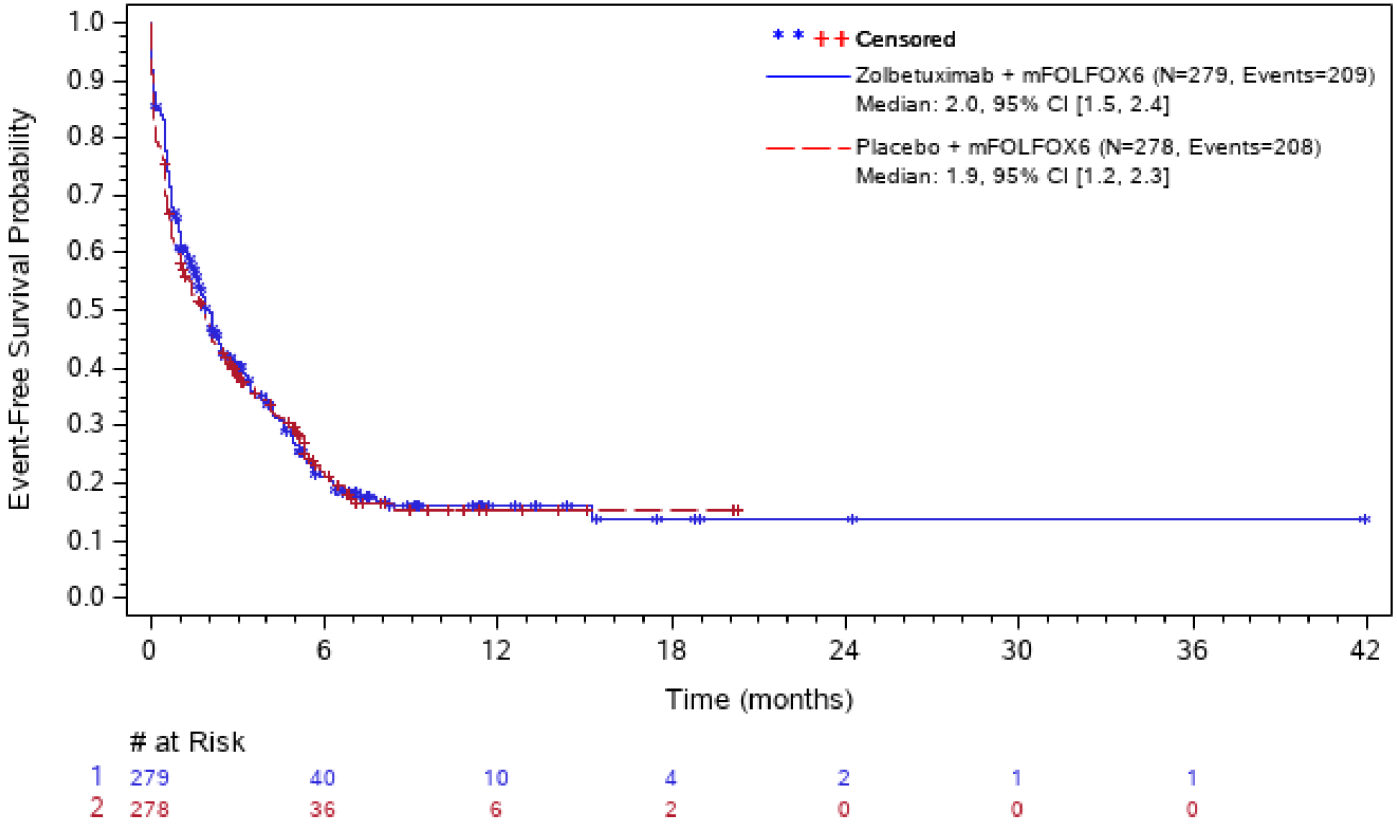
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.95: Kaplan-Meier Plot of Time to first TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



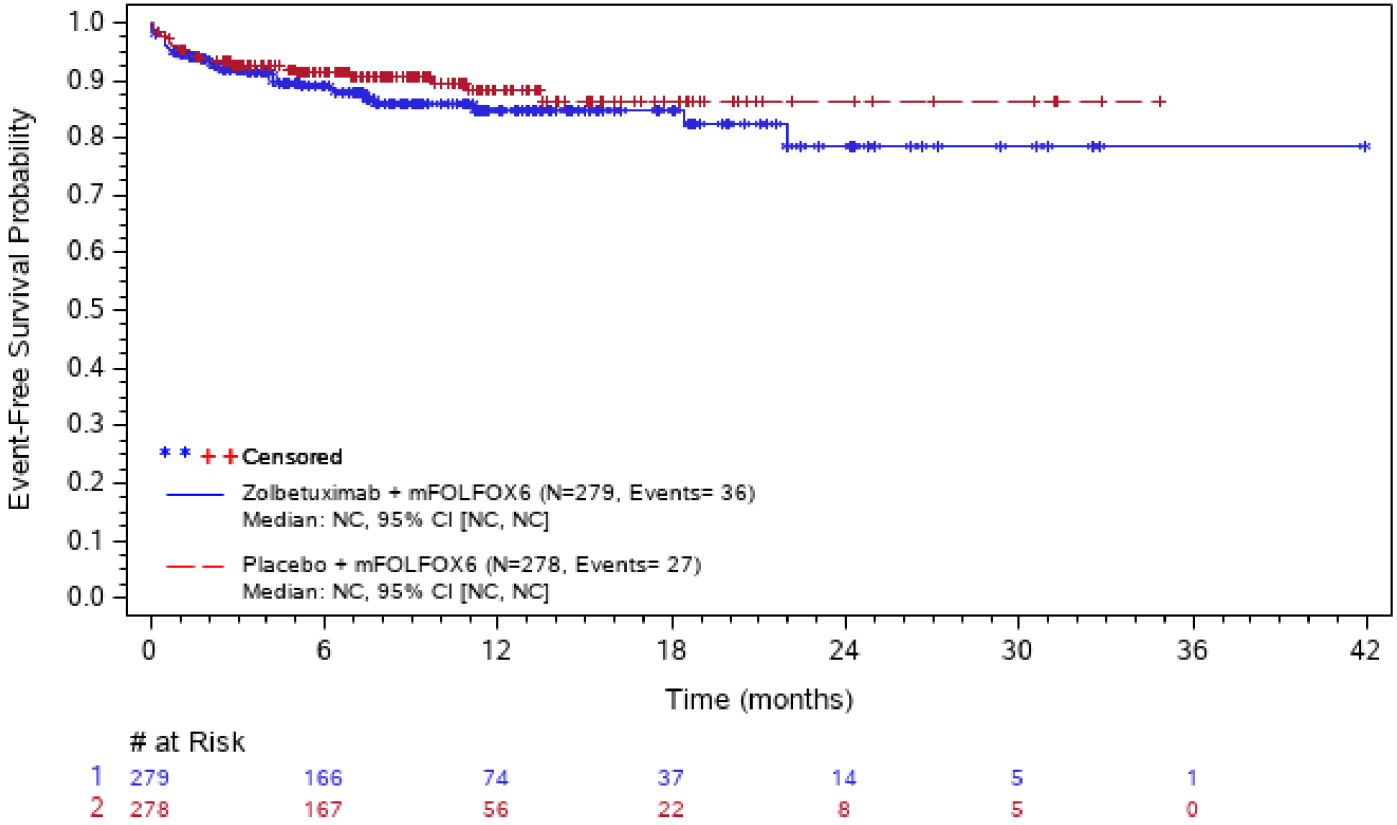
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.96: Kaplan-Meier Plot of Time to first TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



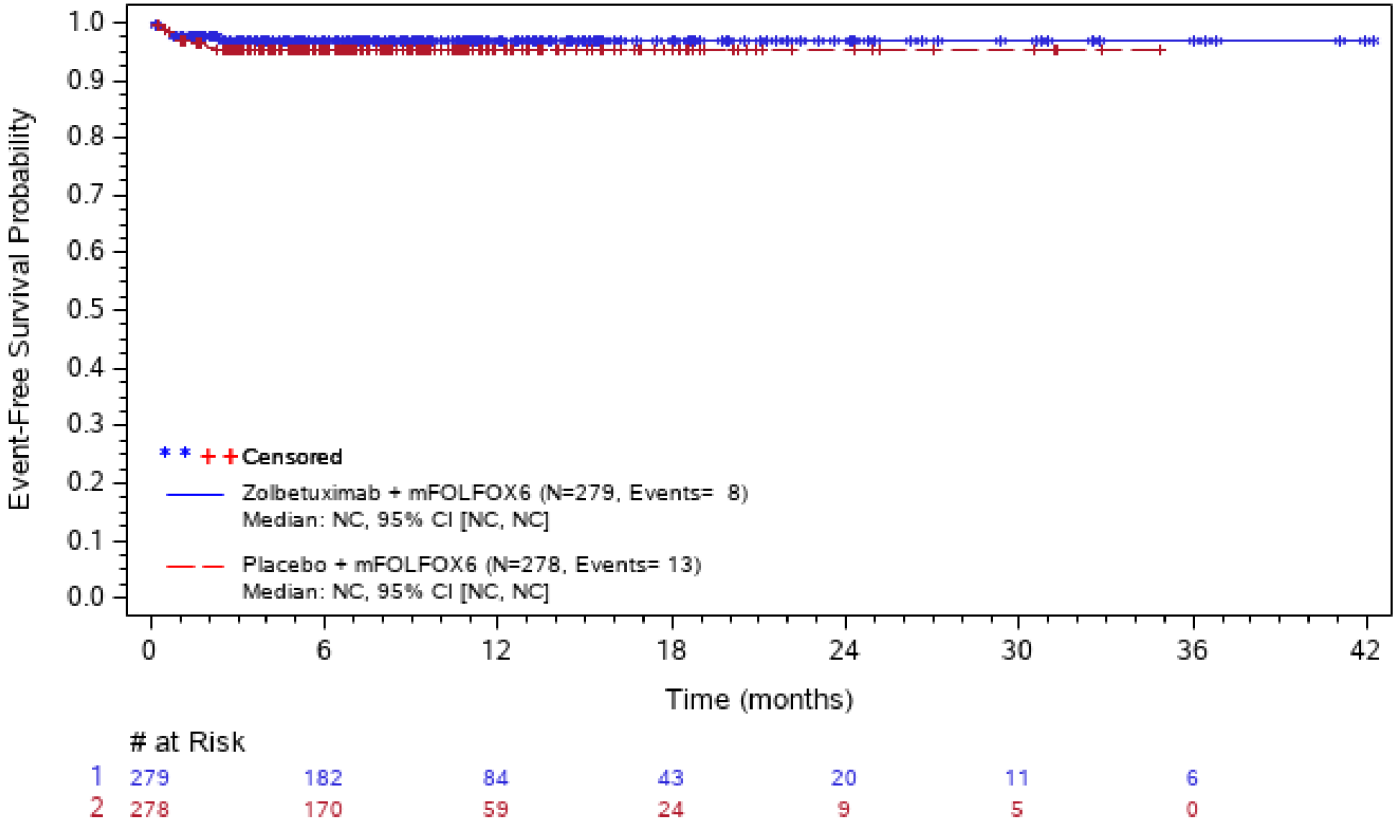
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.97: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Safety Analysis Set



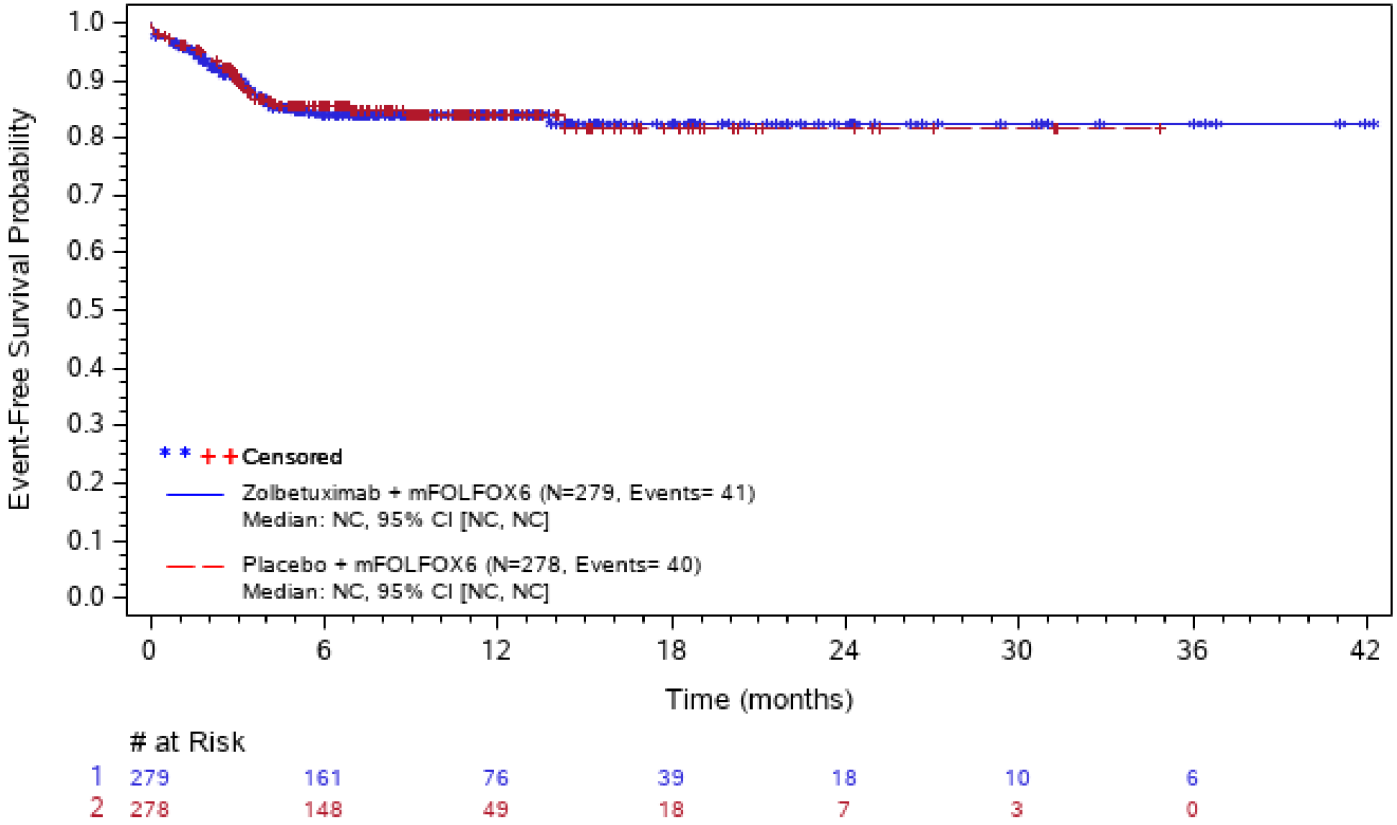
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.98: Kaplan-Meier Plot of Time to first TEAE - Dysaesthesia (PT) - Safety Analysis Set



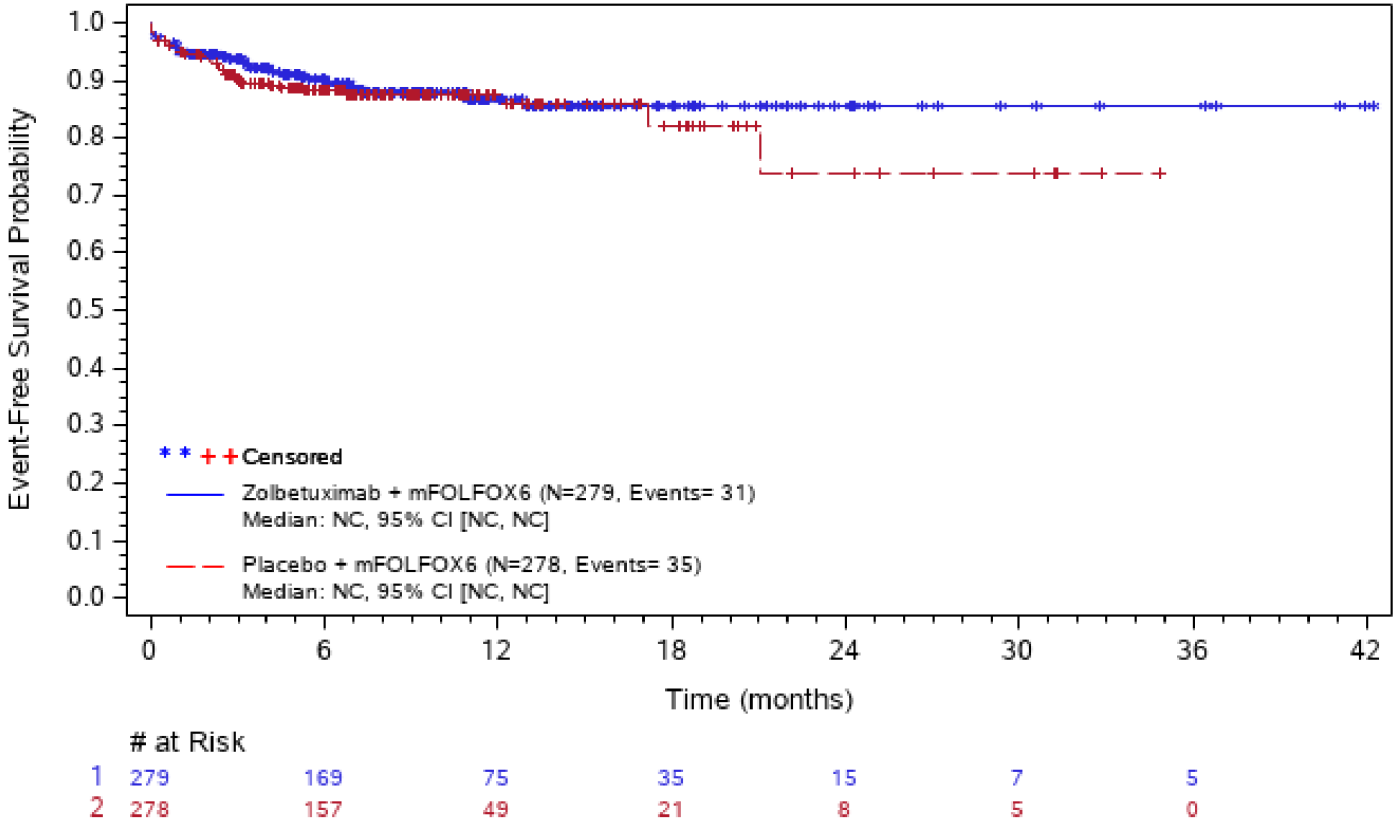
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.99: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Safety Analysis Set



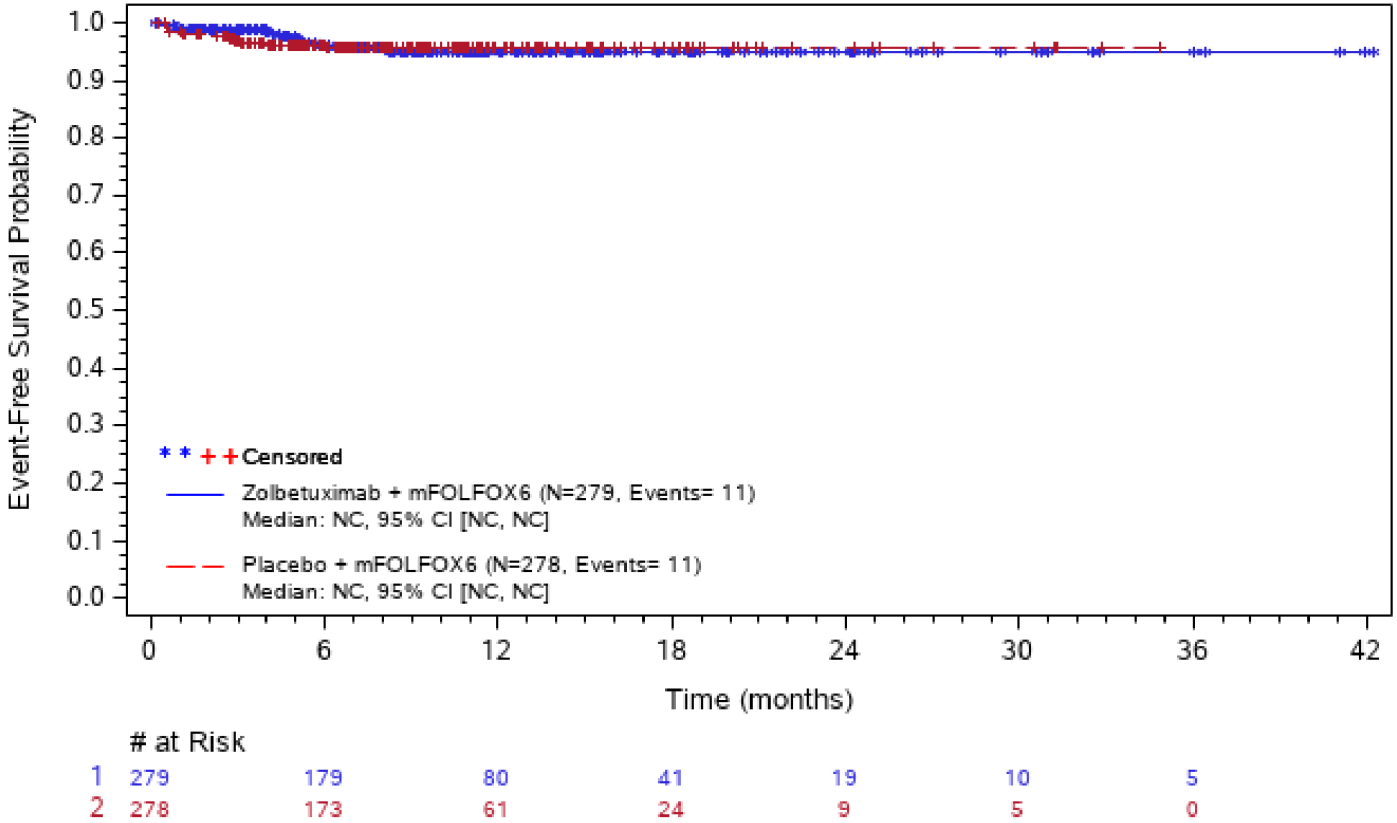
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.100: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Safety Analysis Set



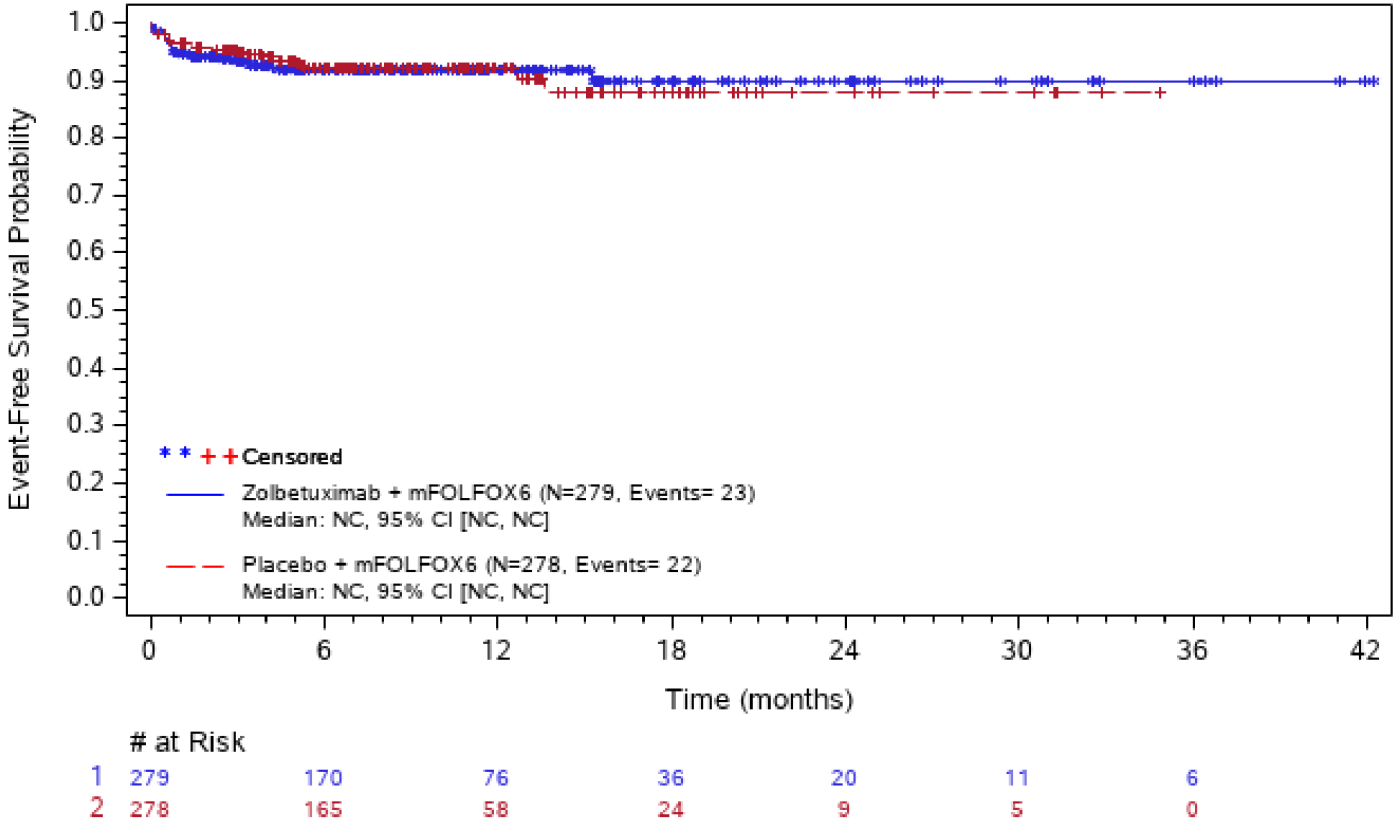
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.101: Kaplan-Meier Plot of Time to first TEAE - Hypoaesthesia (PT) - Safety Analysis Set



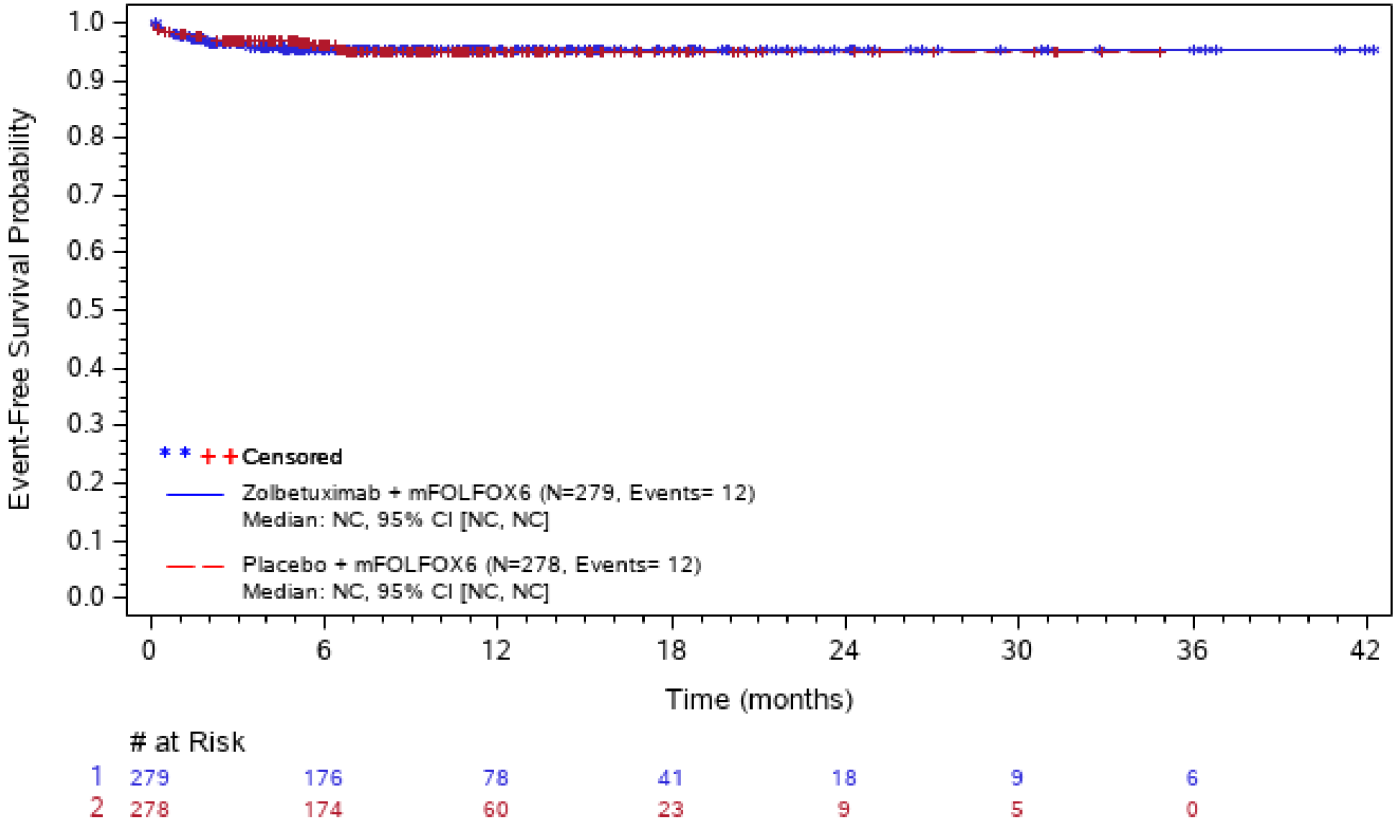
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.102: Kaplan-Meier Plot of Time to first TEAE - Neuropathy Peripheral (PT) - Safety Analysis Set



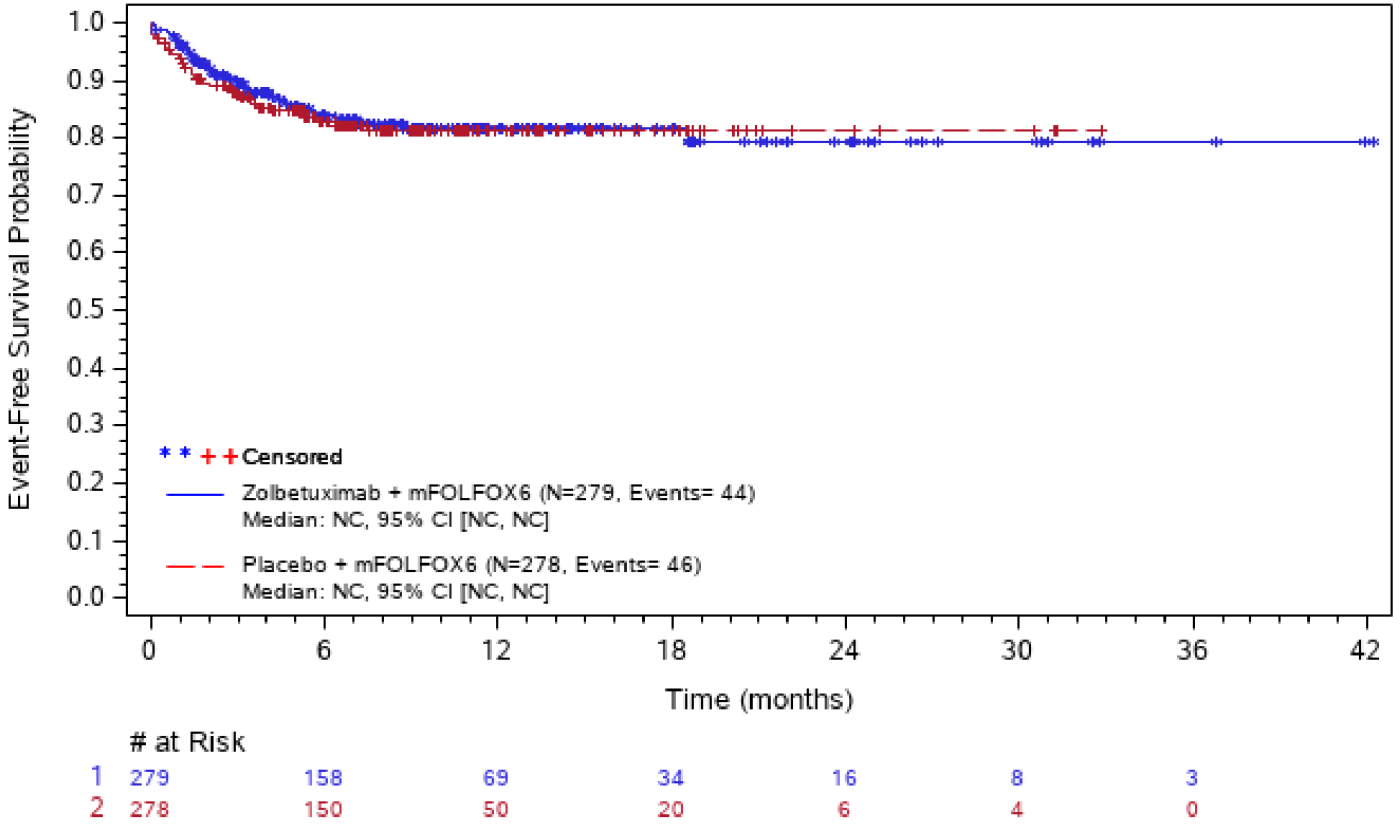
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.103: Kaplan-Meier Plot of Time to first TEAE - Neurotoxicity (PT) - Safety Analysis Set



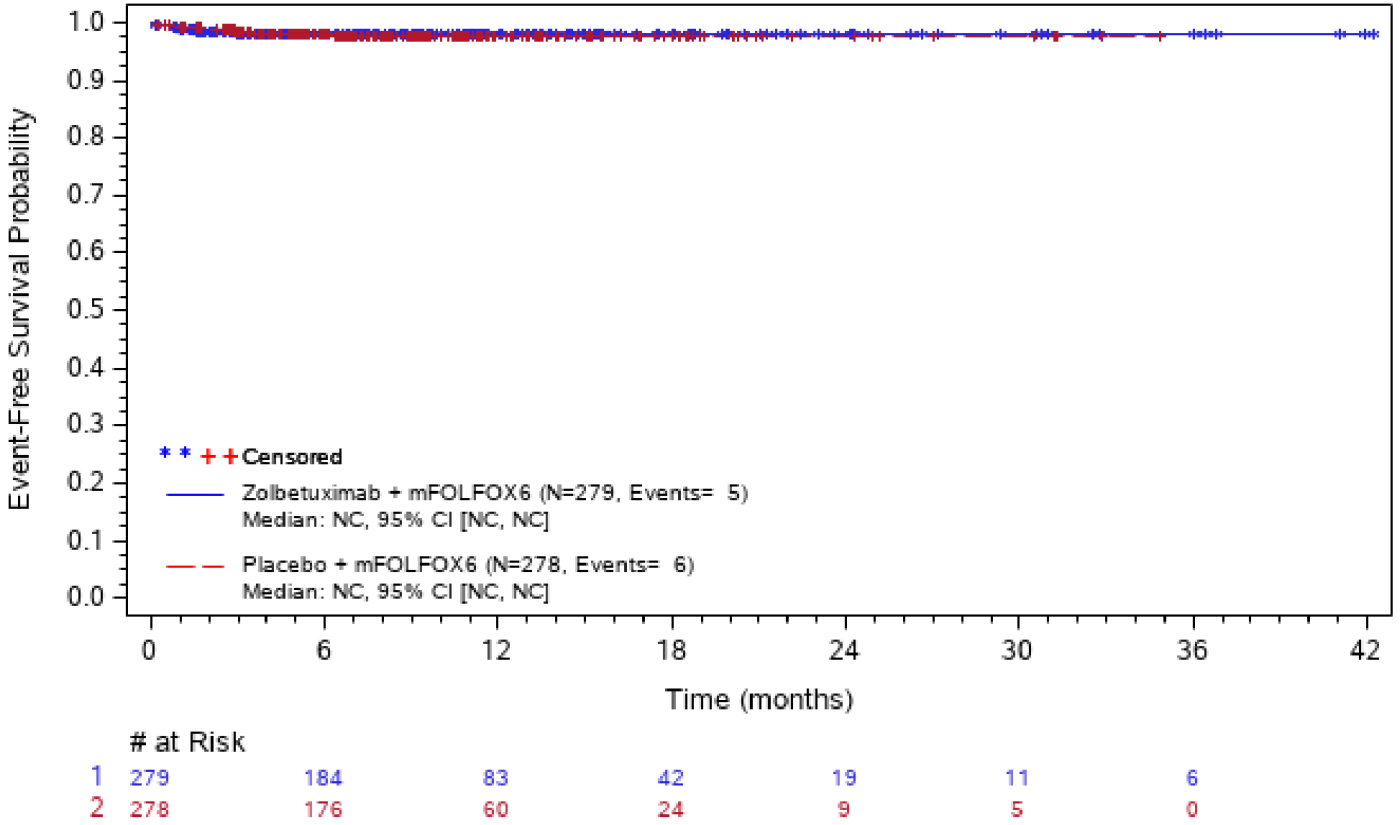
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.104: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Safety Analysis Set



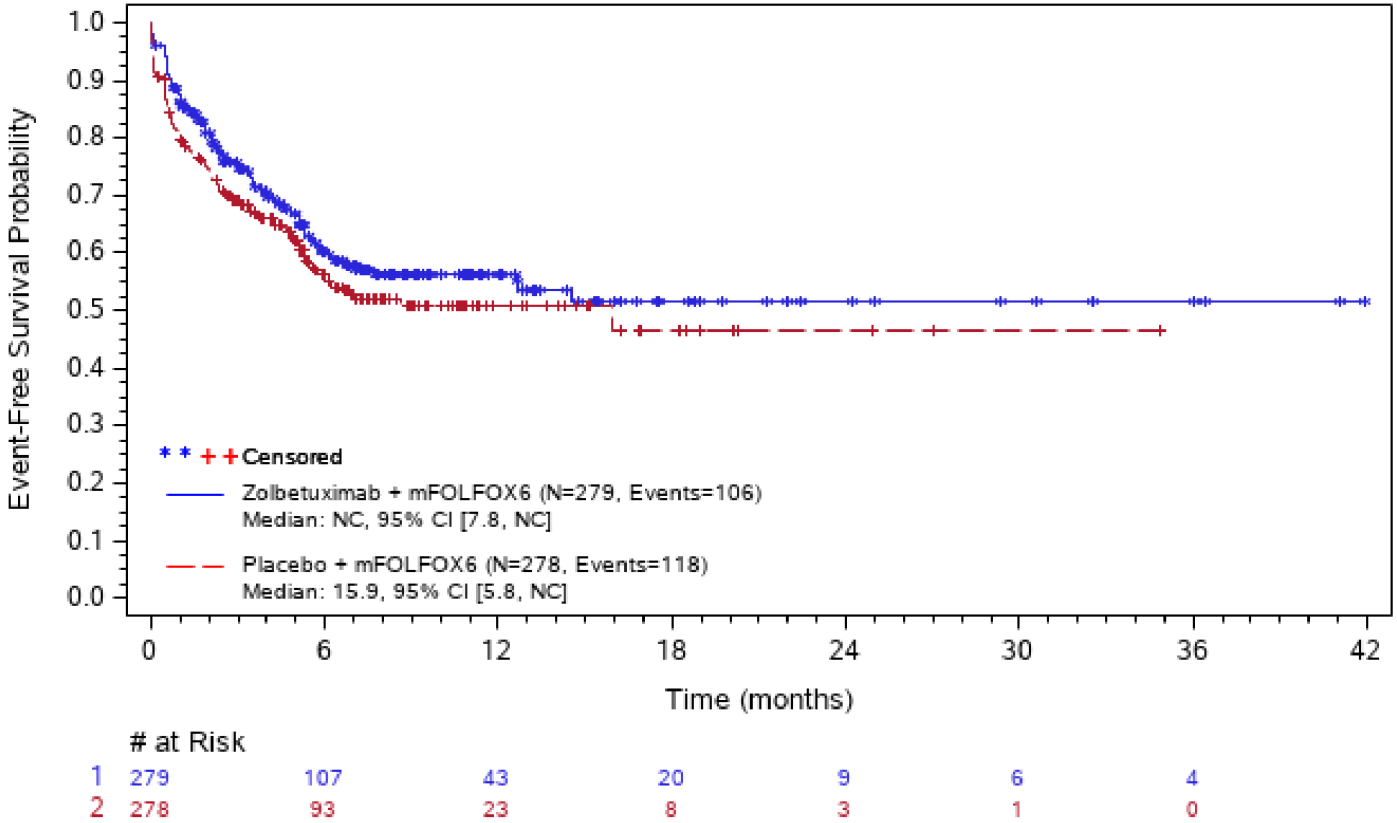
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.105: Kaplan-Meier Plot of Time to first TEAE - Peripheral Motor Neuropathy (PT) - Safety Analysis Set



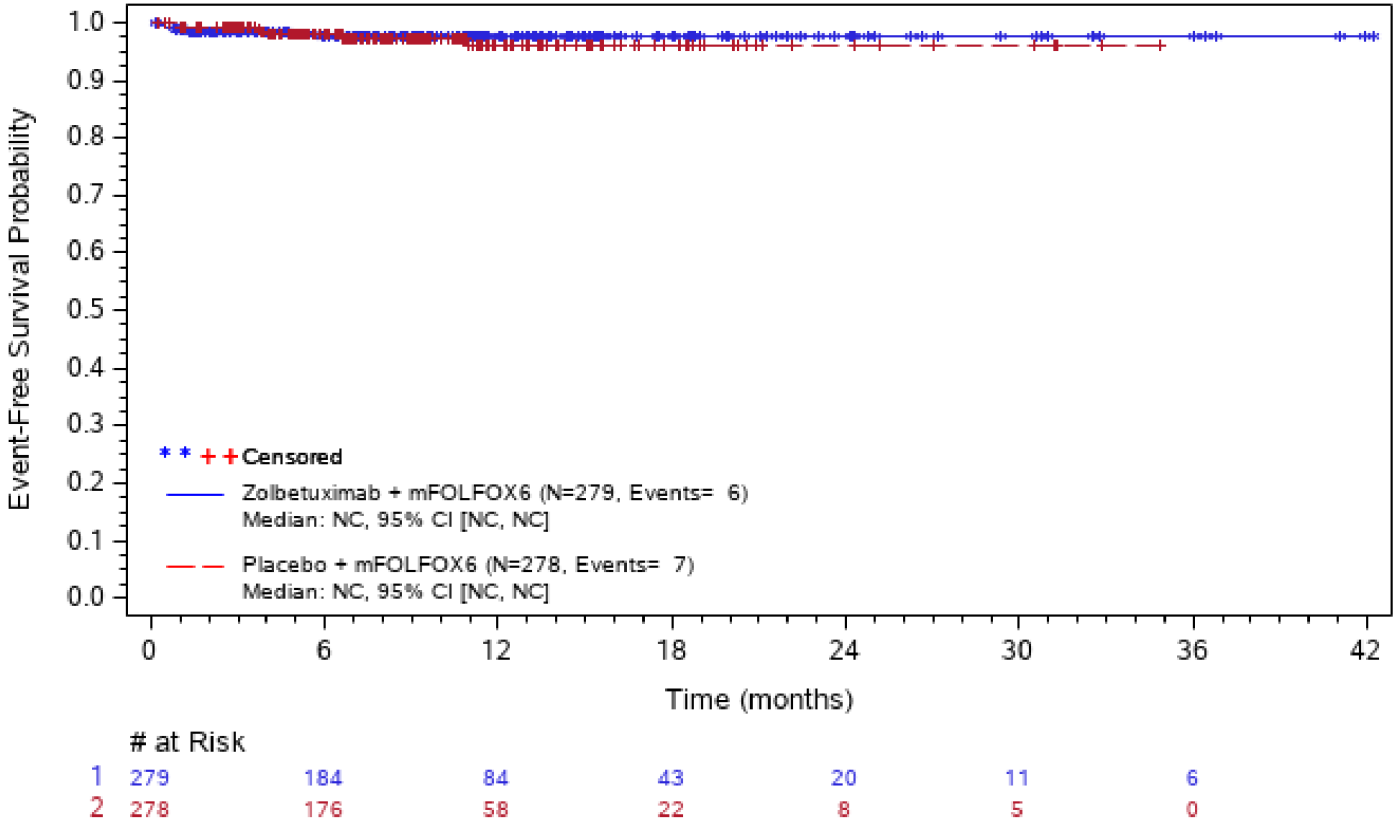
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.106: Kaplan-Meier Plot of Time to first TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set



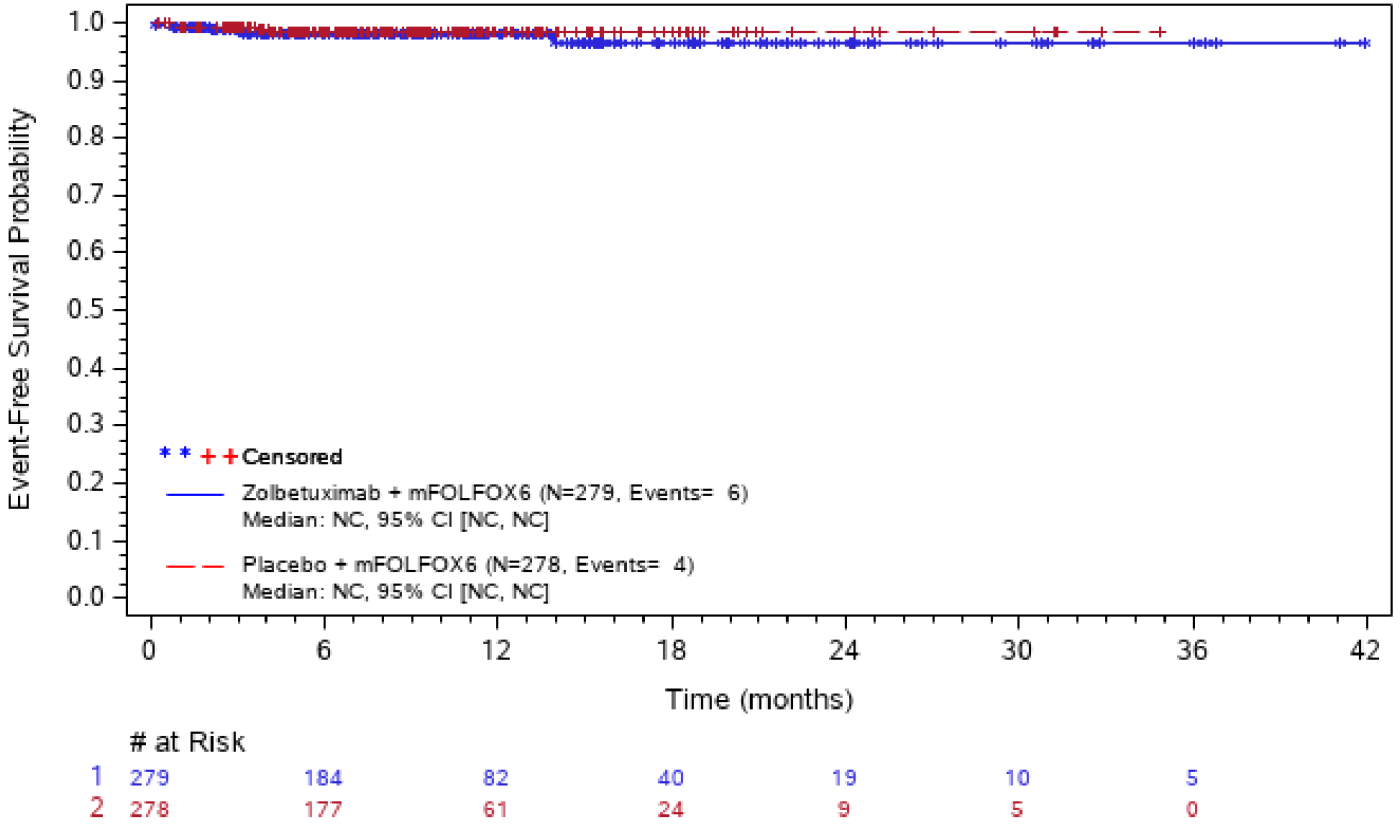
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.107: Kaplan-Meier Plot of Time to first TEAE - Syncope (PT) - Safety Analysis Set



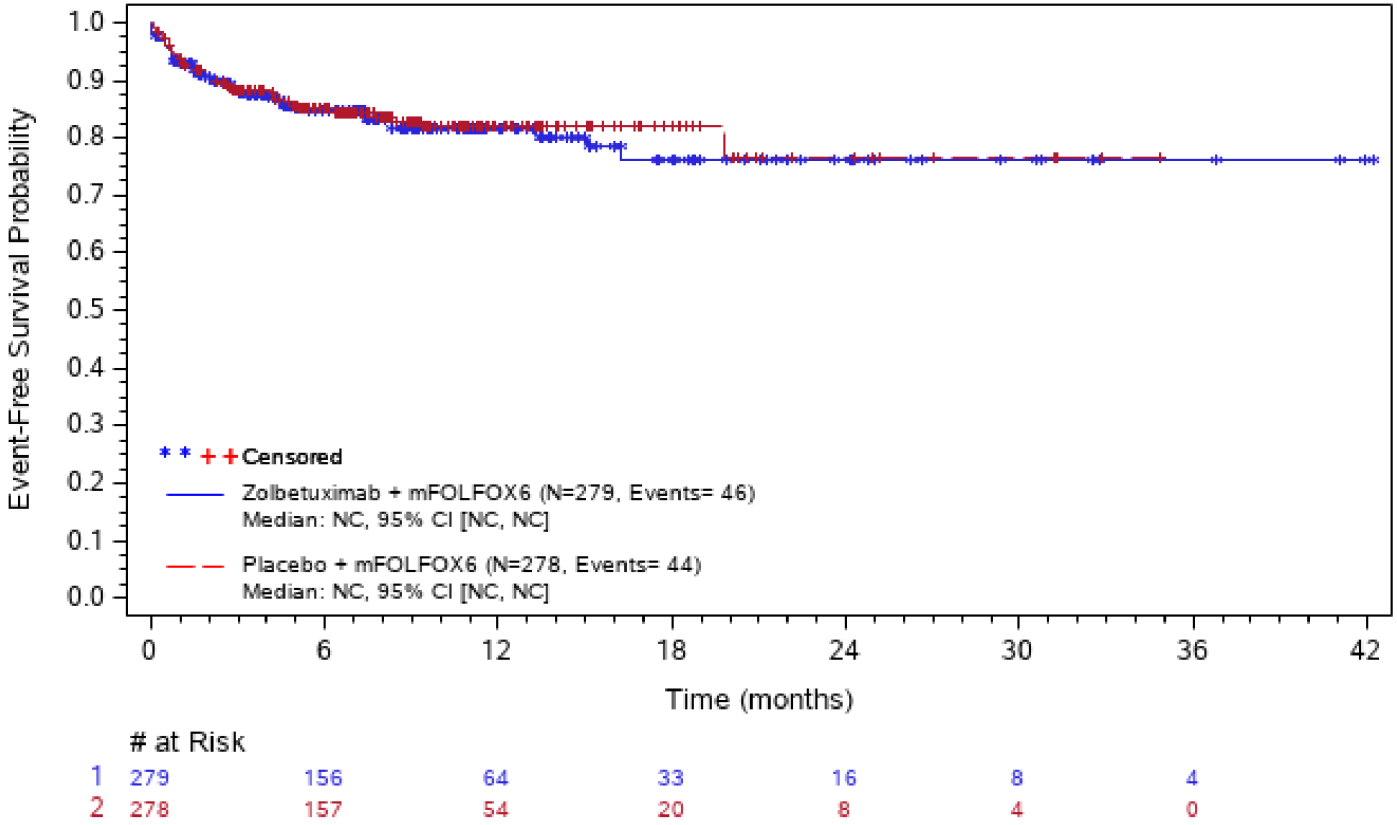
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.108: Kaplan-Meier Plot of Time to first TEAE - Taste Disorder (PT) - Safety Analysis Set



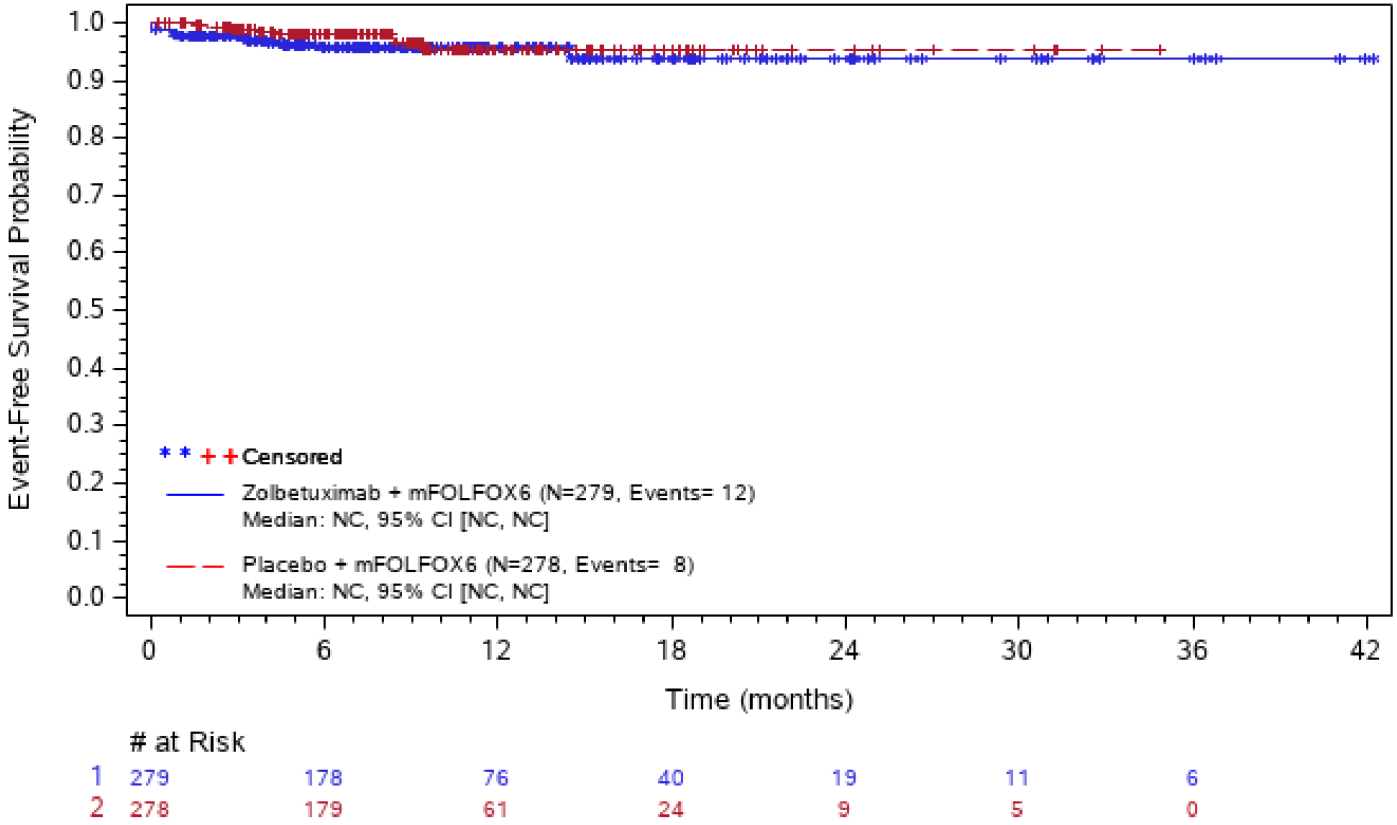
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.109: Kaplan-Meier Plot of Time to first TEAE - Psychiatric Disorders (SOC) - Safety Analysis Set



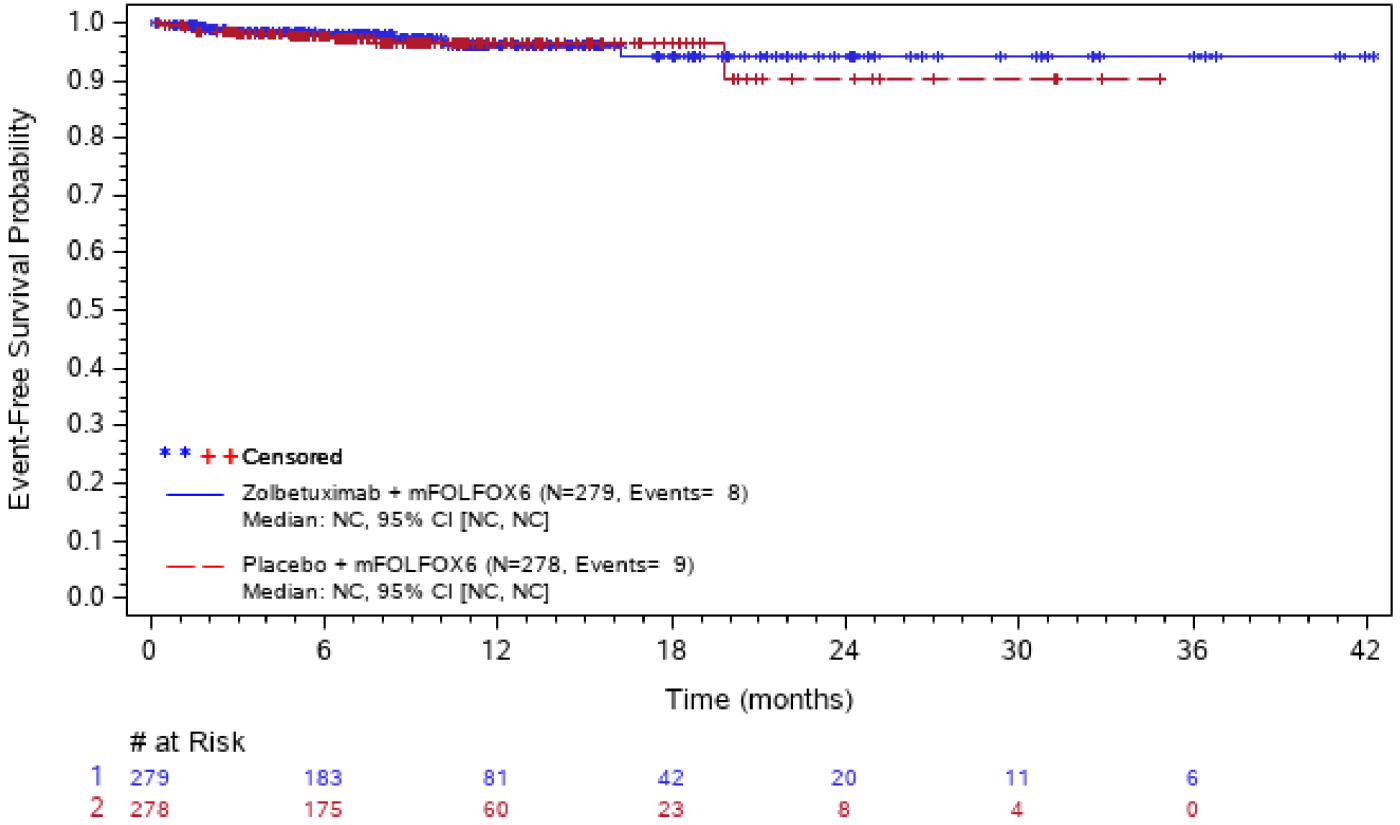
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.110: Kaplan-Meier Plot of Time to first TEAE - Anxiety (PT) - Safety Analysis Set



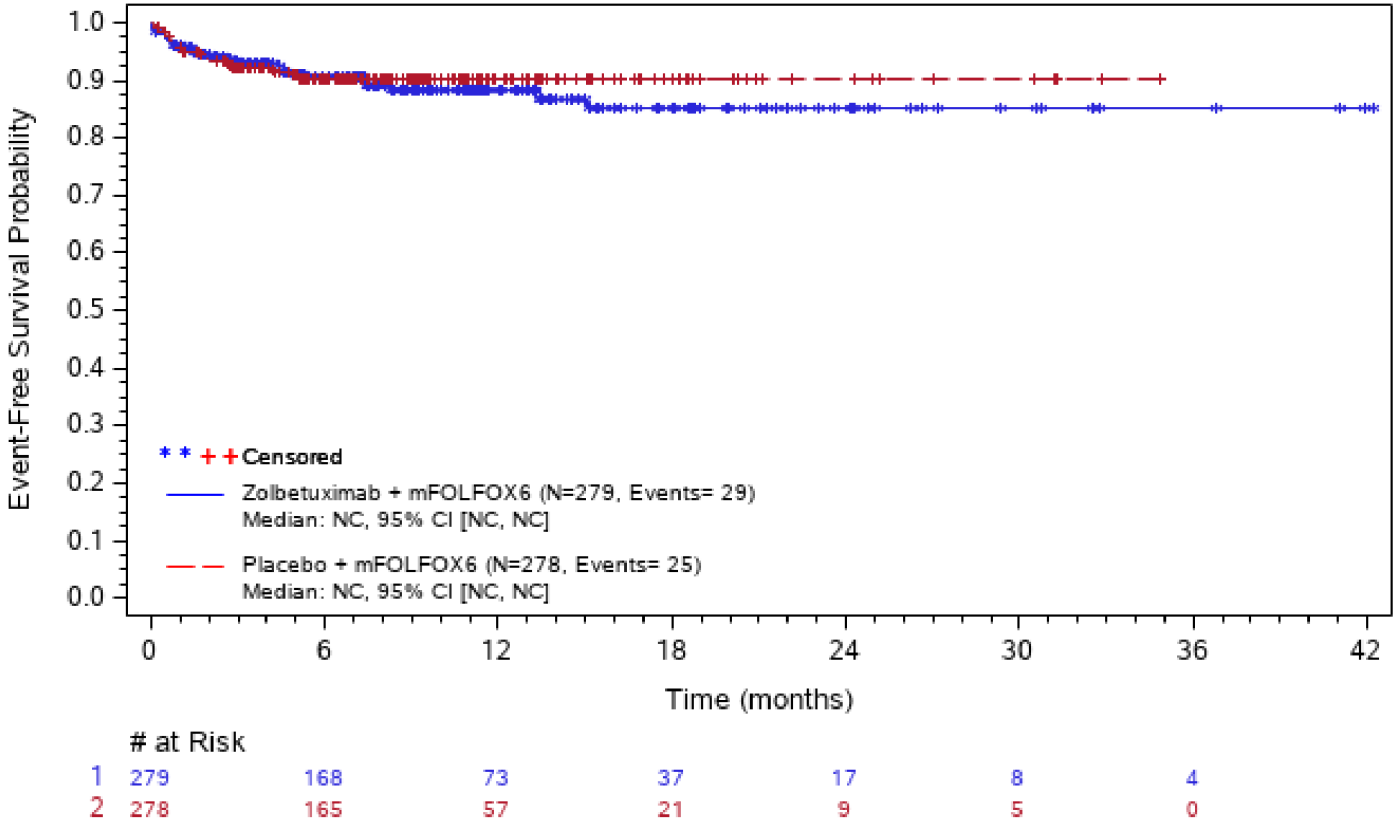
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.111: Kaplan-Meier Plot of Time to first TEAE - Depression (PT) - Safety Analysis Set



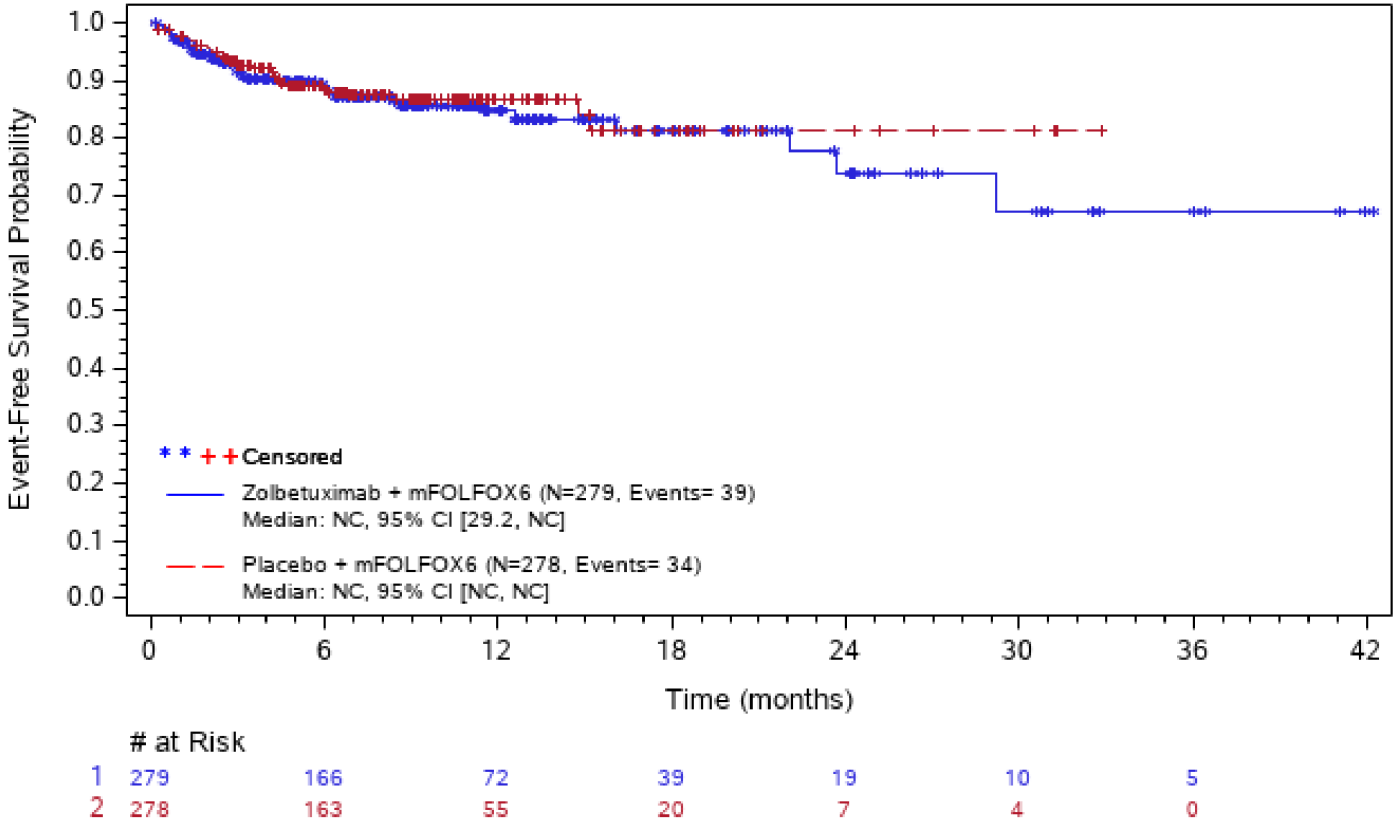
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.112: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Safety Analysis Set



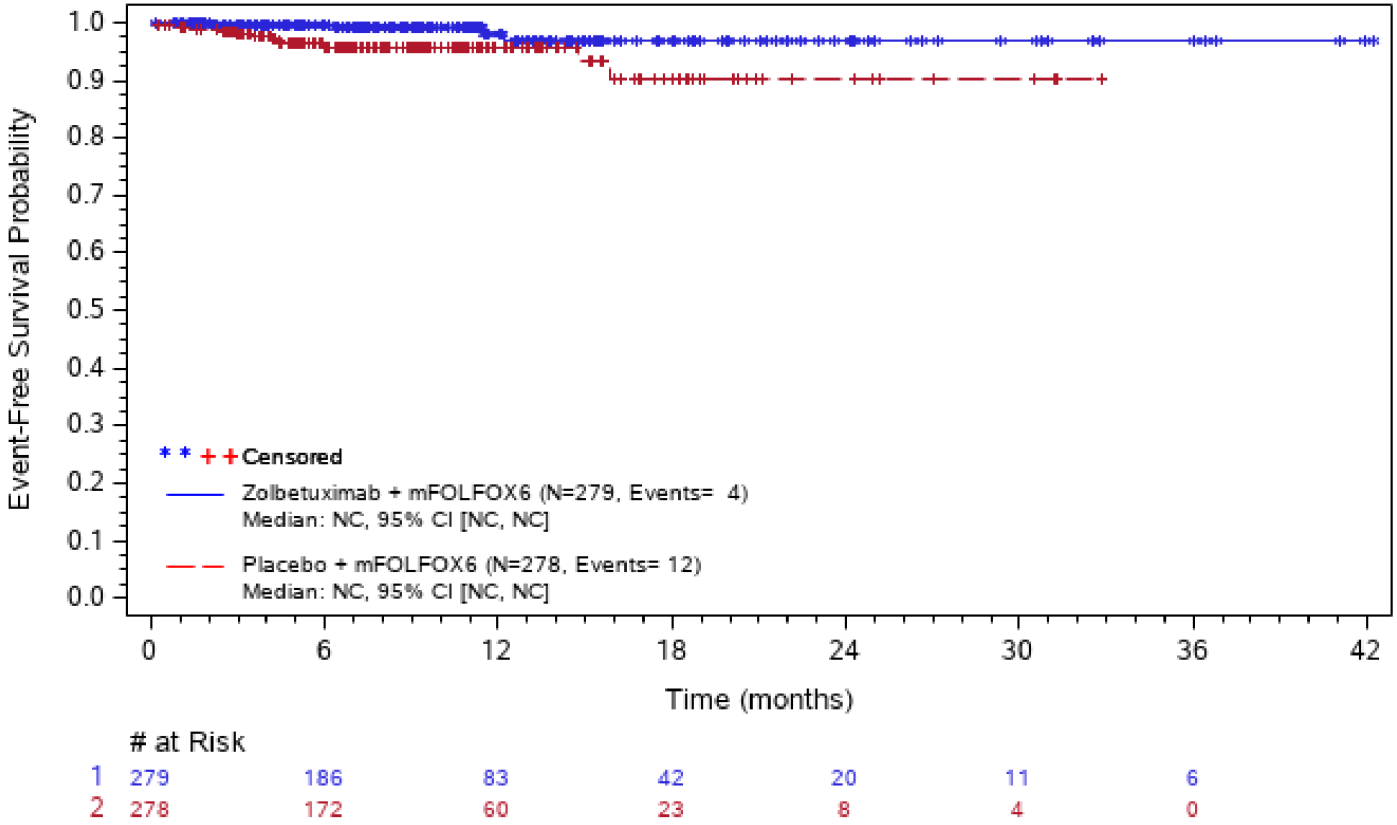
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.113: Kaplan-Meier Plot of Time to first TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



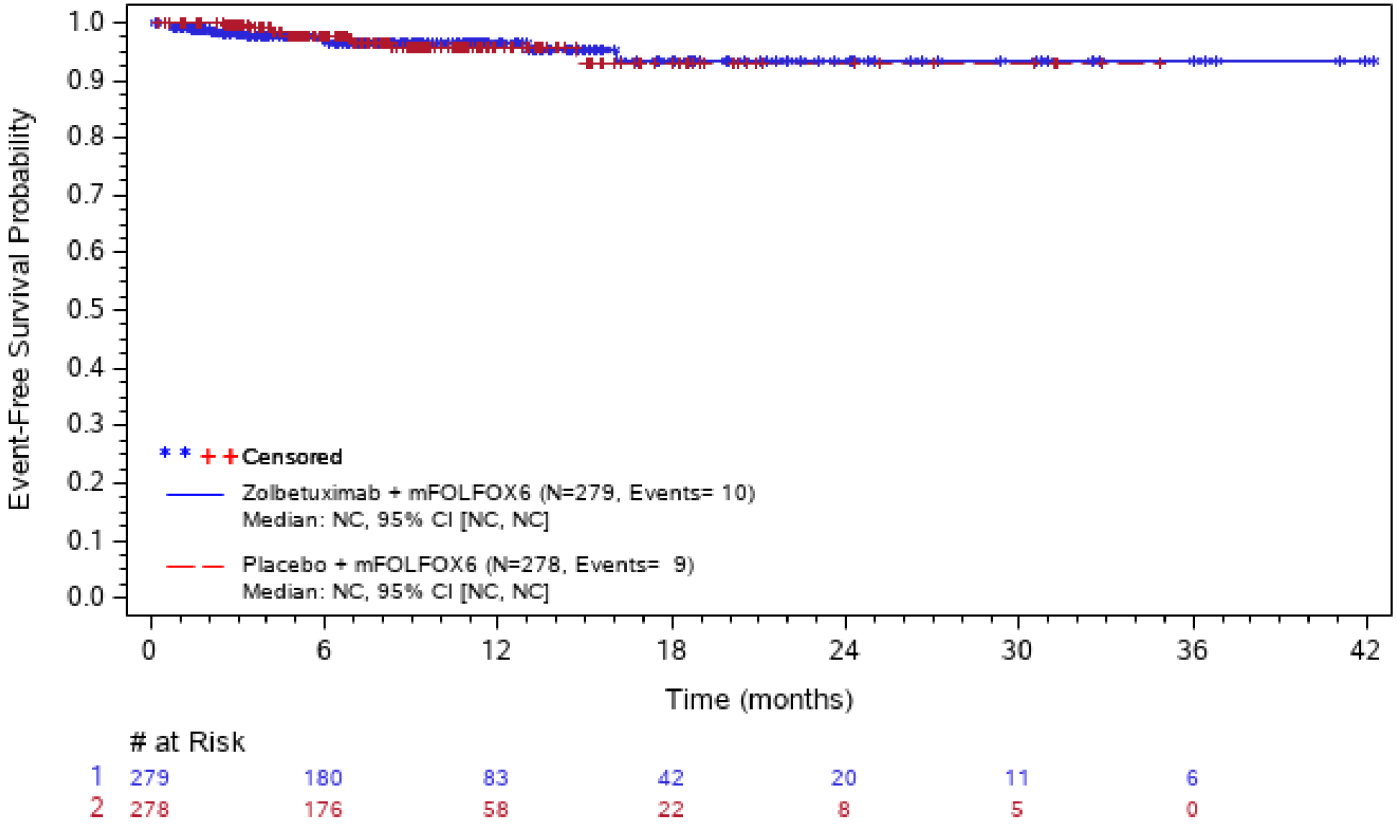
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.114: Kaplan-Meier Plot of Time to first TEAE - Dysuria (PT) - Safety Analysis Set



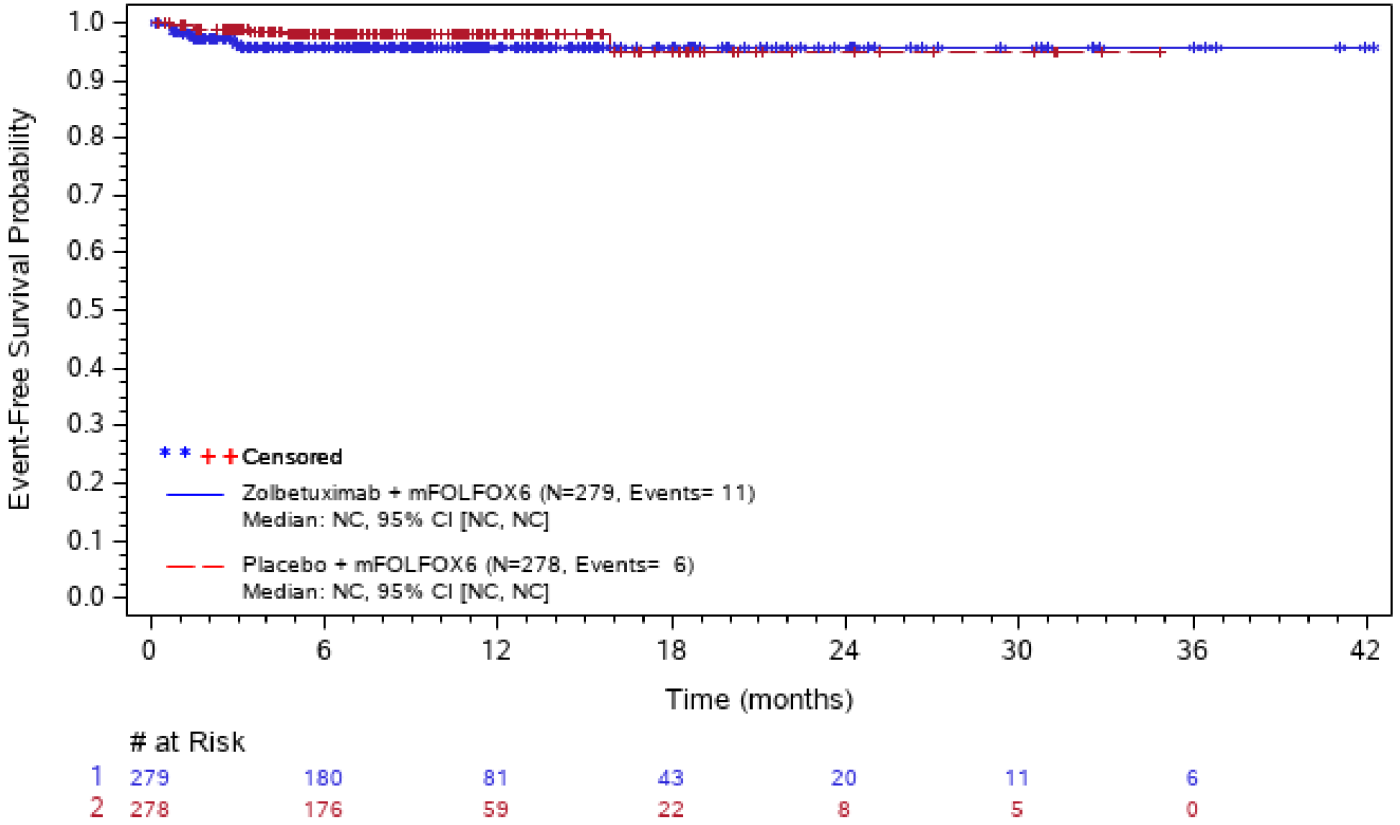
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.115: Kaplan-Meier Plot of Time to first TEAE - Haematuria (PT) - Safety Analysis Set



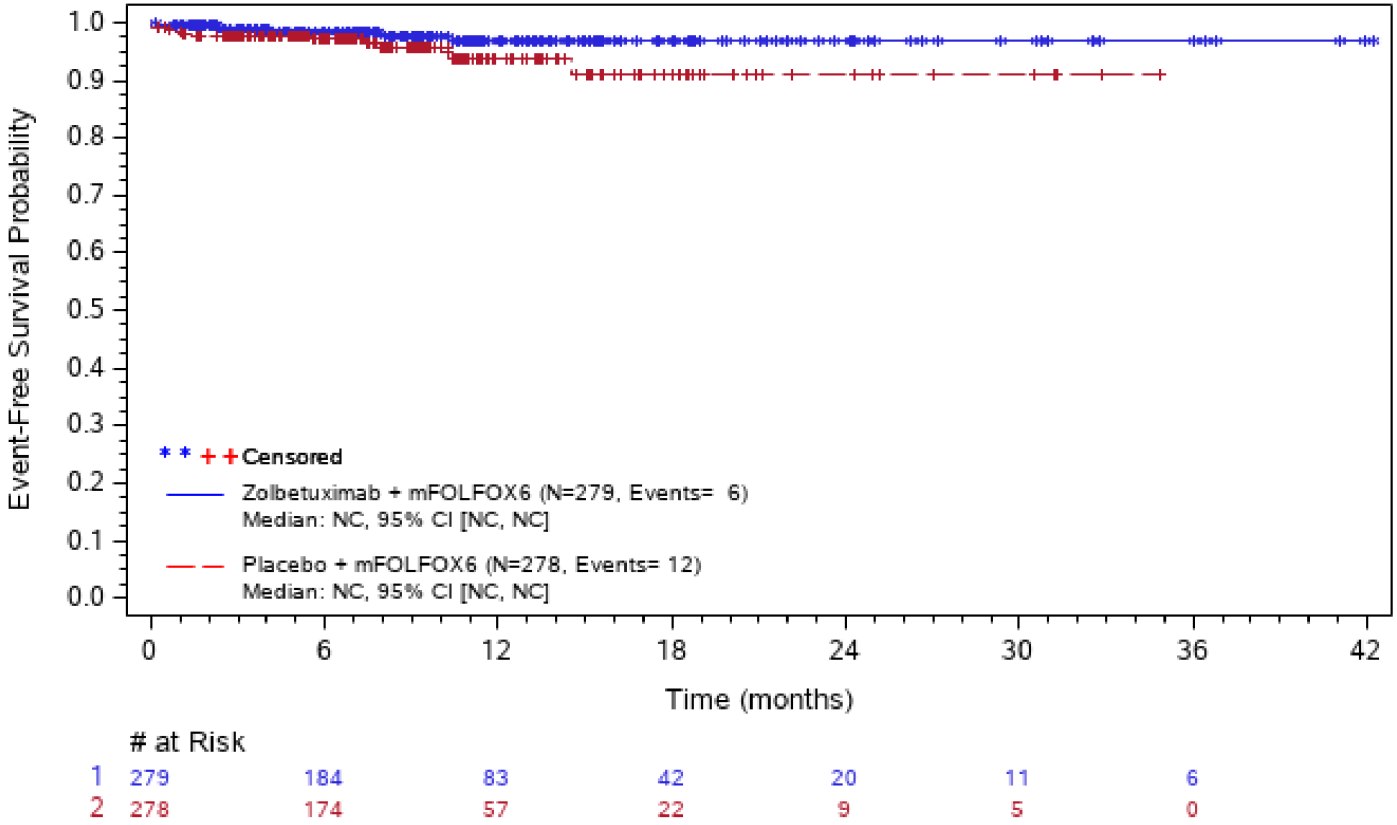
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.116: Kaplan-Meier Plot of Time to first TEAE - Proteinuria (PT) - Safety Analysis Set



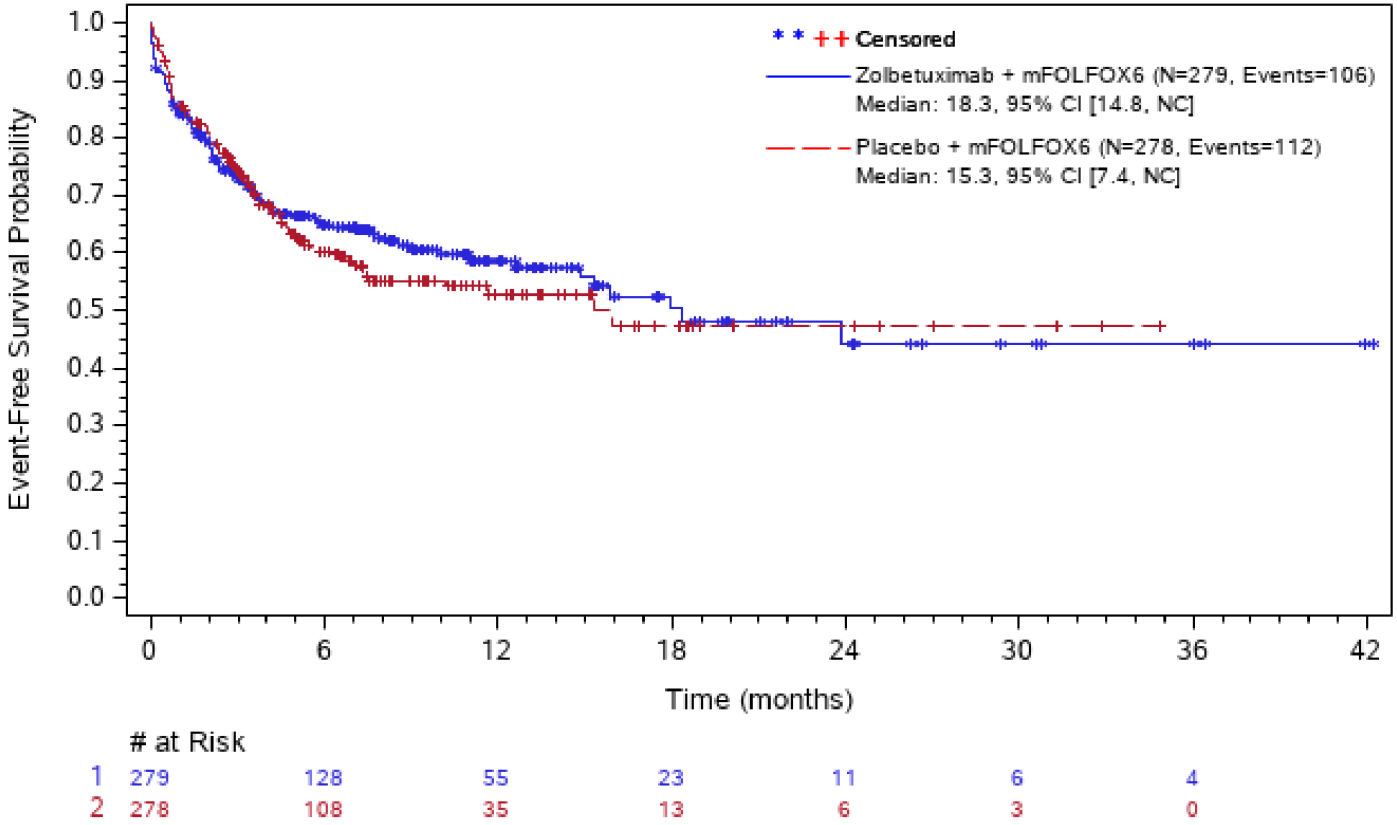
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.117: Kaplan-Meier Plot of Time to first TEAE - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set



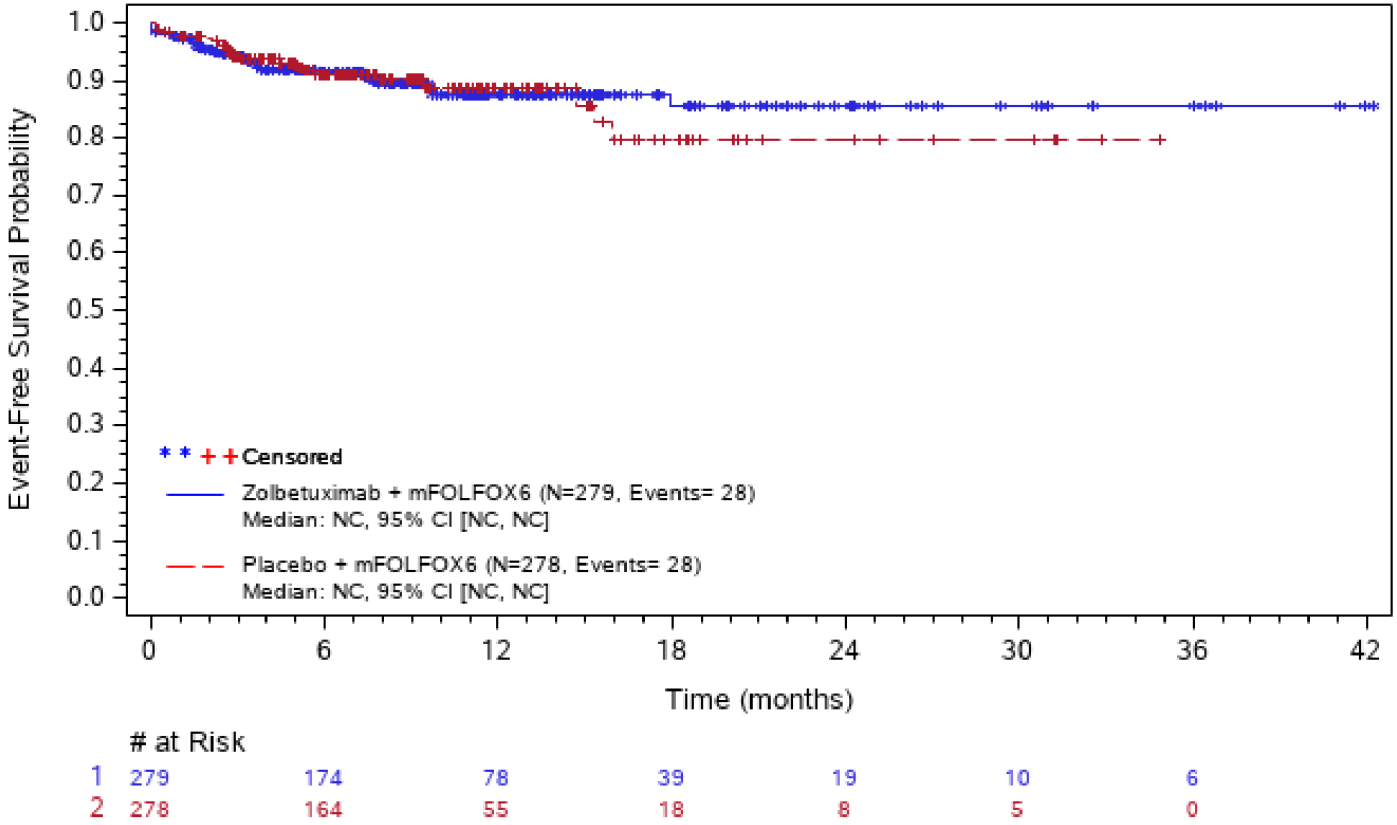
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.118: Kaplan-Meier Plot of Time to first TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



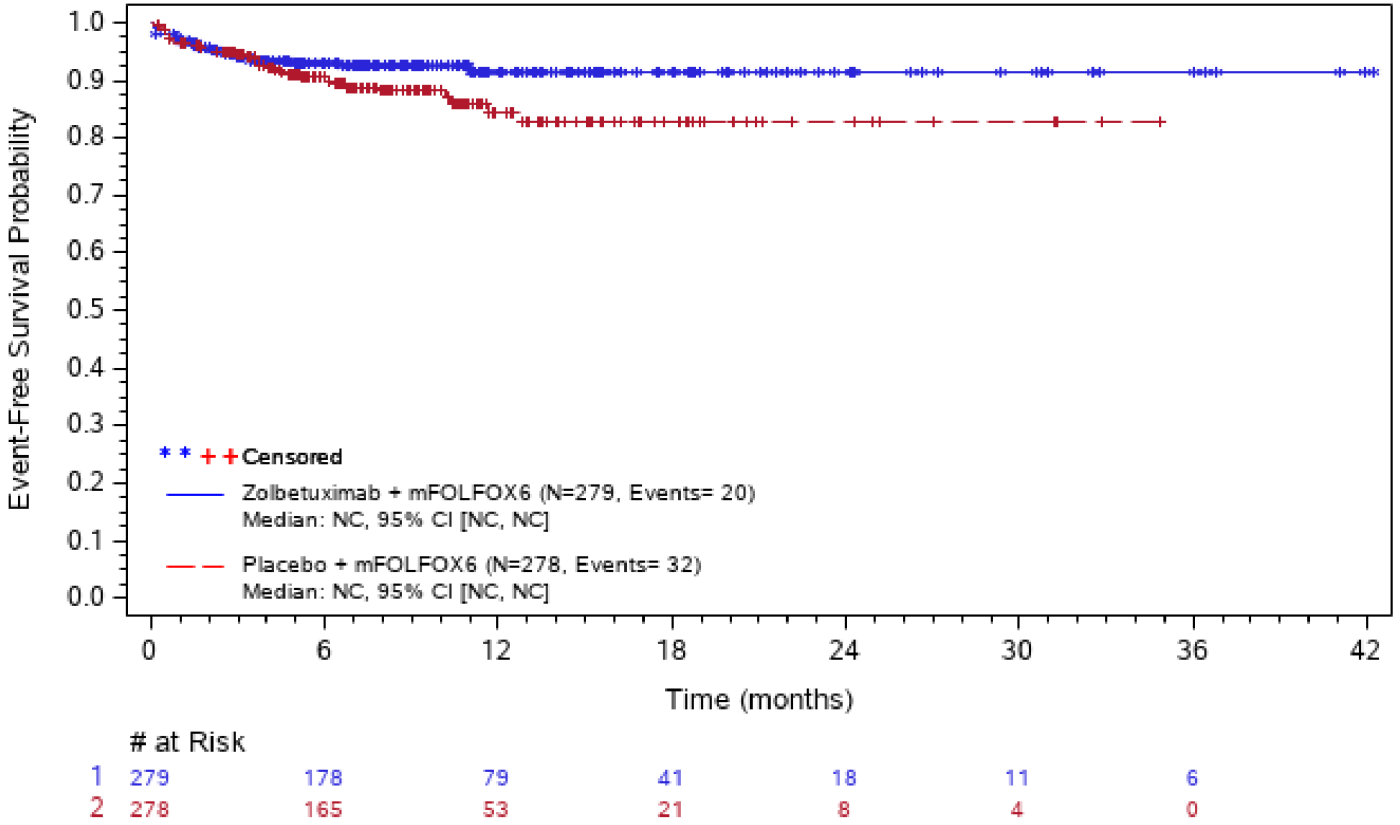
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.119: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Safety Analysis Set



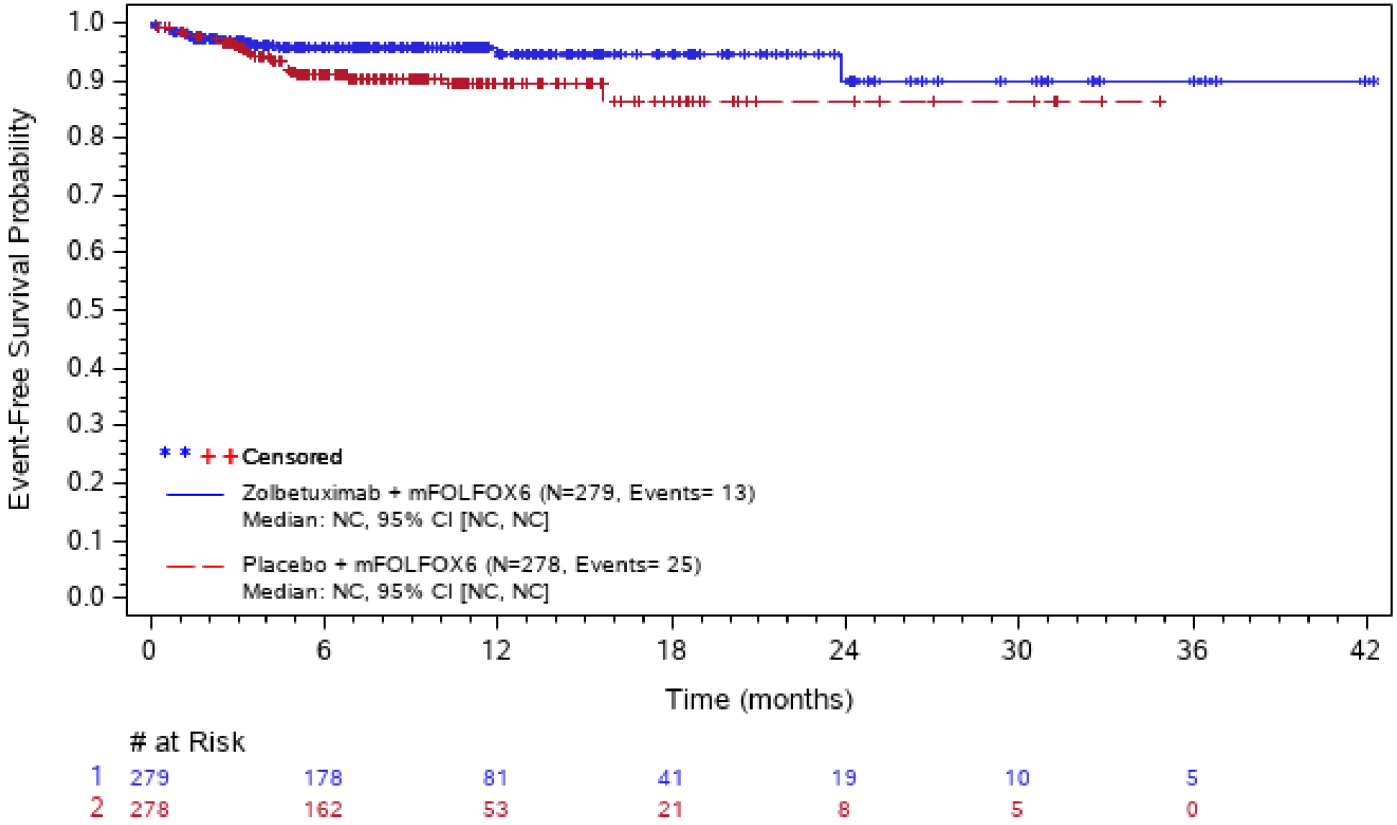
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.120: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Safety Analysis Set



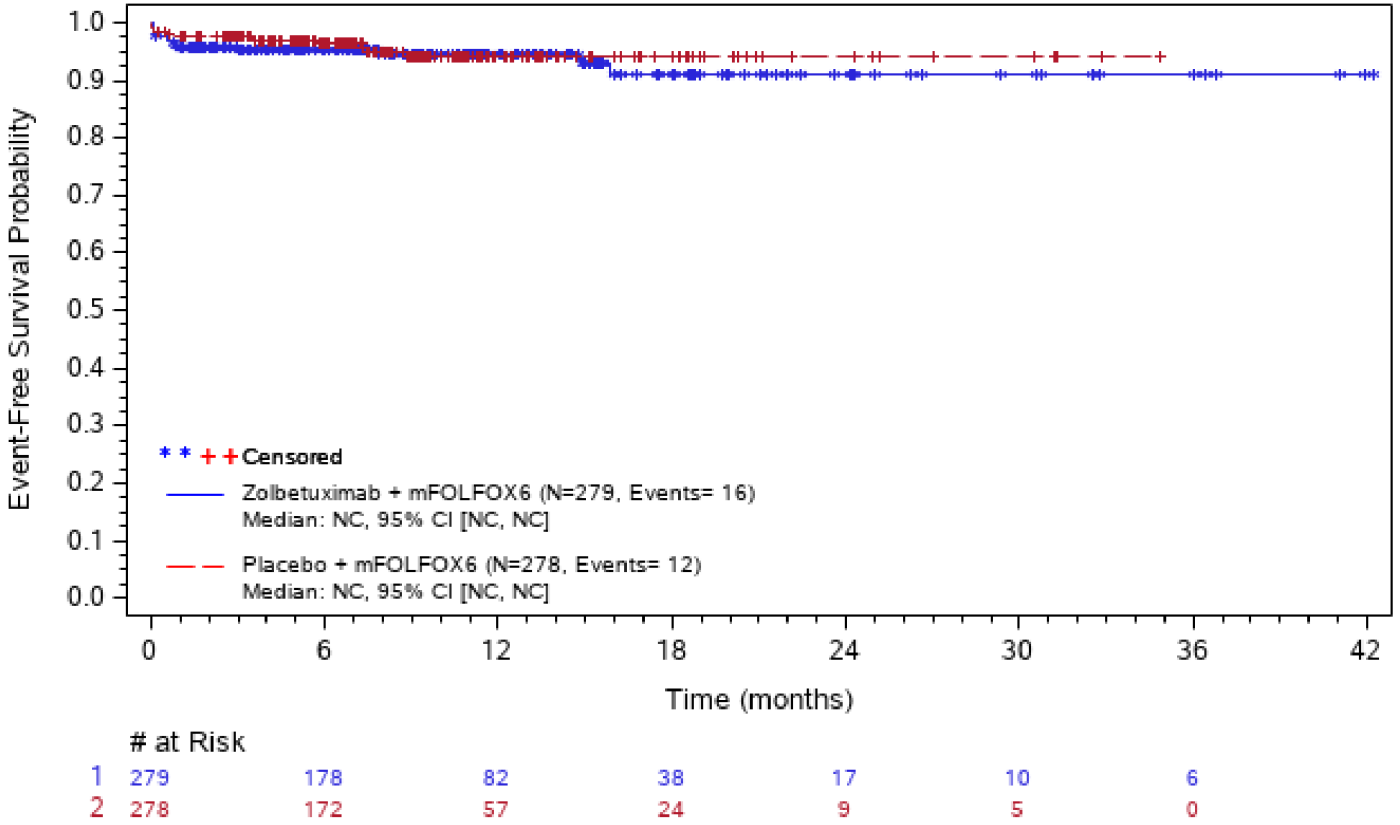
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.121: Kaplan-Meier Plot of Time to first TEAE - Epistaxis (PT) - Safety Analysis Set



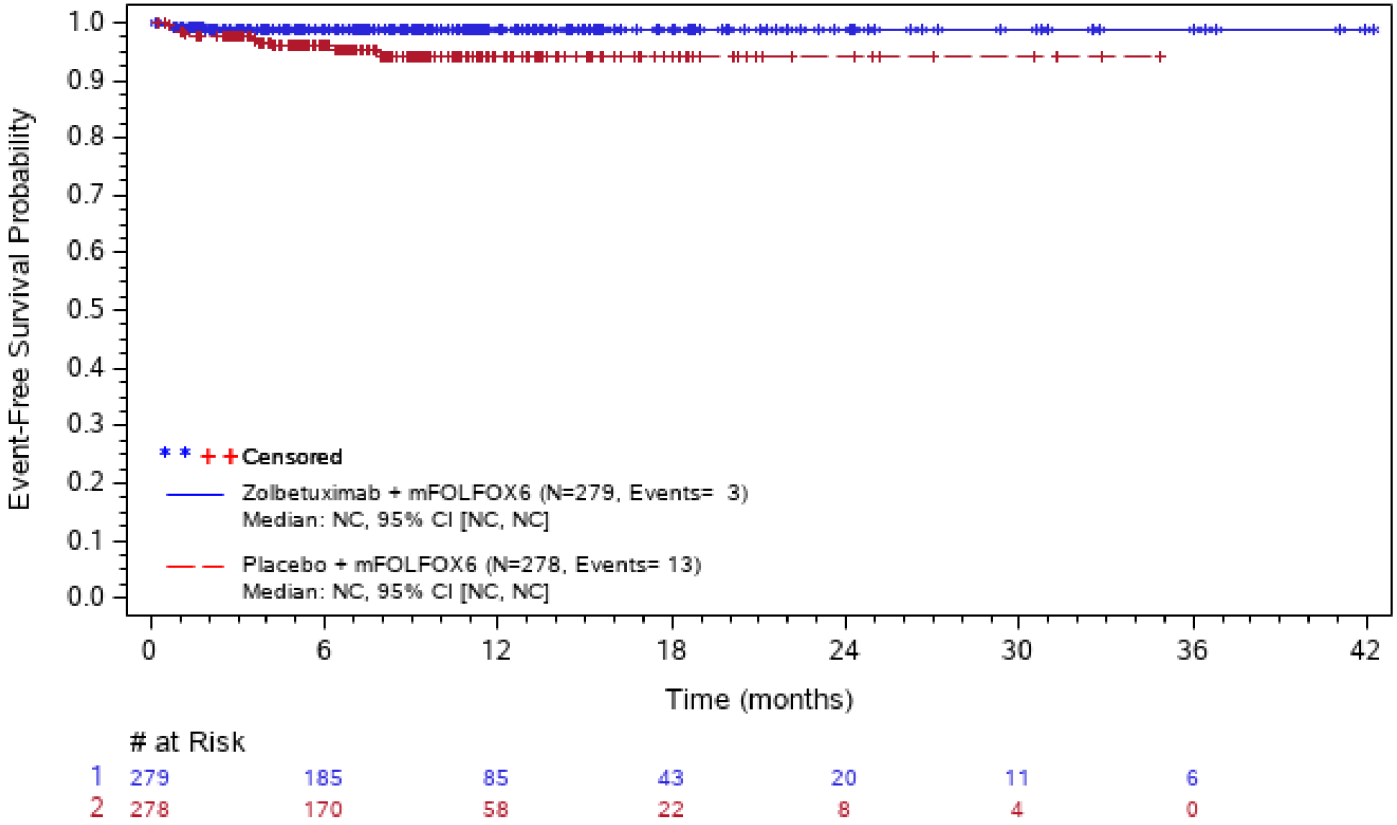
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.122: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Safety Analysis Set



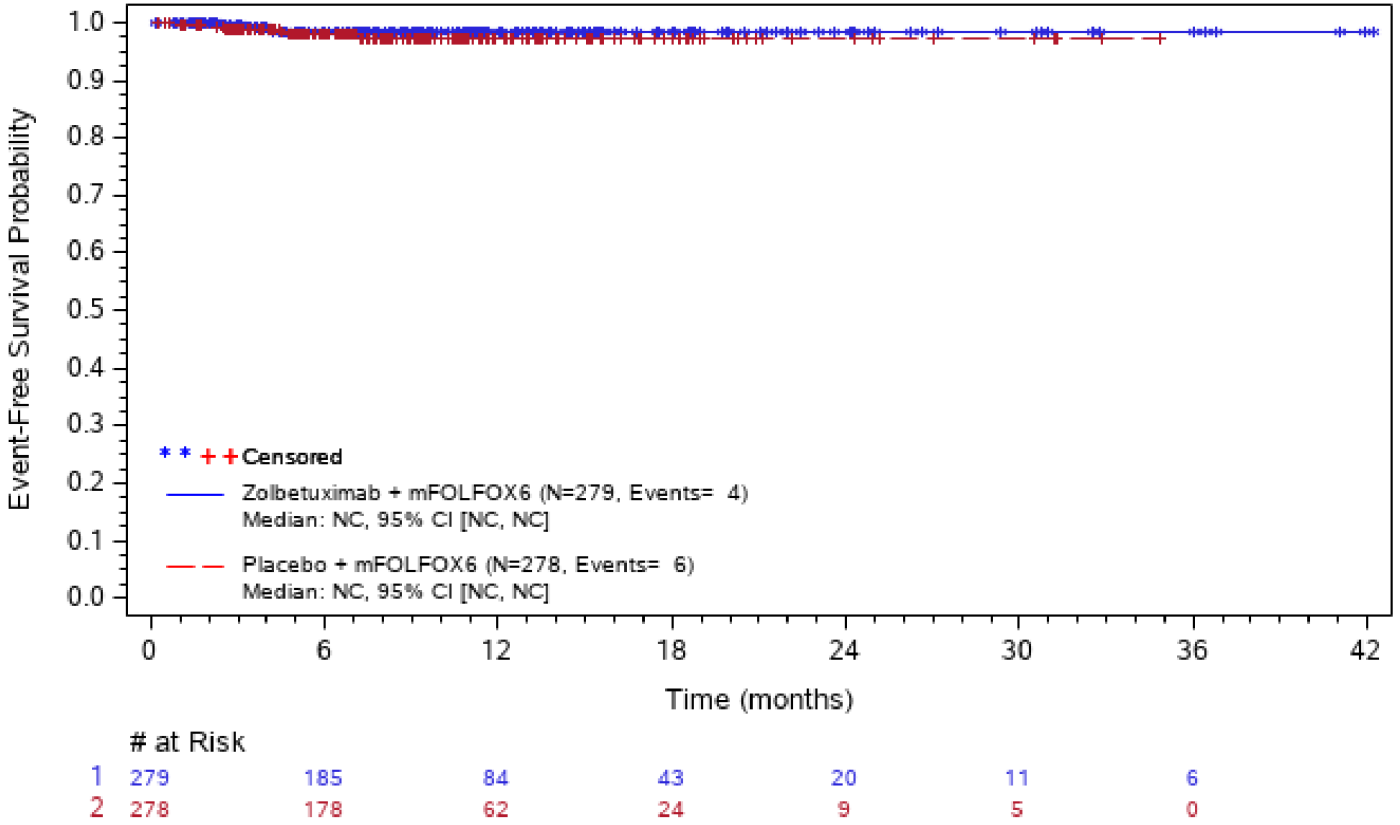
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.123: Kaplan-Meier Plot of Time to first TEAE - Oropharyngeal Pain (PT) - Safety Analysis Set



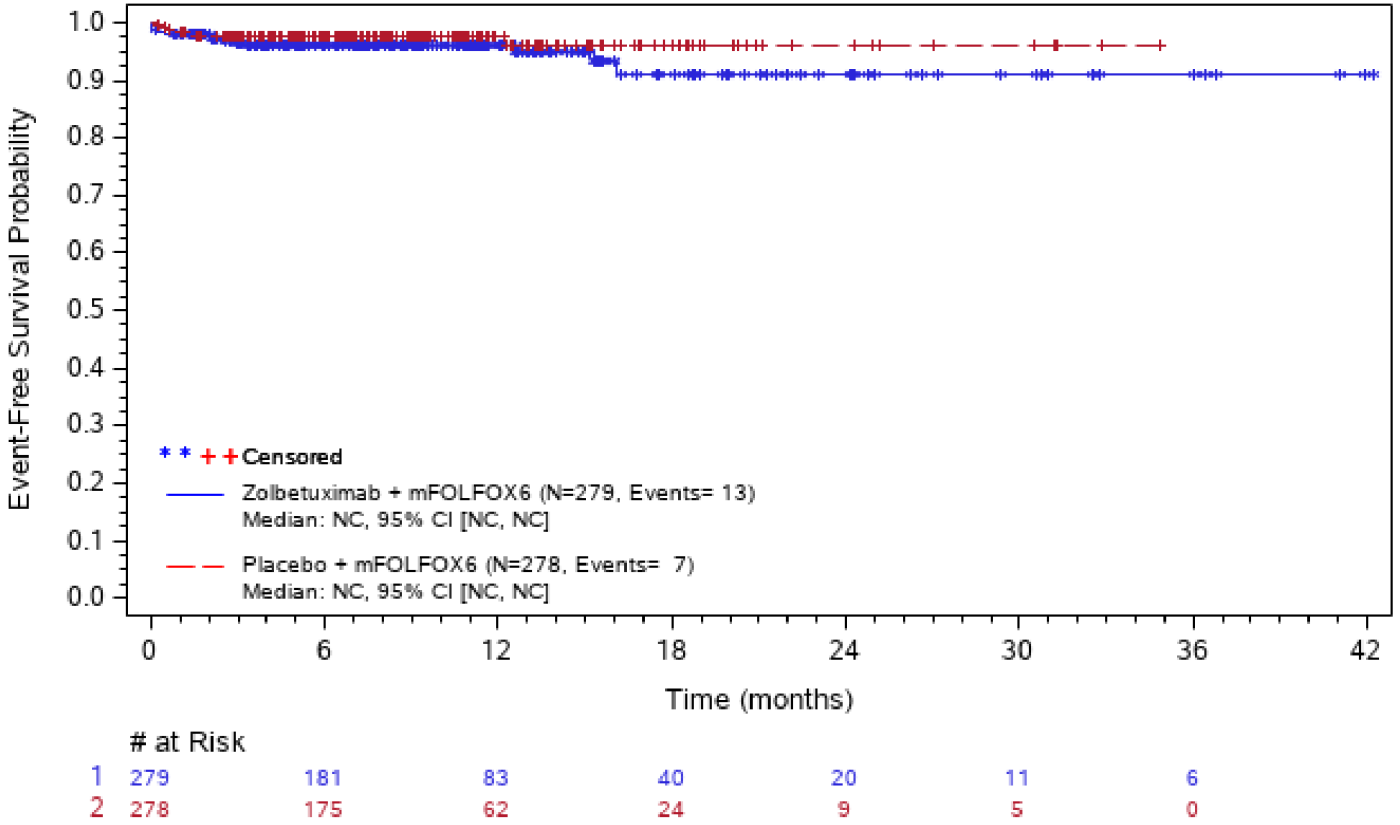
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.124: Kaplan-Meier Plot of Time to first TEAE - Pleural Effusion (PT) - Safety Analysis Set



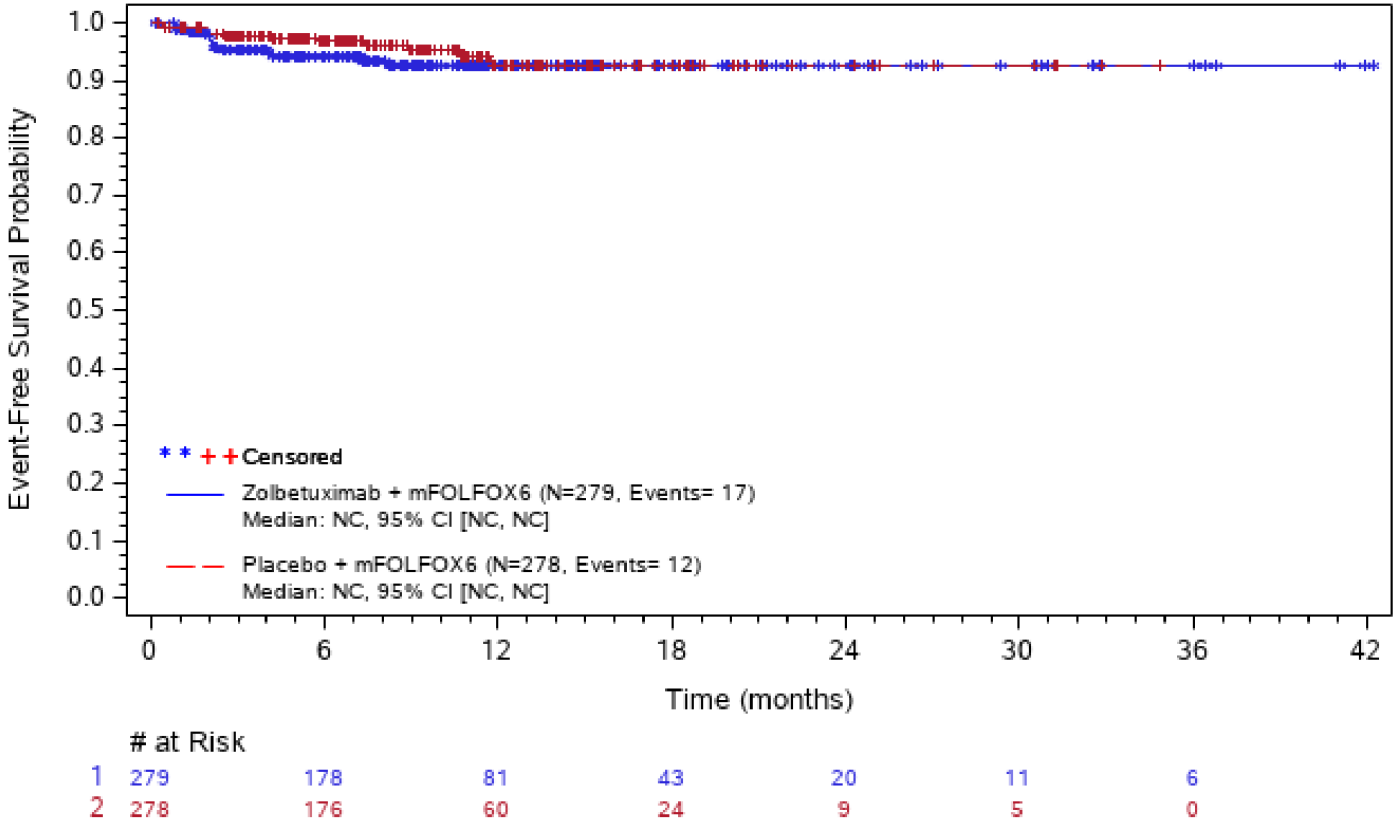
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.125: Kaplan-Meier Plot of Time to first TEAE - Productive Cough (PT) - Safety Analysis Set



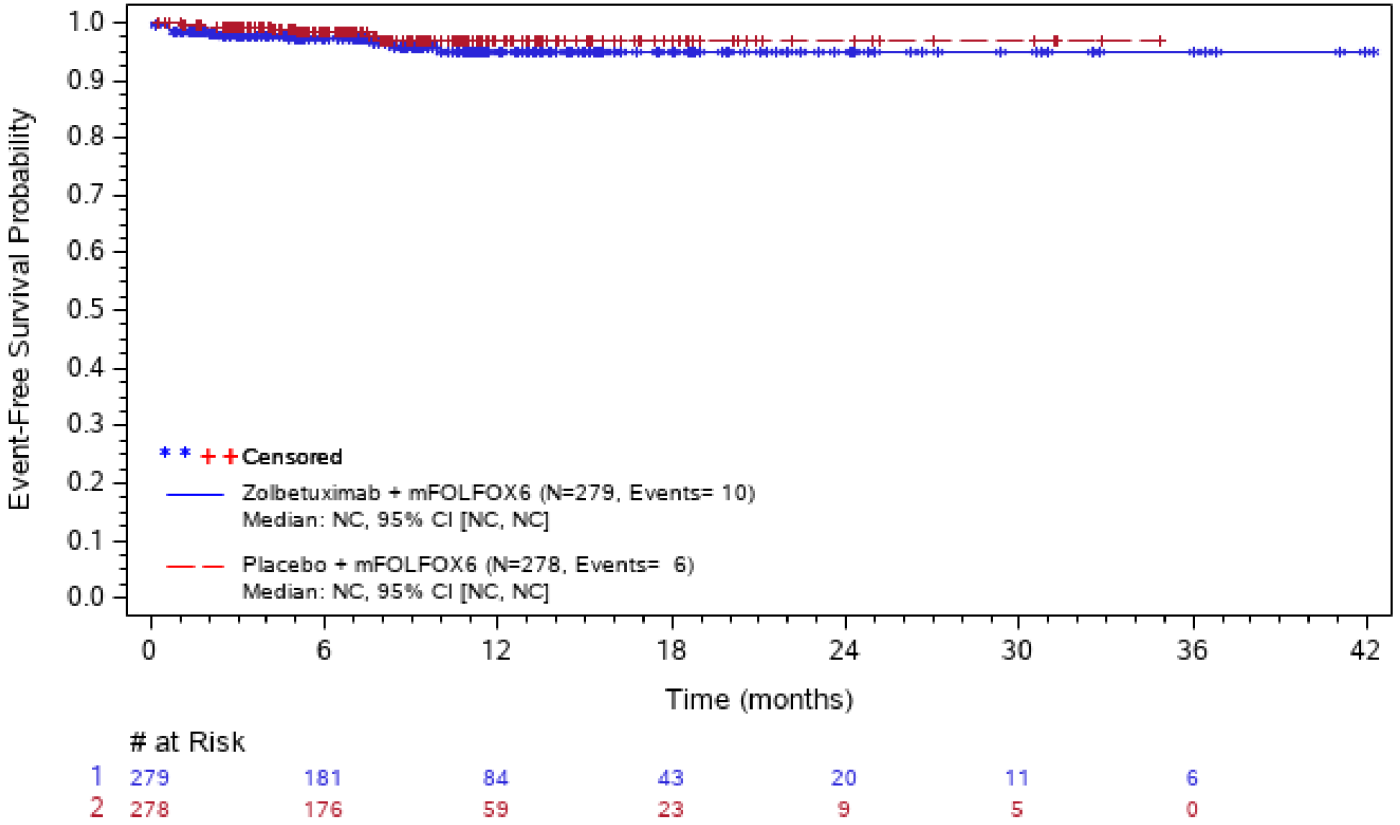
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.126: Kaplan-Meier Plot of Time to first TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



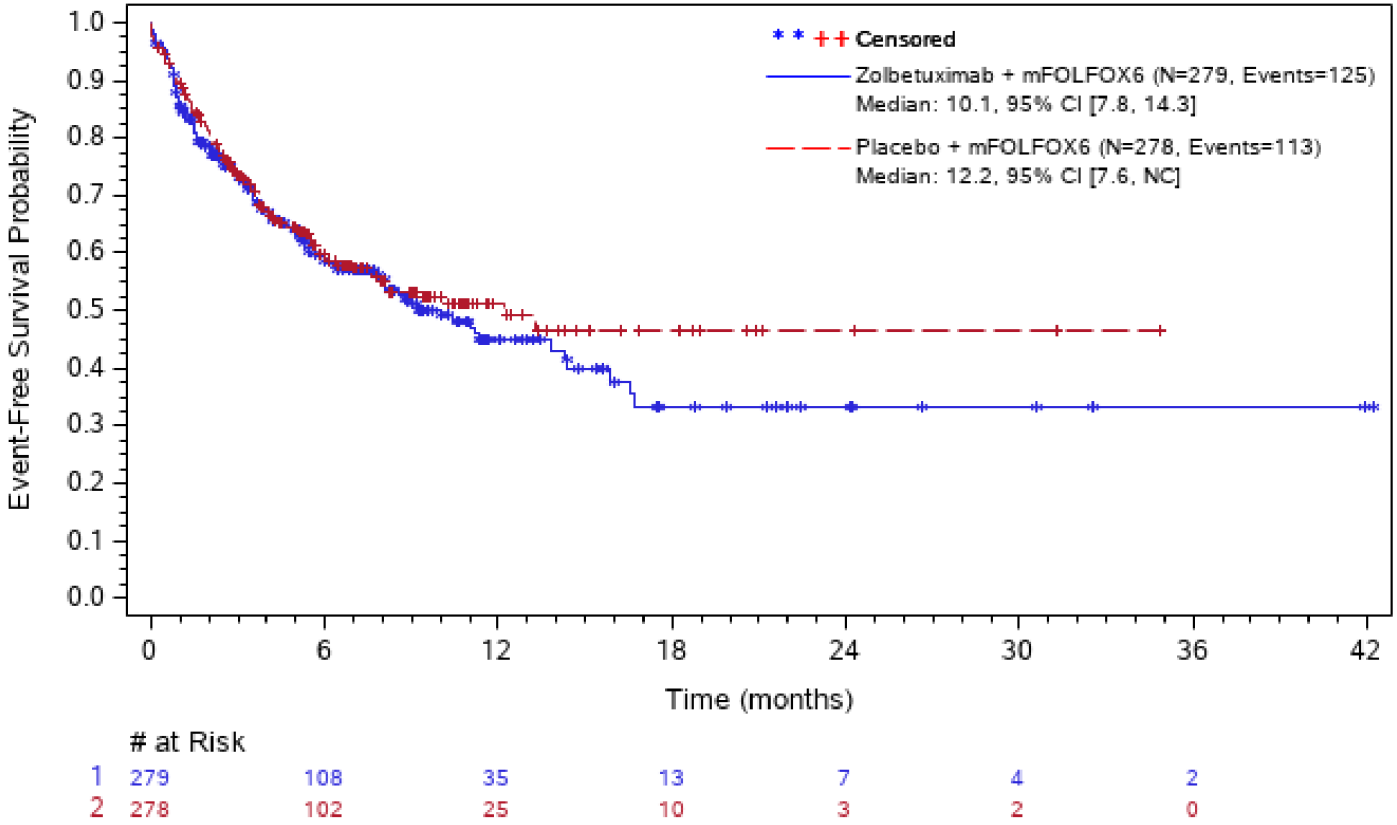
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.127: Kaplan-Meier Plot of Time to first TEAE - Rhinorrhoea (PT) - Safety Analysis Set



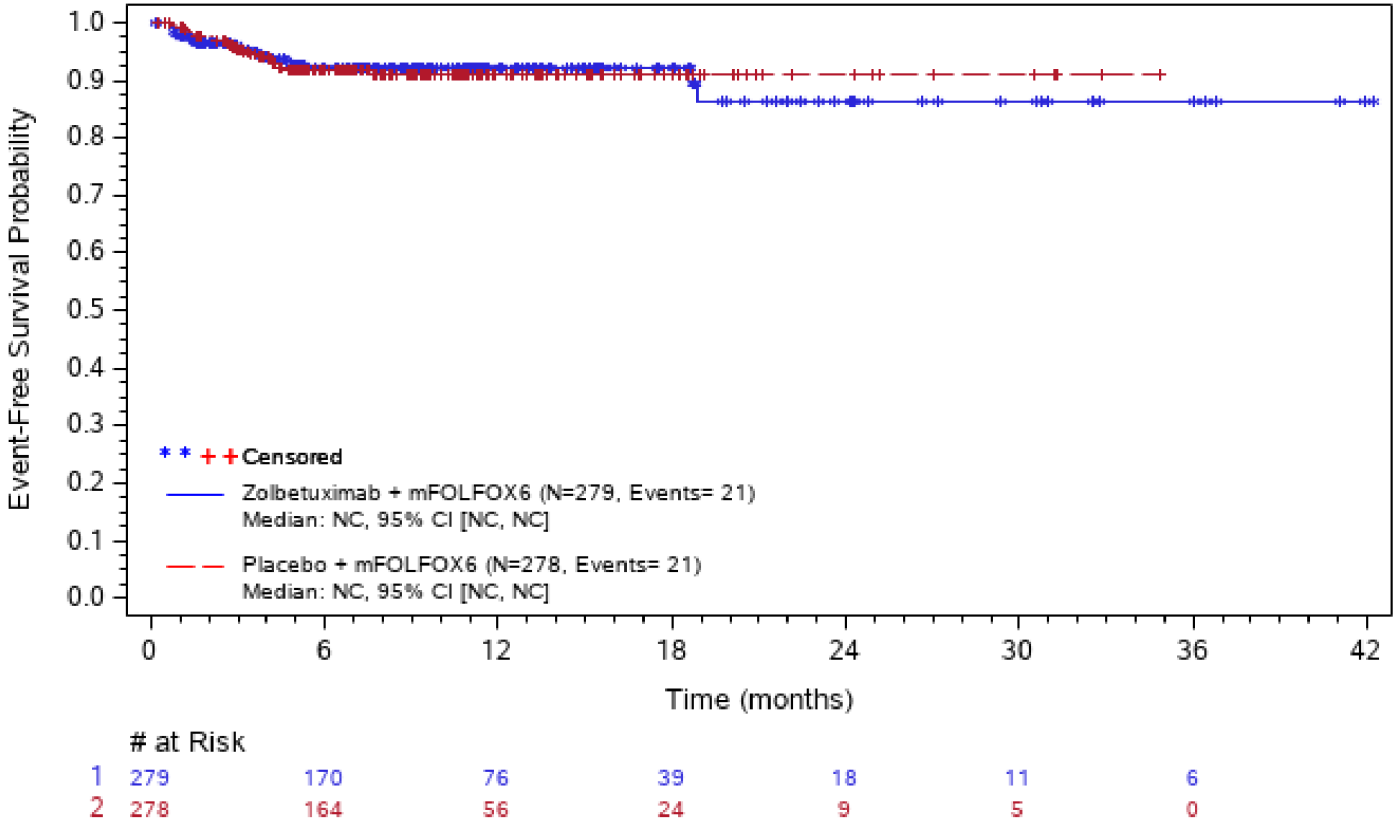
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.128: Kaplan-Meier Plot of Time to first TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set



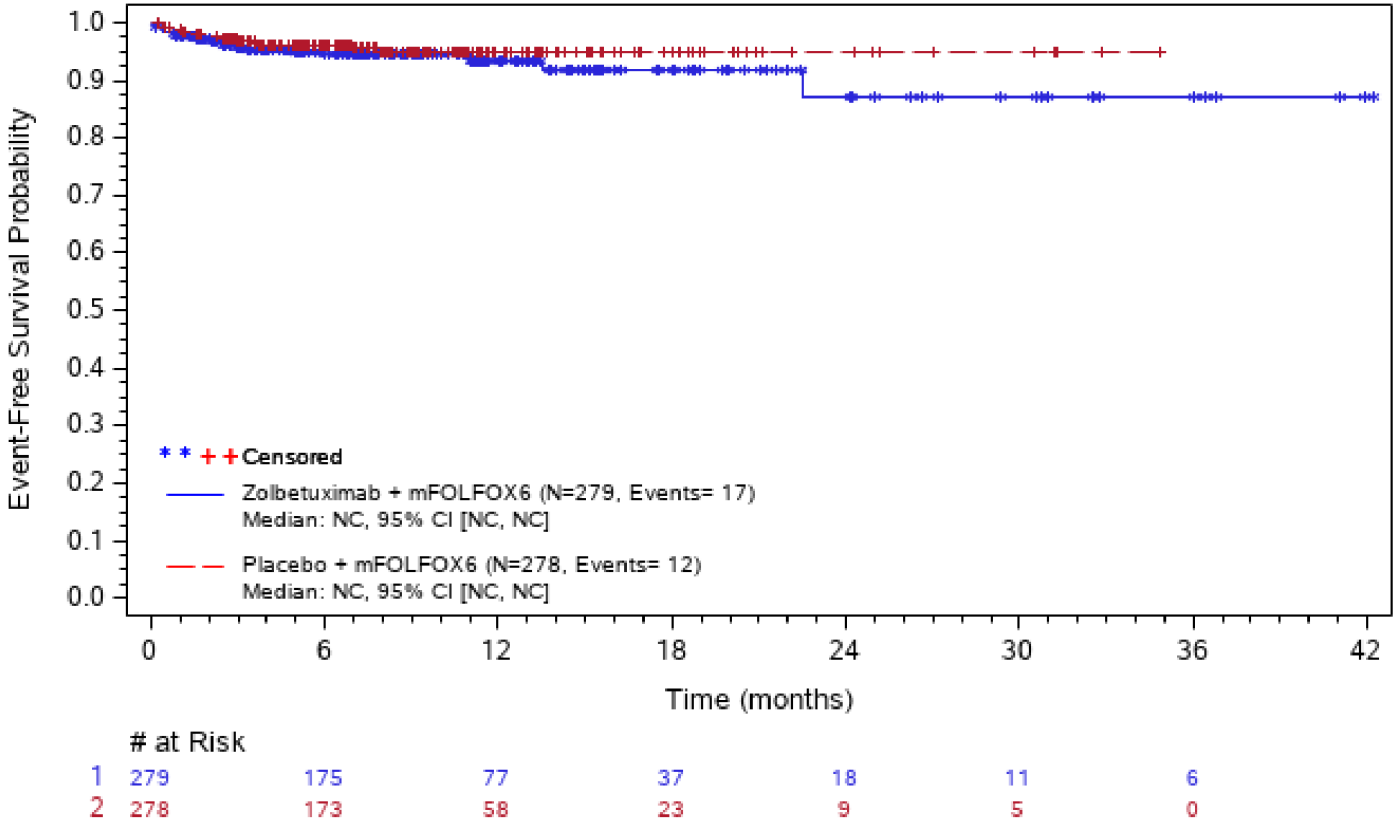
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.129: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Safety Analysis Set



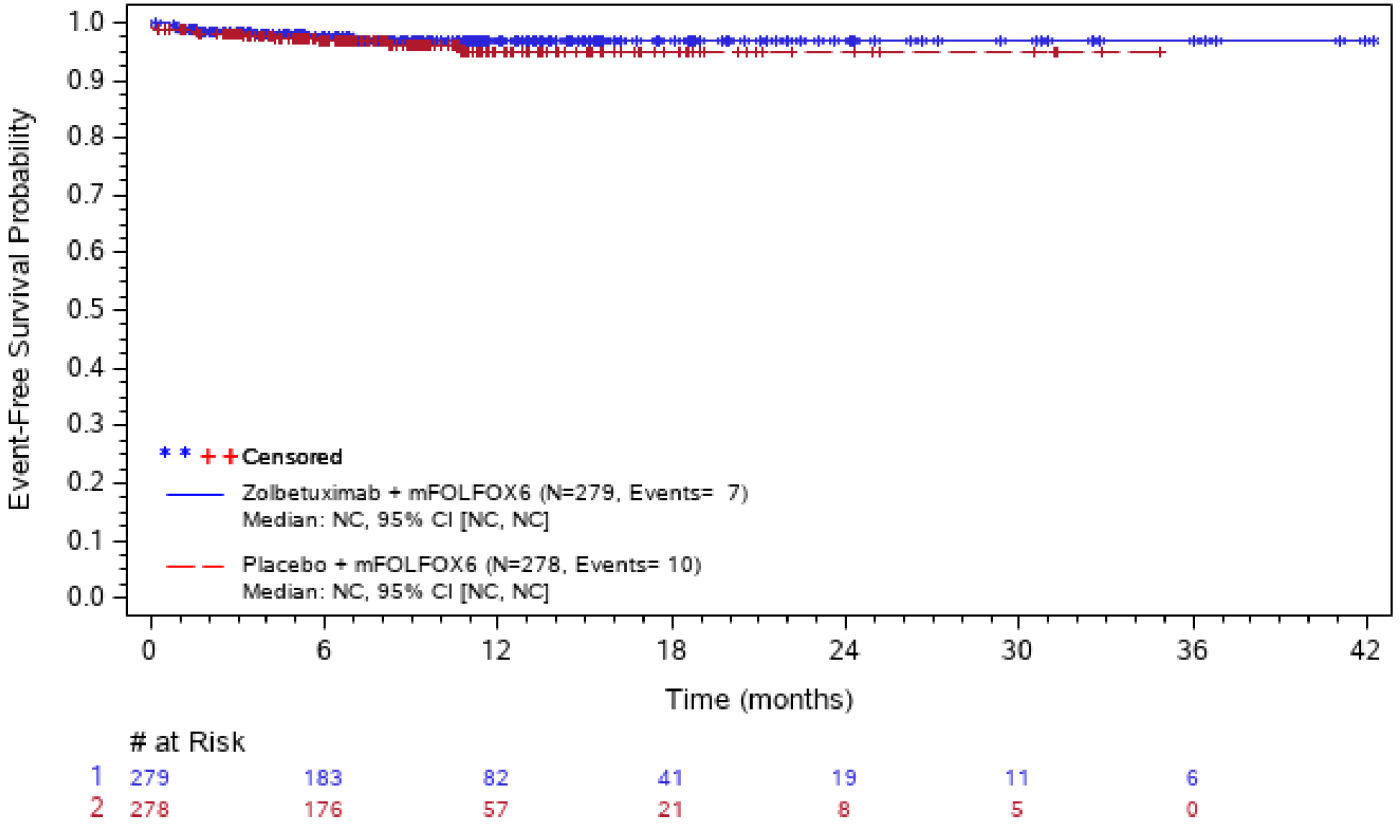
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.130: Kaplan-Meier Plot of Time to first TEAE - Dry Skin (PT) - Safety Analysis Set



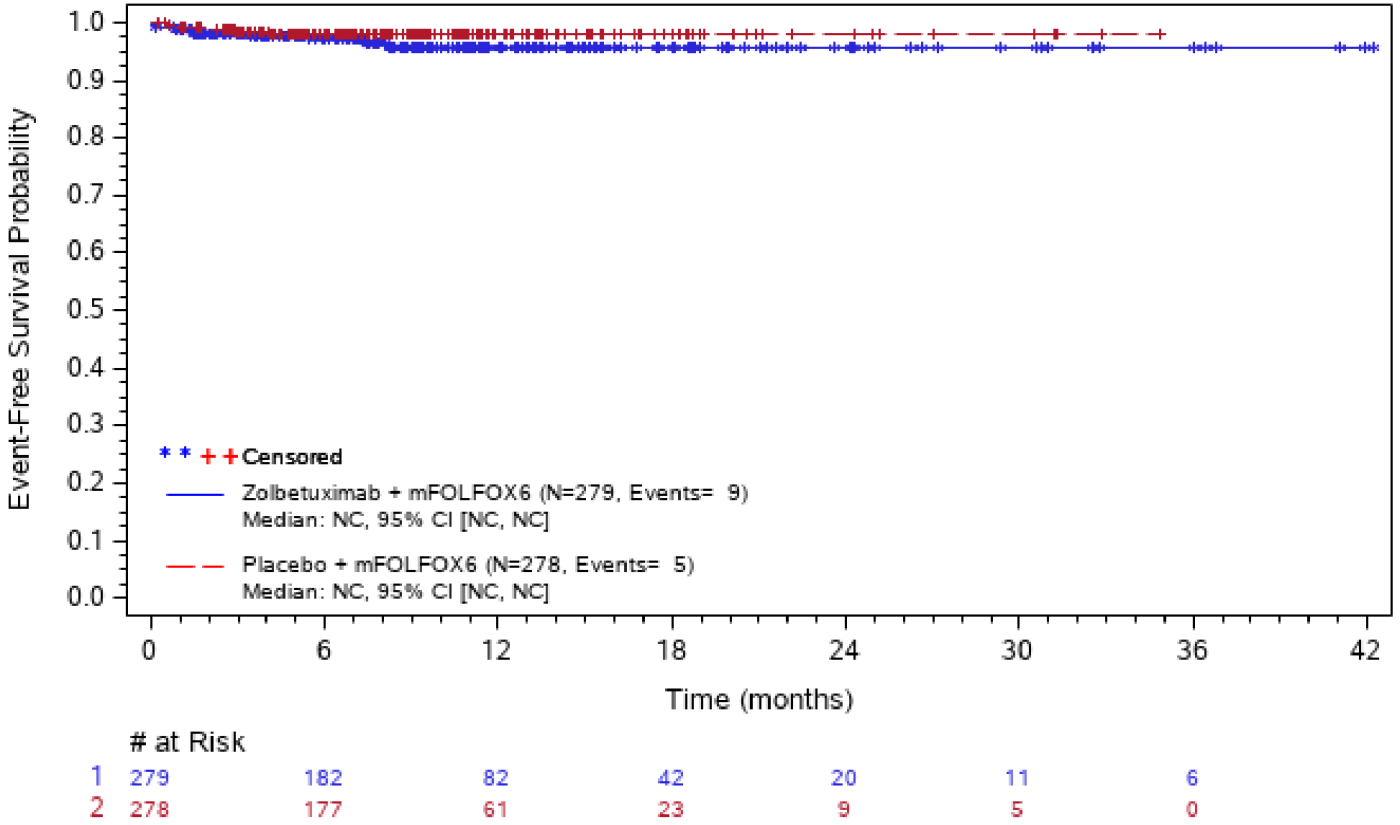
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.131: Kaplan-Meier Plot of Time to first TEAE - Erythema (PT) - Safety Analysis Set



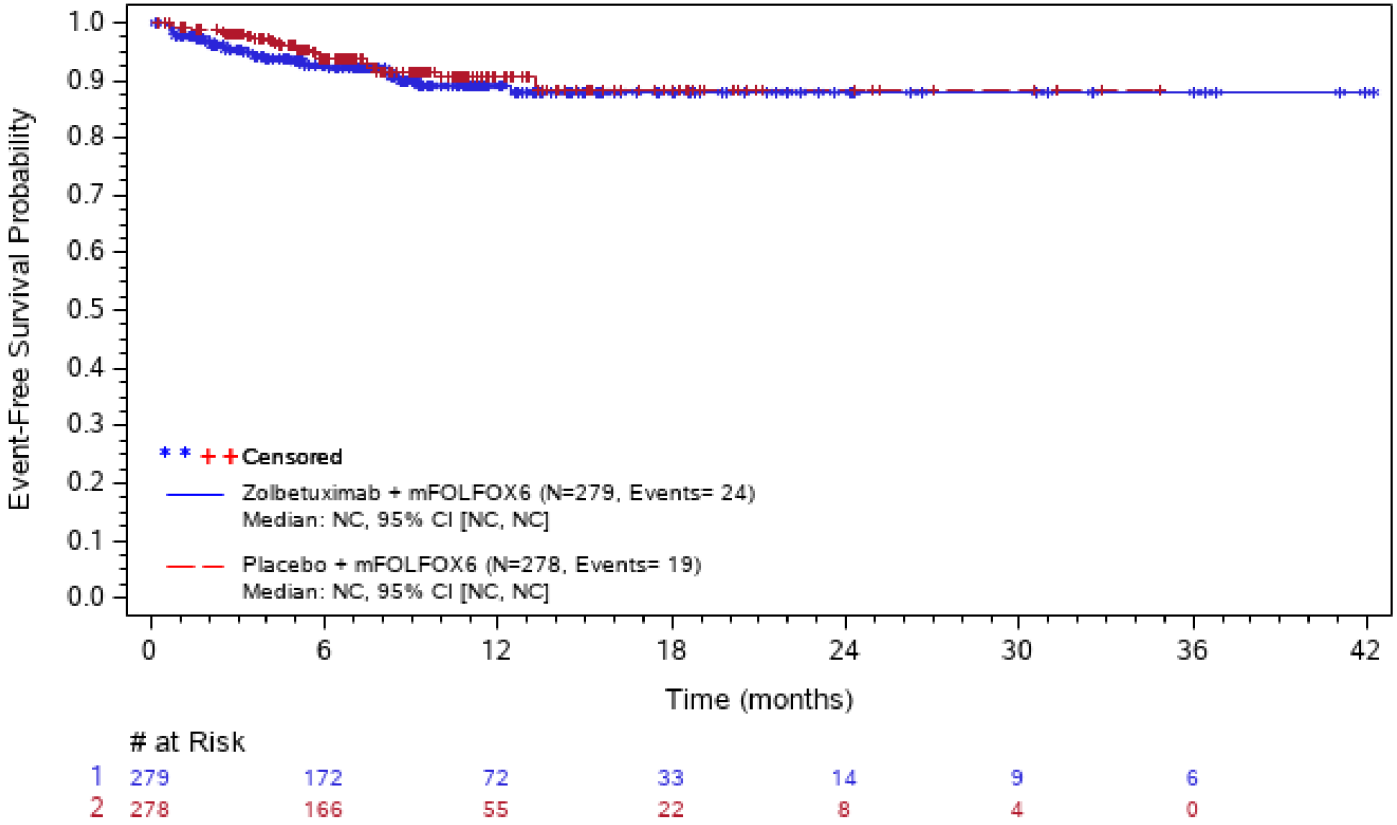
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.132: Kaplan-Meier Plot of Time to first TEAE - Hyperhidrosis (PT) - Safety Analysis Set



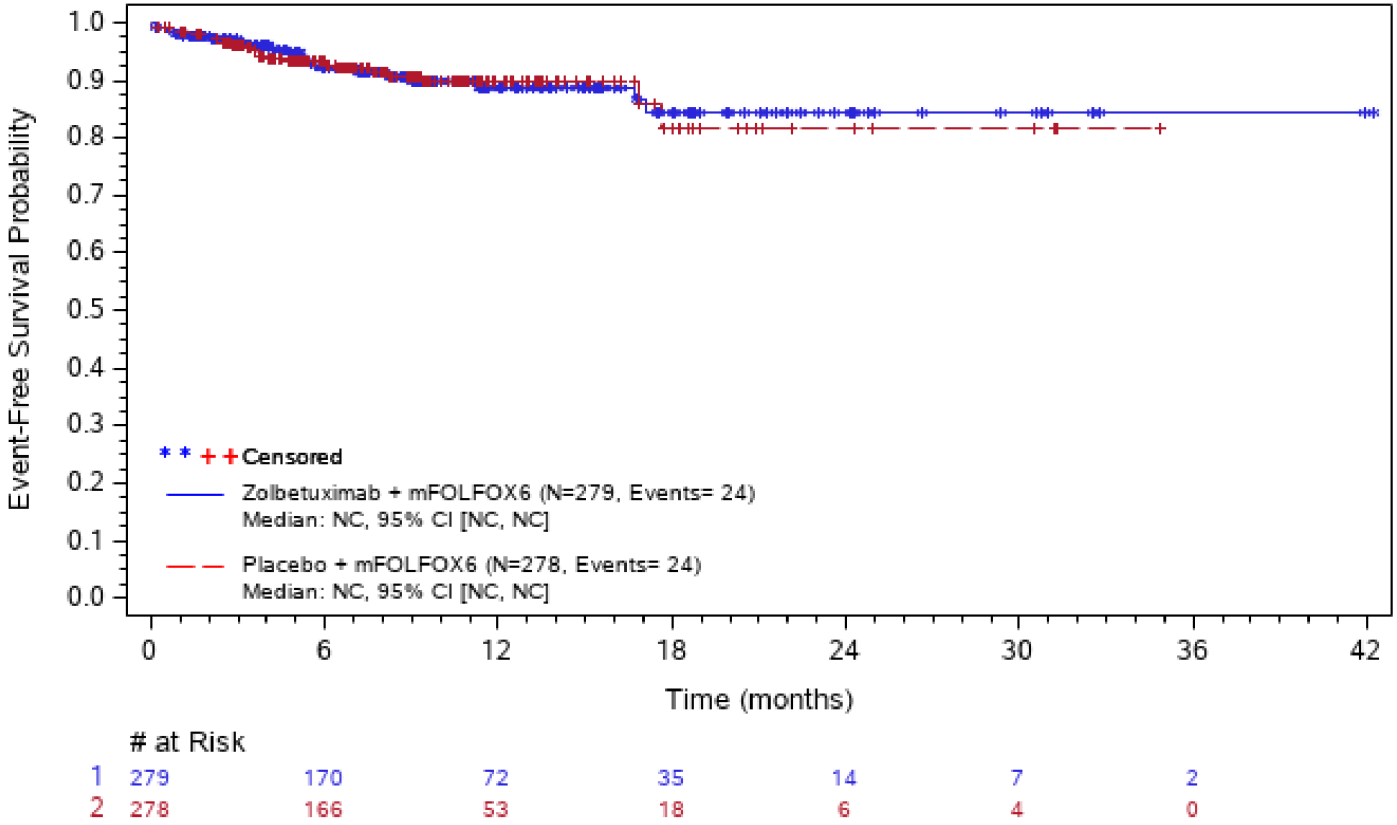
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.133: Kaplan-Meier Plot of Time to first TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set



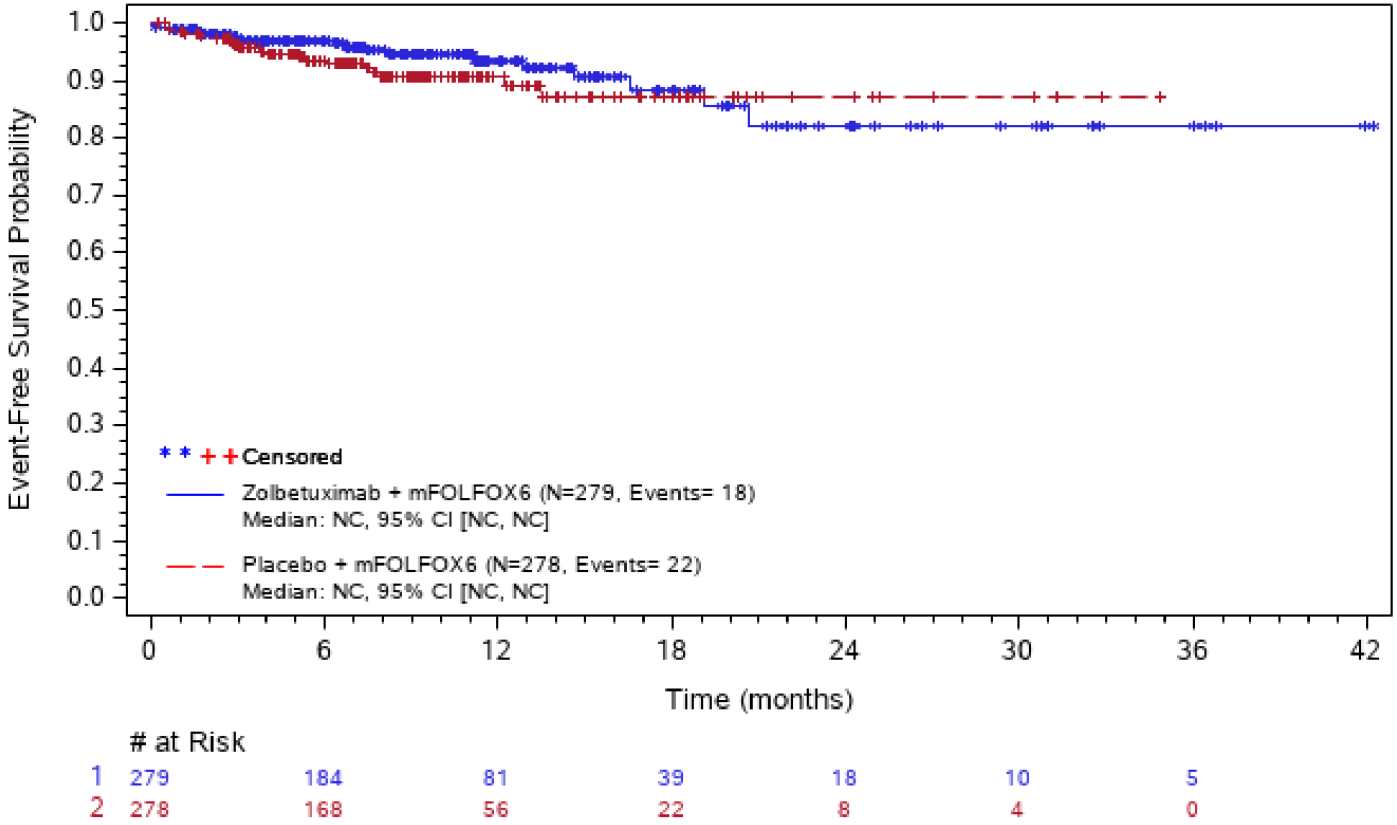
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.134: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Safety Analysis Set



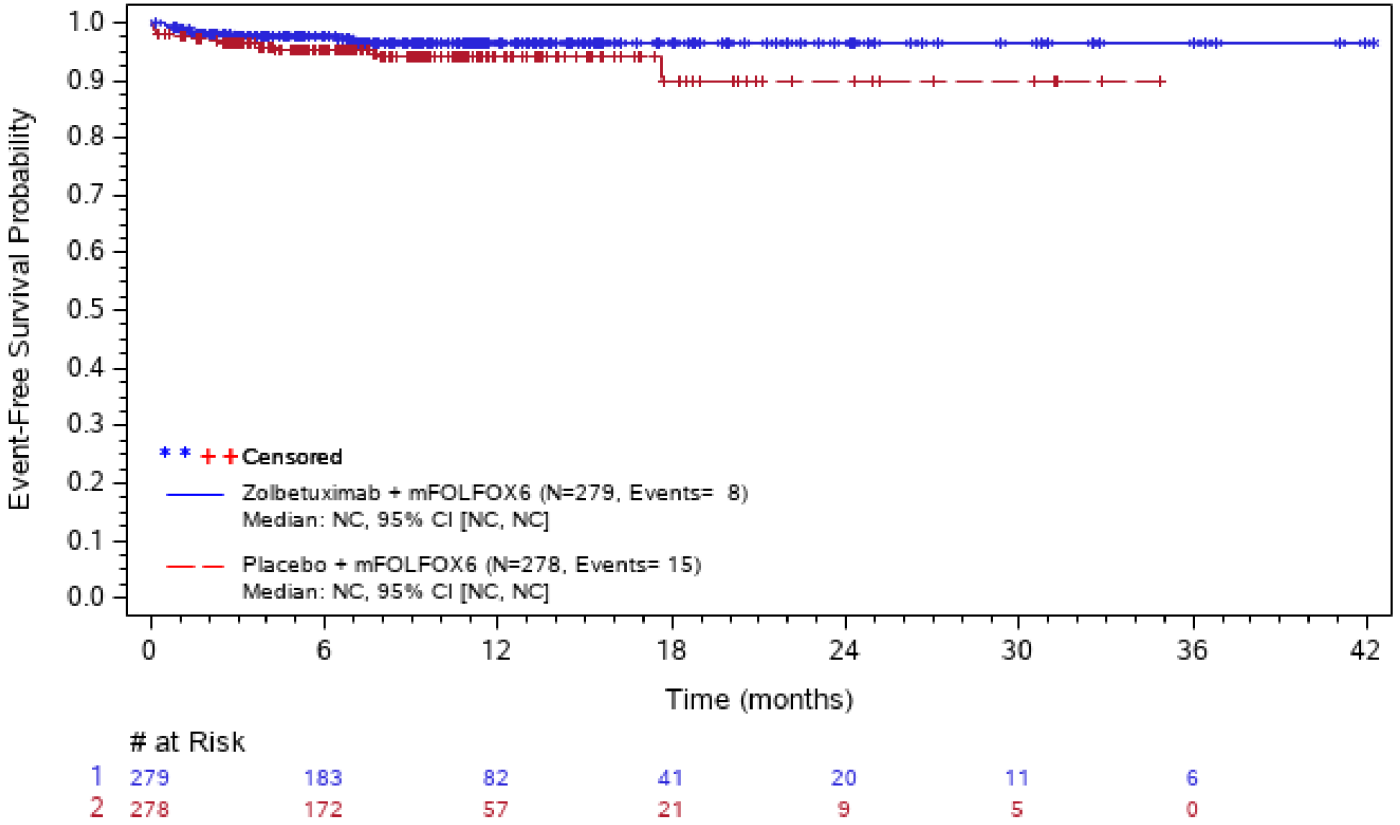
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.135: Kaplan-Meier Plot of Time to first TEAE - Rash (PT) - Safety Analysis Set



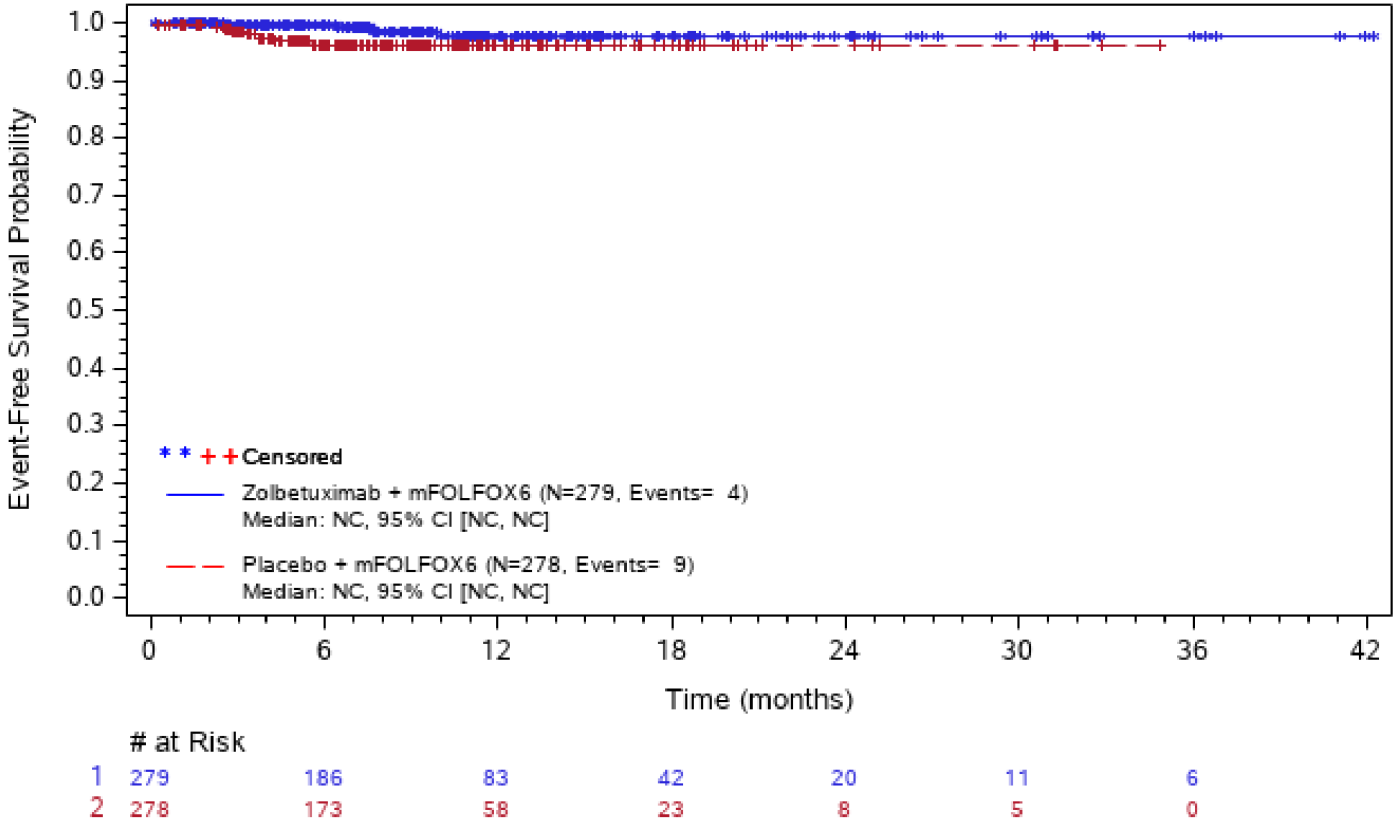
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.136: Kaplan-Meier Plot of Time to first TEAE - Rash Maculo-Papular (PT) - Safety Analysis Set



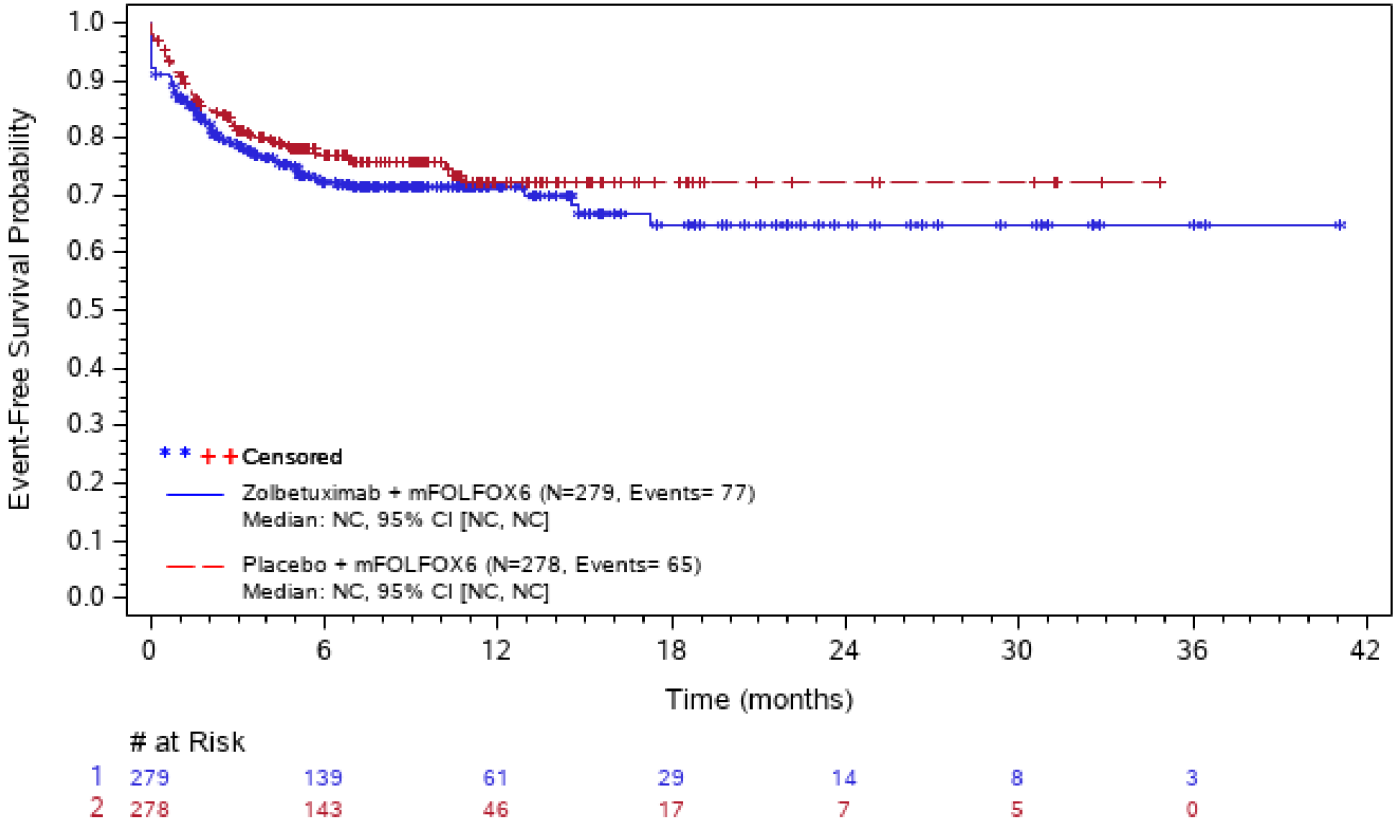
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.137: Kaplan-Meier Plot of Time to first TEAE - Urticaria (PT) - Safety Analysis Set



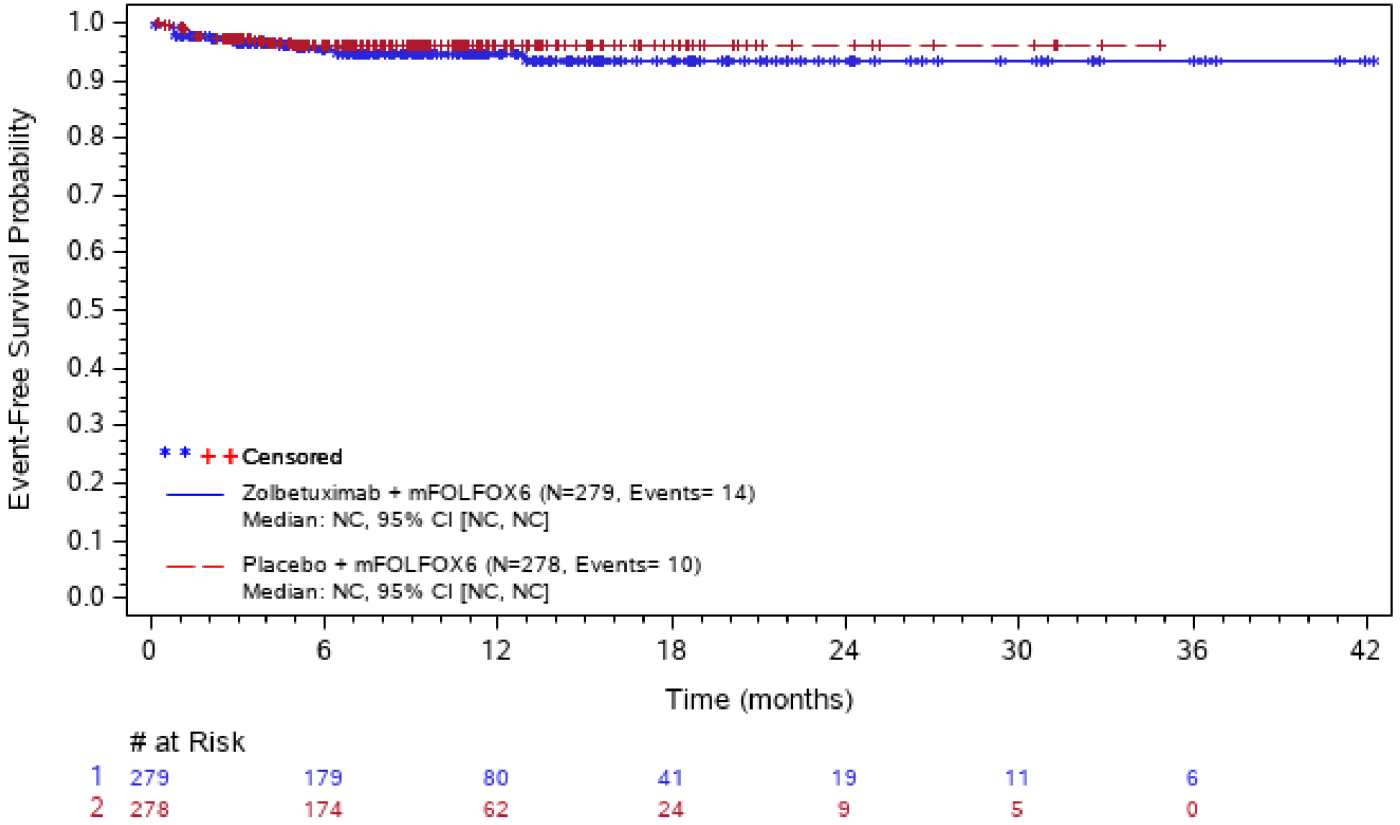
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.138: Kaplan-Meier Plot of Time to first TEAE - Vascular Disorders (SOC) - Safety Analysis Set



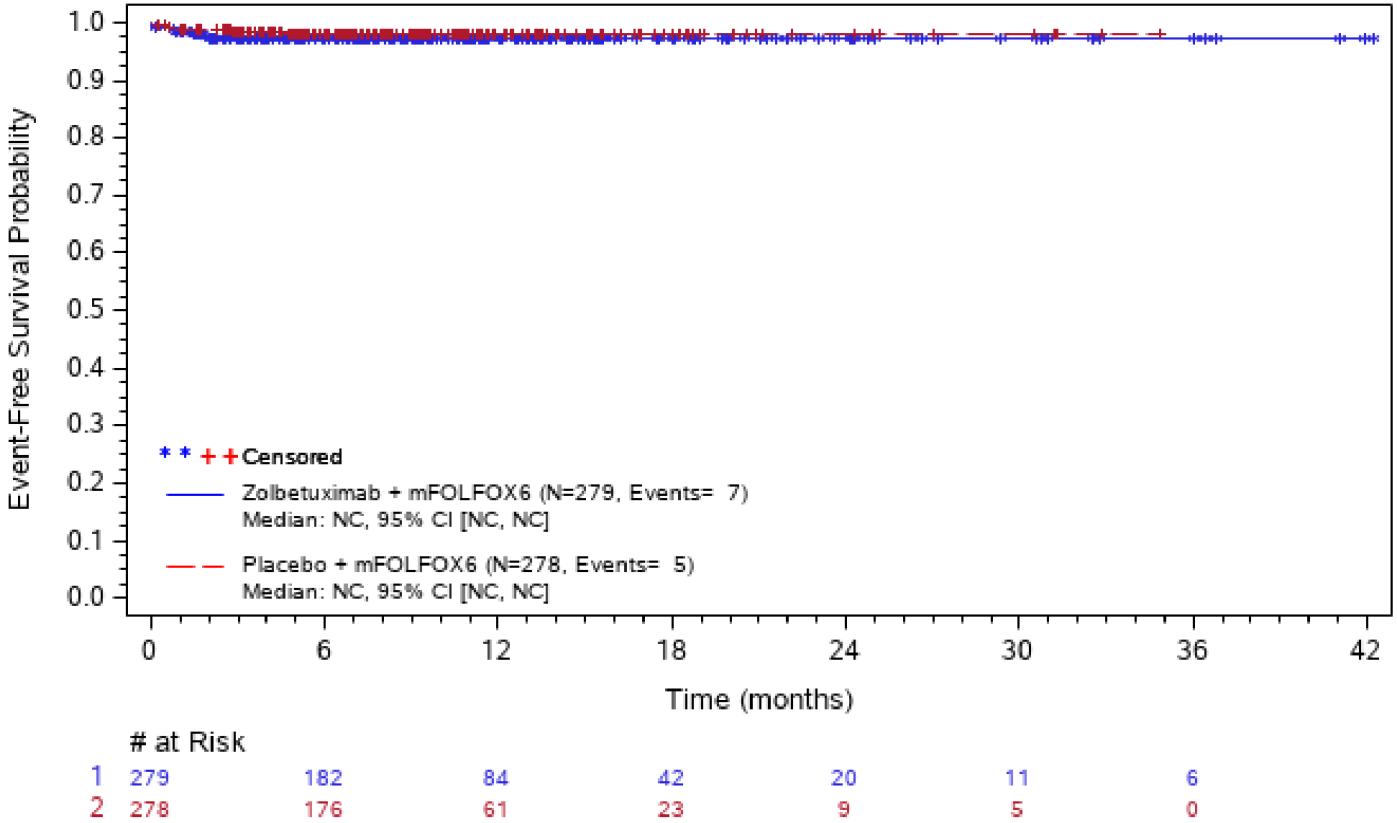
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.139: Kaplan-Meier Plot of Time to first TEAE - Deep Vein Thrombosis (PT) - Safety Analysis Set



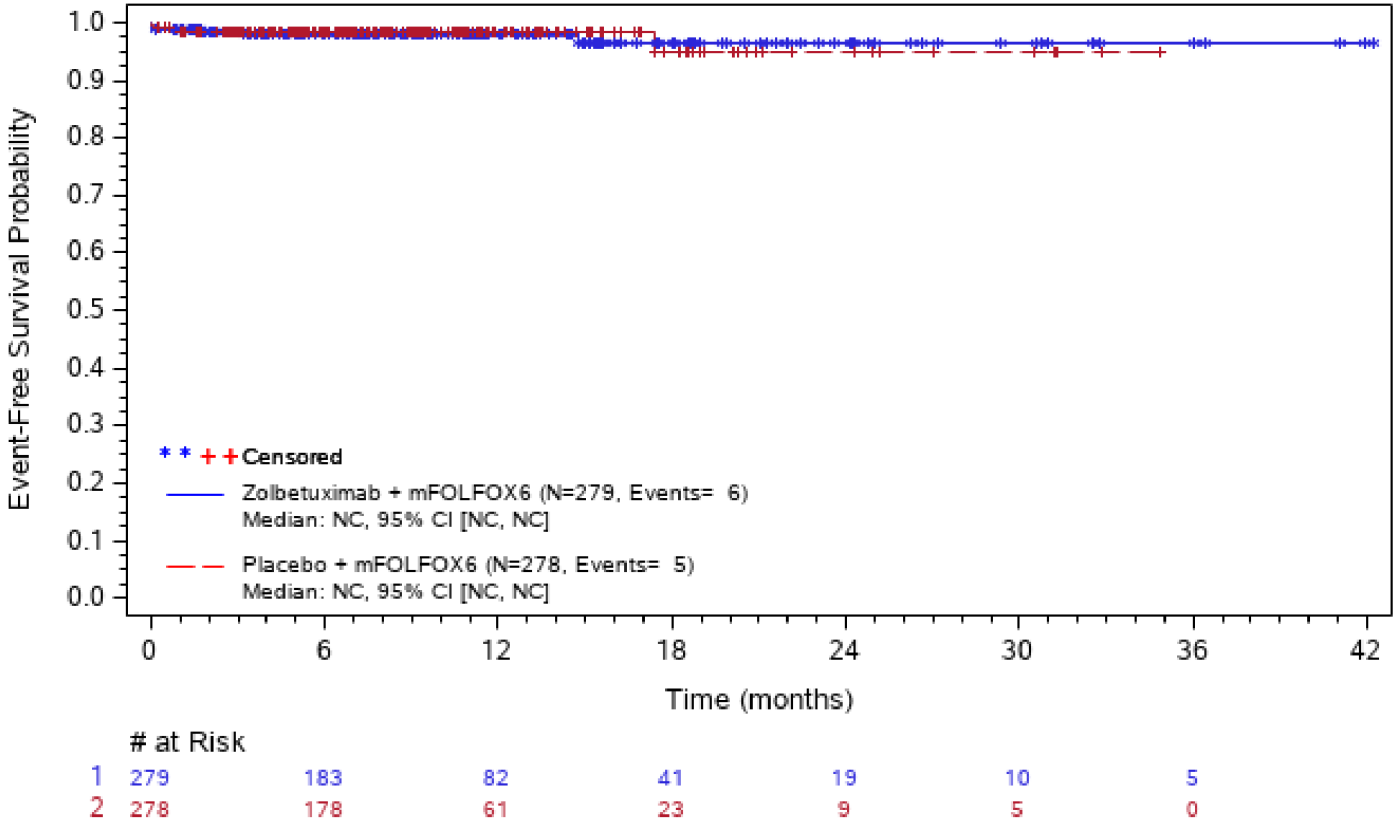
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.140: Kaplan-Meier Plot of Time to first TEAE - Flushing (PT) - Safety Analysis Set



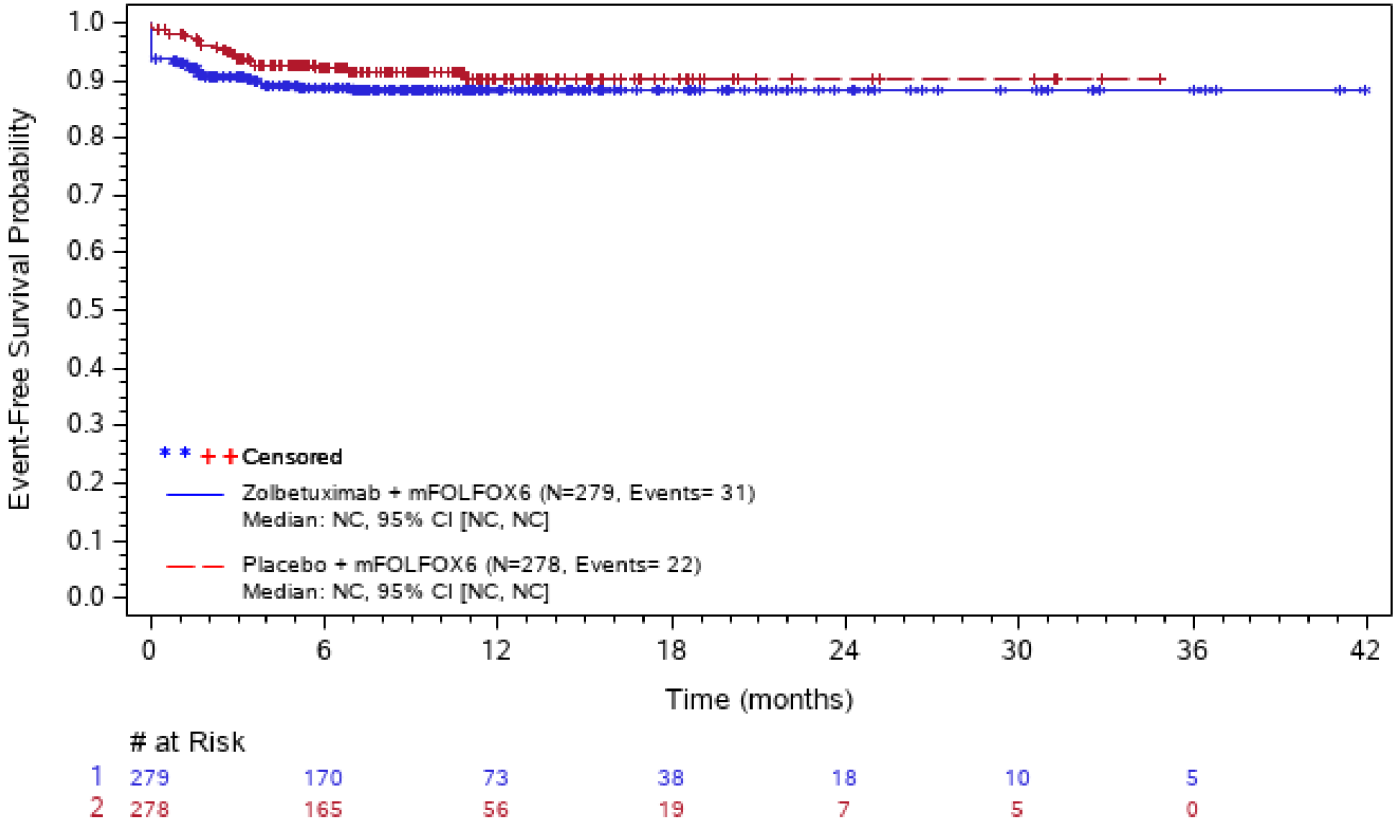
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.141: Kaplan-Meier Plot of Time to first TEAE - Hot Flush (PT) - Safety Analysis Set



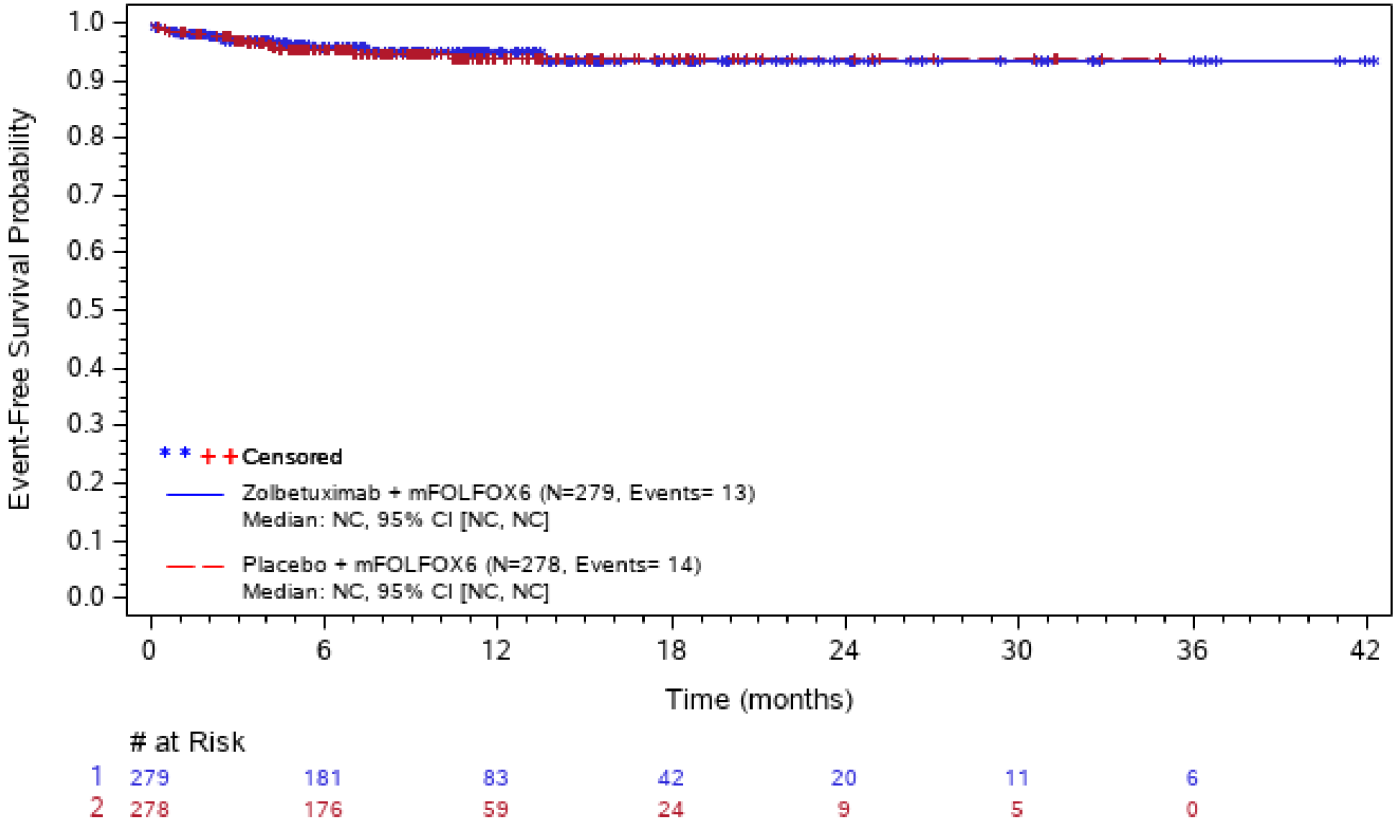
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.142: 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: 09SEP22

Figure 301.1.2001.143: Kaplan-Meier Plot of Time to first TEAE - Hypotension (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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.1.2001.167.1: Summary and Results of Severe TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	100 (35.8%)	90 (32.4%)	
Number of patients censored	179 (64.2%)	188 (67.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [21.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.163 [0.874, 1.547]
Log-rank test			
Two-sided stratified log-rank p-value			0.2968

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.168.1: Summary and Results of Severe TEAEs - Anaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	26 (9.4%)	
Number of patients censored	255 (91.4%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.910 [0.522, 1.588]
Log-rank test			
Two-sided stratified log-rank p-value			0.7402

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.169.1: Summary and Results of Severe TEAEs - Leukopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.548 [0.659, 9.856]
Log-rank test			
Two-sided stratified log-rank p-value			0.1599

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.170.1: Summary and Results of Severe TEAEs - Neutropenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	79 (28.3%)	65 (23.4%)	
Number of patients censored	200 (71.7%)	213 (76.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.279 [0.920, 1.777]
Log-rank test			
Two-sided stratified log-rank p-value			0.1382

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.171.1: Summary and Results of Severe TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	98 (35.1%)	55 (19.8%)	
Number of patients censored	181 (64.9%)	223 (80.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [20.0, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.028 [1.455, 2.827]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.171.2: Summary and Results of Severe TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	65 (36.5)	NC [17.8, NC]	177	40 (22.6)	NC [NC, NC]	1.814 [1.223, 2.692]	0.0032	0.4473
>65 years	101	33 (32.7)	NC [20.0, NC]	101	15 (14.9)	NC [NC, NC]	2.369 [1.285, 4.366]	0.0045	
Sex									
Male	174	54 (31.0)	NC [NC, NC]	173	34 (19.7)	NC [NC, NC]	1.693 [1.102, 2.602]	0.0165	0.3011
Female	105	44 (41.9)	NC [5.1, NC]	105	21 (20.0)	NC [NC, NC]	2.433 [1.446, 4.095]	0.0006	
Region									
Asia	87	18 (20.7)	NC [NC, NC]	88	14 (15.9)	NC [NC, NC]	1.191 [0.588, 2.413]	0.6366	0.1209
Non-Asia	192	80 (41.7)	NC [9.1, NC]	190	41 (21.6)	NC [NC, NC]	2.314 [1.588, 3.373]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	73 (33.8)	NC [20.0, NC]	216	41 (19.0)	NC [NC, NC]	1.965 [1.340, 2.883]	0.0005	0.9472
>=3	63	25 (39.7)	NC [4.1, NC]	62	14 (22.6)	NC [NC, NC]	1.948 [1.012, 3.751]	0.0422	

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 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: 09SEP22

Table 301.1.2001.172.1: Summary and Results of Severe TEAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	6 (2.2%)	
Number of patients censored	267 (95.7%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.177 [0.816, 5.813]
Log-rank test			
Two-sided stratified log-rank p-value			0.1115

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.173.1: Summary and Results of Severe TEAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	9 (3.2%)	
Number of patients censored	267 (95.7%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.309 [0.550, 3.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.5418

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.174.1: Summary and Results of Severe TEAEs - Dysphagia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	8 (2.9%)	
Number of patients censored	276 (98.9%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.390 [0.103, 1.469]
Log-rank test			
Two-sided stratified log-rank p-value			0.1488

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.175.1: Summary and Results of Severe TEAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	3 (1.1%)	
Number of patients censored	271 (97.1%)	275 (98.9%)	
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			2.457 [0.639, 9.442]
Log-rank test			
Two-sided stratified log-rank p-value			0.1766

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.176.1: Summary and Results of Severe TEAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	18 (6.5%)	
Number of patients censored	234 (83.9%)	260 (93.5%)	
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			2.662 [1.539, 4.606]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.176.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	29 (16.3)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	2.233 [1.180, 4.226]	0.0121	0.3353
>65 years	101	16 (15.8)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.138 [1.381, 12.398]	0.0060	
Sex									
Male	174	23 (13.2)	NC [NC, NC]	173	10 (5.8)	NC [NC, NC]	2.422 [1.153, 5.089]	0.0166	0.7141
Female	105	22 (21.0)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	2.961 [1.317, 6.657]	0.0061	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	6 (6.8)	NC [NC, NC]	1.434 [0.506, 4.059]	0.5030	0.2087
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	3.304 [1.718, 6.351]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	34 (15.7)	NC [NC, NC]	216	11 (5.1)	NC [NC, NC]	3.277 [1.660, 6.472]	0.0003	0.2395
>=3	63	11 (17.5)	NC [NC, NC]	62	7 (11.3)	NC [NC, NC]	1.660 [0.643, 4.285]	0.2920	

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 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: 09SEP22

Table 301.1.2001.177.1: Summary and Results of Severe TEAEs - Stomatitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.088 [0.522, 8.359]
Log-rank test			
Two-sided stratified log-rank p-value			0.2872

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.178.1: Summary and Results of Severe TEAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	16 (5.8%)	
Number of patients censored	234 (83.9%)	262 (94.2%)	
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			3.020 [1.704, 5.352]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.178.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	30 (16.9)	NC [NC, NC]	177	13 (7.3)	NC [NC, NC]	2.451 [1.278, 4.702]	0.0060	0.2916
>65 years	101	15 (14.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	5.289 [1.531, 18.271]	0.0032	
Sex									
Male	174	21 (12.1)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	2.381 [1.090, 5.205]	0.0264	0.4647
Female	105	24 (22.9)	NC [NC, NC]	105	7 (6.7)	NC [NC, NC]	3.782 [1.629, 8.778]	0.0009	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	4 (4.5)	NC [NC, NC]	2.121 [0.648, 6.945]	0.2093	0.5905
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	3.289 [1.711, 6.322]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	35 (16.2)	NC [NC, NC]	216	10 (4.6)	NC [NC, NC]	3.712 [1.837, 7.500]	<.0001	0.2223
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.757 [0.638, 4.837]	0.2728	

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 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: 09SEP22

Table 301.1.2001.179.1: Summary and Results of Severe TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	46 (16.5%)	32 (11.5%)	
Number of patients censored	233 (83.5%)	246 (88.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	31.3 [27.3, NC]	NC [26.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.384 [0.877, 2.185]
Log-rank test			
Two-sided stratified log-rank p-value			0.1616

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.180.1: Summary and Results of Severe TEAEs - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	7 (2.5%)	
Number of patients censored	259 (92.8%)	271 (97.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [28.2, NC]	NC [26.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.520 [1.053, 6.029]
Log-rank test			
Two-sided stratified log-rank p-value			0.0319

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.180.2: Summary and Results of Severe TEAEs by Subgroups - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	12 (6.7)	31.3 [27.3, NC]	177	6 (3.4)	NC [26.5, NC]	1.764 [0.658, 4.730]	0.2535	0.3089
>65 years	101	8 (7.9)	NC [28.2, NC]	101	1 (1.0)	NC [NC, NC]	7.301 [0.907, 58.791]	0.0290	
Sex									
Male	174	15 (8.6)	31.3 [28.2, NC]	173	3 (1.7)	NC [NC, NC]	4.440 [1.276, 15.453]	0.0105	0.1398
Female	105	5 (4.8)	NC [27.3, NC]	105	4 (3.8)	NC [26.5, NC]	1.098 [0.293, 4.117]	0.8897	
Region									
Asia	87	6 (6.9)	31.3 [27.3, NC]	88	3 (3.4)	NC [26.5, NC]	1.035 [0.249, 4.302]	0.9623	0.3057
Non-Asia	192	14 (7.3)	NC [NC, NC]	190	4 (2.1)	NC [NC, NC]	3.741 [1.231, 11.371]	0.0125	
Number of Organs with Metastatic Sites									
0-2	216	16 (7.4)	NC [28.2, NC]	216	6 (2.8)	NC [26.5, NC]	2.112 [0.812, 5.494]	0.1175	0.5640
>=3	63	4 (6.3)	NC [NC, NC]	62	1 (1.6)	NC [NC, NC]	4.181 [0.465, 37.563]	0.1654	

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 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: 09SEP22

Table 301.1.2001.181.1: Summary and Results of Severe TEAEs - Fatigue (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	14 (5.0%)	
Number of patients censored	262 (93.9%)	264 (95.0%)	
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			1.169 [0.574, 2.381]
Log-rank test			
Two-sided stratified log-rank p-value			0.6665

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.182.1: Summary and Results of Severe TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	8 (2.9%)	
Number of patients censored	270 (96.8%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.075 [0.412, 2.808]
Log-rank test			
Two-sided stratified log-rank p-value			0.8820

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.183.1: Summary and Results of Severe TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	27 (9.7%)	25 (9.0%)	
Number of patients censored	252 (90.3%)	253 (91.0%)	
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			1.021 [0.590, 1.769]
Log-rank test			
Two-sided stratified log-rank p-value			0.9395

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.184.1: Summary and Results of Severe TEAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	9 (3.2%)	
Number of patients censored	273 (97.8%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.607 [0.212, 1.737]
Log-rank test			
Two-sided stratified log-rank p-value			0.3476

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.185.1: Summary and Results of Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	7 (2.5%)	
Number of patients censored	267 (95.7%)	271 (97.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.867 [0.695, 5.014]
Log-rank test			
Two-sided stratified log-rank p-value			0.2085

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.186.1: Summary and Results of Severe TEAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	93 (33.3%)	85 (30.6%)	
Number of patients censored	186 (66.7%)	193 (69.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.105 [0.823, 1.485]
Log-rank test			
Two-sided stratified log-rank p-value			0.4944

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.187.1: Summary and Results of Severe TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	7 (2.5%)	
Number of patients censored	275 (98.6%)	271 (97.5%)	
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			0.571 [0.167, 1.953]
Log-rank test			
Two-sided stratified log-rank p-value			0.3652

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.188.1: Summary and Results of Severe TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	69 (24.7%)	69 (24.8%)	
Number of patients censored	210 (75.3%)	209 (75.2%)	
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			1.000 [0.715, 1.398]
Log-rank test			
Two-sided stratified log-rank p-value			0.9895

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.189.1: Summary and Results of Severe TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	16 (5.8%)	
Number of patients censored	271 (97.1%)	262 (94.2%)	
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			0.490 [0.209, 1.146]
Log-rank test			
Two-sided stratified log-rank p-value			0.0929

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.190.1: Summary and Results of Severe TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	63 (22.6%)	34 (12.2%)	
Number of patients censored	216 (77.4%)	244 (87.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.911 [1.253, 2.914]
Log-rank test			
Two-sided stratified log-rank p-value			0.0022

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.190.2: Summary and Results of Severe TEAEs by Subgroups - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	37 (20.8)	NC [29.1, NC]	177	19 (10.7)	NC [NC, NC]	2.013 [1.156, 3.504]	0.0116	0.7363
>65 years	101	26 (25.7)	NC [20.1, NC]	101	15 (14.9)	NC [NC, NC]	1.762 [0.932, 3.331]	0.0769	
Sex									
Male	174	40 (23.0)	NC [NC, NC]	173	23 (13.3)	NC [19.5, NC]	1.804 [1.080, 3.015]	0.0224	0.6678
Female	105	23 (21.9)	NC [29.1, NC]	105	11 (10.5)	NC [NC, NC]	2.143 [1.043, 4.400]	0.0333	
Region									
Asia	87	15 (17.2)	NC [29.1, NC]	88	13 (14.8)	NC [19.5, NC]	0.930 [0.437, 1.979]	0.8517	0.0461
Non-Asia	192	48 (25.0)	NC [NC, NC]	190	21 (11.1)	NC [NC, NC]	2.541 [1.521, 4.244]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	48 (22.2)	NC [29.1, NC]	216	25 (11.6)	NC [NC, NC]	1.952 [1.202, 3.171]	0.0059	0.7686
>=3	63	15 (23.8)	NC [NC, NC]	62	9 (14.5)	NC [NC, NC]	1.714 [0.750, 3.918]	0.1955	

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 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: 09SEP22

Table 301.1.2001.191.1: Summary and Results of Severe TEAEs - Decreased Appetite (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	9 (3.2%)	
Number of patients censored	263 (94.3%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.753 [0.772, 3.984]
Log-rank test			
Two-sided stratified log-rank p-value			0.1745

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.192.1: Summary and Results of Severe TEAEs - Hypoalbuminaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	2 (0.7%)	
Number of patients censored	268 (96.1%)	276 (99.3%)	
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			6.020 [1.334, 27.164]
Log-rank test			
Two-sided stratified log-rank p-value			0.0078

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.192.2: Summary and Results of Severe TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	8 (4.5)	NC [NC, NC]	177	2 (1.1)	NC [NC, NC]	4.285 [0.910, 20.180]	0.0447	0.9918
>65 years	101	3 (3.0)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	2.95E7 [0.000, NC]	0.0837	
Sex									
Male	174	6 (3.4)		173	2 (1.2)				
Female	105	5 (4.8)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	0.9994
Non-Asia	192	11 (5.7)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	6.009 [1.332, 27.110]	0.0079	
Number of Organs with Metastatic Sites									
0-2	216	8 (3.7)	NC [NC, NC]	216	2 (0.9)	NC [NC, NC]	4.210 [0.894, 19.830]	0.0479	0.9932
>=3	63	3 (4.8)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.22E7 [0.000, NC]	0.0712	

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 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: 09SEP22

Table 301.1.2001.193.1: Summary and Results of Severe TEAEs - Hypokalaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	10 (3.6%)	
Number of patients censored	263 (94.3%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.661 [0.749, 3.686]
Log-rank test			
Two-sided stratified log-rank p-value			0.2069

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.194.1: Summary and Results of Severe TEAEs - Hypophosphataemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			1.039 [0.371, 2.907]
Log-rank test			
Two-sided stratified log-rank p-value			0.9420

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.195.1: Summary and Results of Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	18 (6.5%)	
Number of patients censored	265 (95.0%)	260 (93.5%)	
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			0.798 [0.396, 1.609]
Log-rank test			
Two-sided stratified log-rank p-value			0.5270

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.196.1: Summary and Results of Severe TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.909 [0.392, 2.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.8246

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.197.1: Summary and Results of Severe TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	36 (12.9%)	33 (11.9%)	
Number of patients censored	243 (87.1%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.104 [0.687, 1.774]
Log-rank test			
Two-sided stratified log-rank p-value			0.6844

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.198.1: Summary and Results of Severe TEAEs - Paraesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.482 [0.417, 5.269]
Log-rank test			
Two-sided stratified log-rank p-value			0.5403

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.199.1: Summary and Results of Severe TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	15 (5.4%)	
Number of patients censored	268 (96.1%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.724 [0.329, 1.592]
Log-rank test			
Two-sided stratified log-rank p-value			0.4201

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.200.1: Summary and Results of Severe TEAEs - Syncope (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	5 (1.8%)	
Number of patients censored	274 (98.2%)	273 (98.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.059 [0.306, 3.658]
Log-rank test			
Two-sided stratified log-rank p-value			0.9281

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.201.1: Summary and Results of Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	16 (5.8%)	
Number of patients censored	262 (93.9%)	262 (94.2%)	
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			1.077 [0.541, 2.143]
Log-rank test			
Two-sided stratified log-rank p-value			0.8326

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.202.1: Summary and Results of Severe TEAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	6 (2.2%)	
Number of patients censored	270 (96.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.544 [0.548, 4.347]
Log-rank test			
Two-sided stratified log-rank p-value			0.4076

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.203.1: Summary and Results of Severe TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	13 (4.7%)	
Number of patients censored	257 (92.1%)	265 (95.3%)	
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			1.782 [0.897, 3.538]
Log-rank test			
Two-sided stratified log-rank p-value			0.0948

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.204.1: Summary and Results of Severe TEAEs - Hypertension (PT)
- Safety Analysis Set

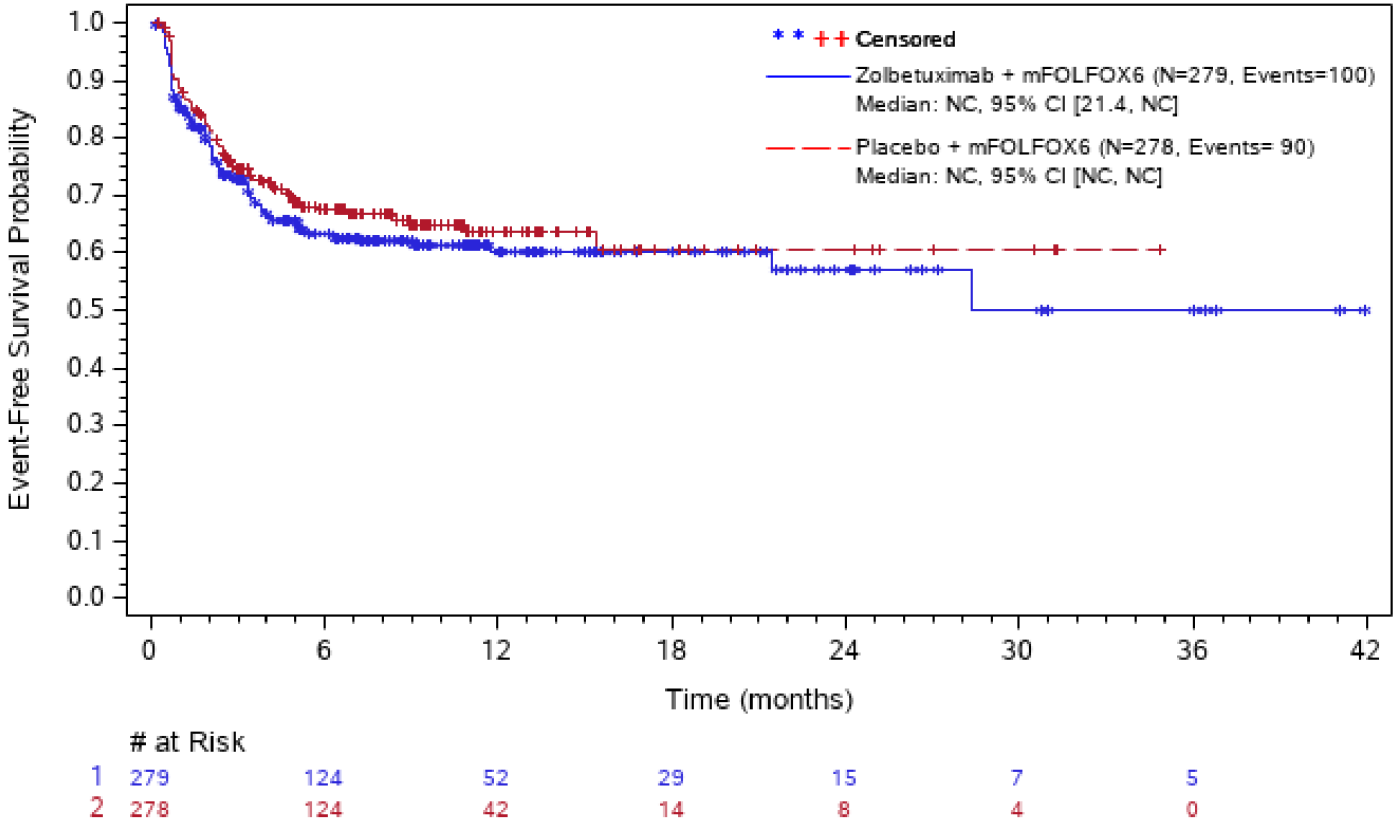
	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	10 (3.6%)	
Number of patients censored	264 (94.6%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.564 [0.702, 3.482]
Log-rank test			
Two-sided stratified log-rank p-value			0.2715

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse - SOC und PT

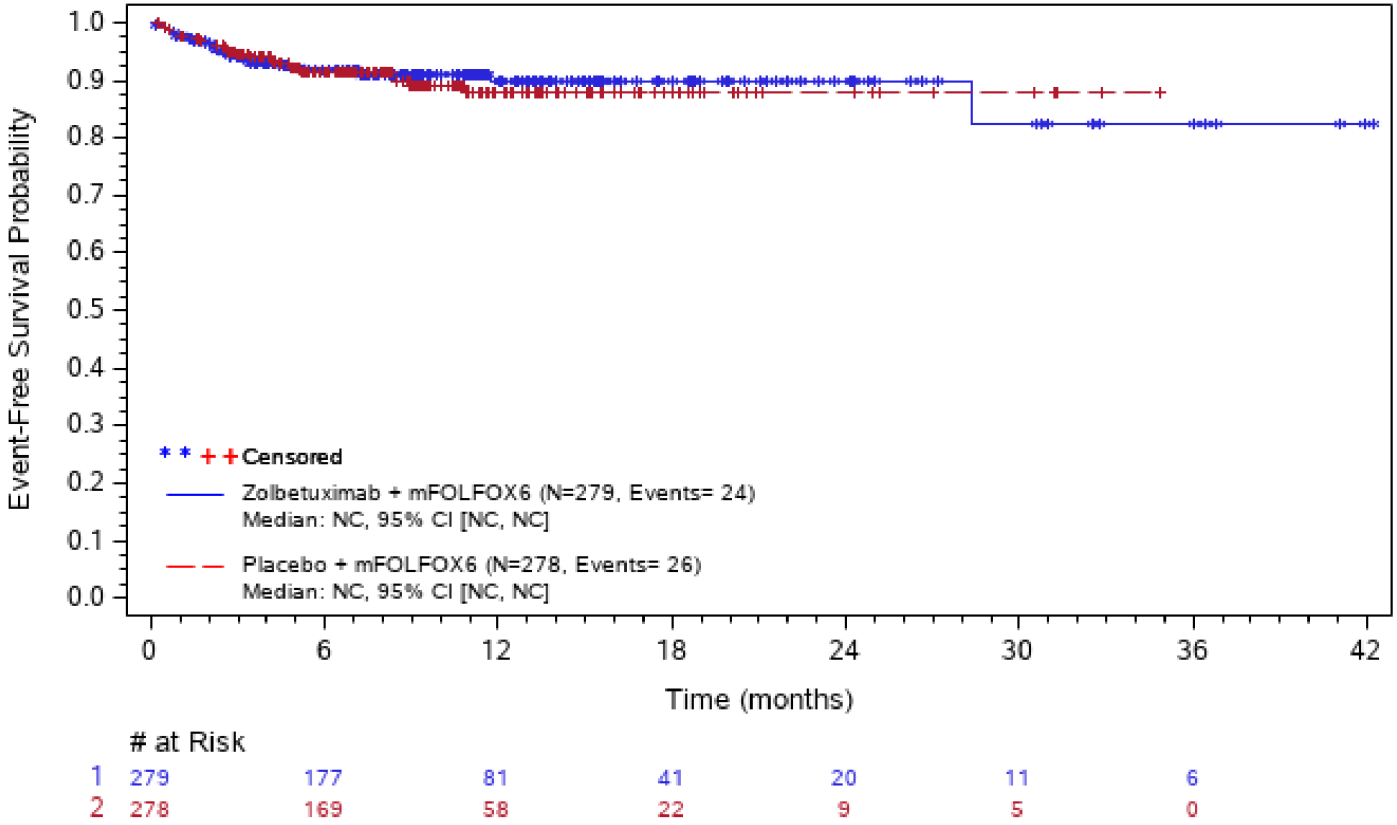
2. Kaplan-Meier-Plots

Figure 301.1.2001.167: Kaplan-Meier Plot of Time to first Severe TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



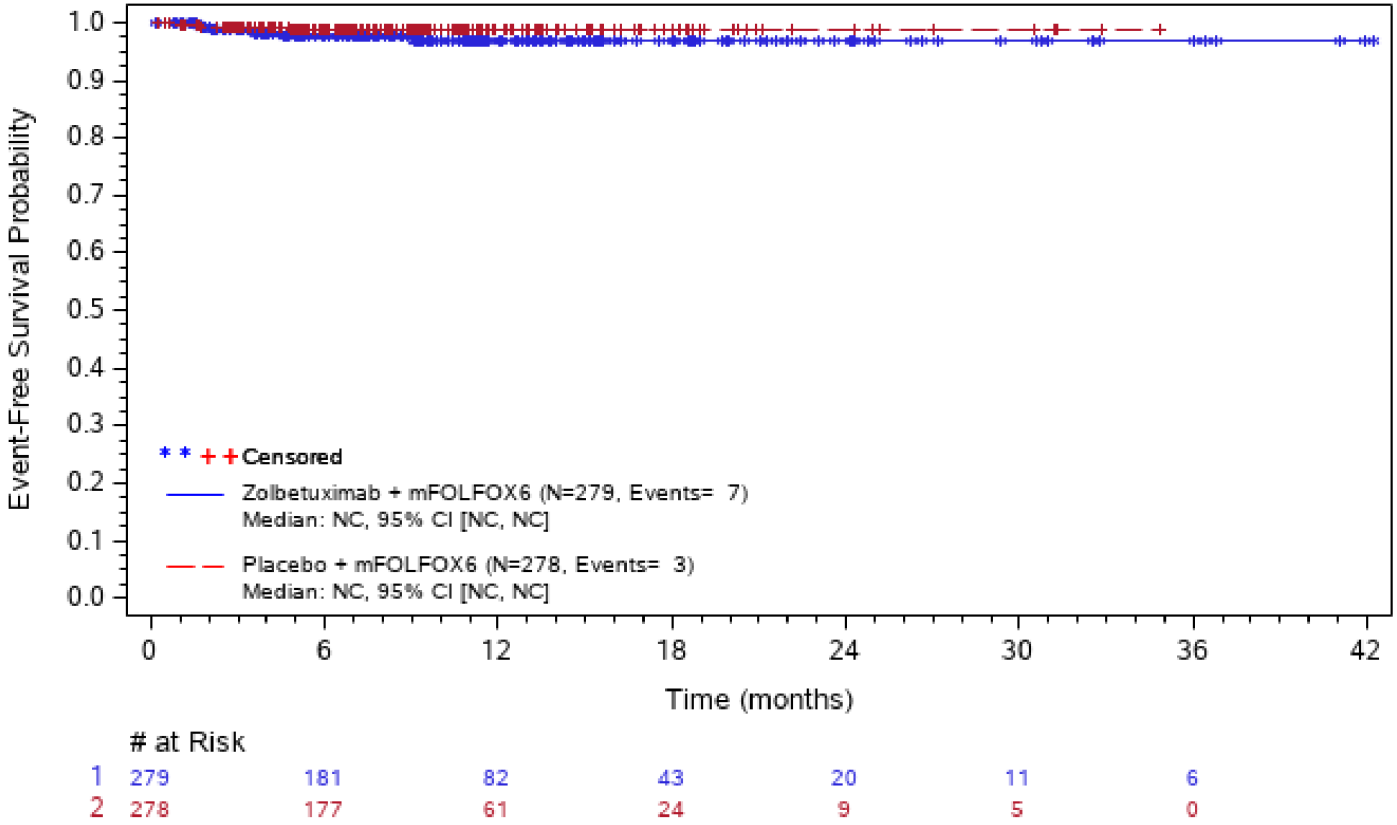
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.168: Kaplan-Meier Plot of Time to first Severe TEAE - Anaemia (PT) - Safety Analysis Set



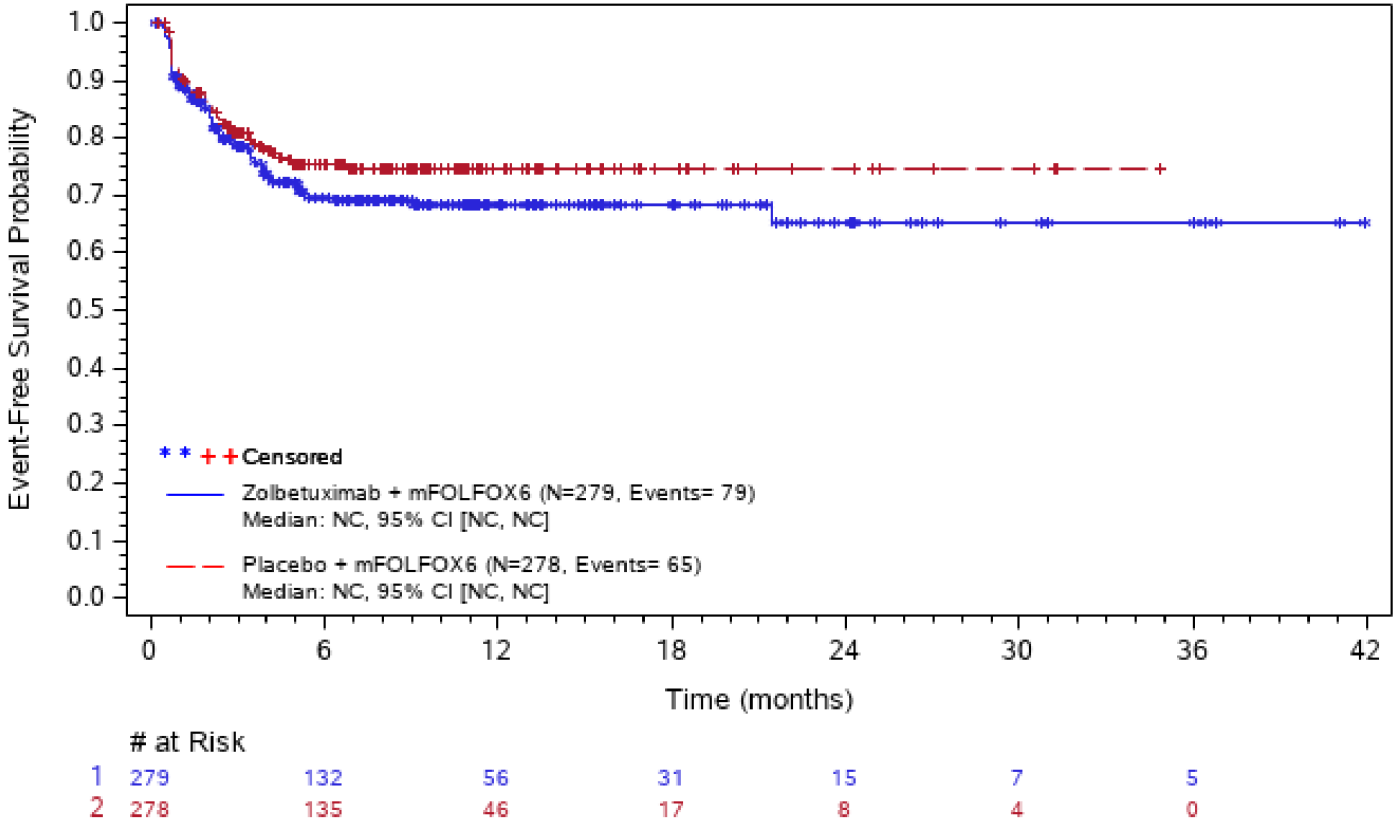
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.169: Kaplan-Meier Plot of Time to first Severe TEAE - Leukopenia (PT) - Safety Analysis Set



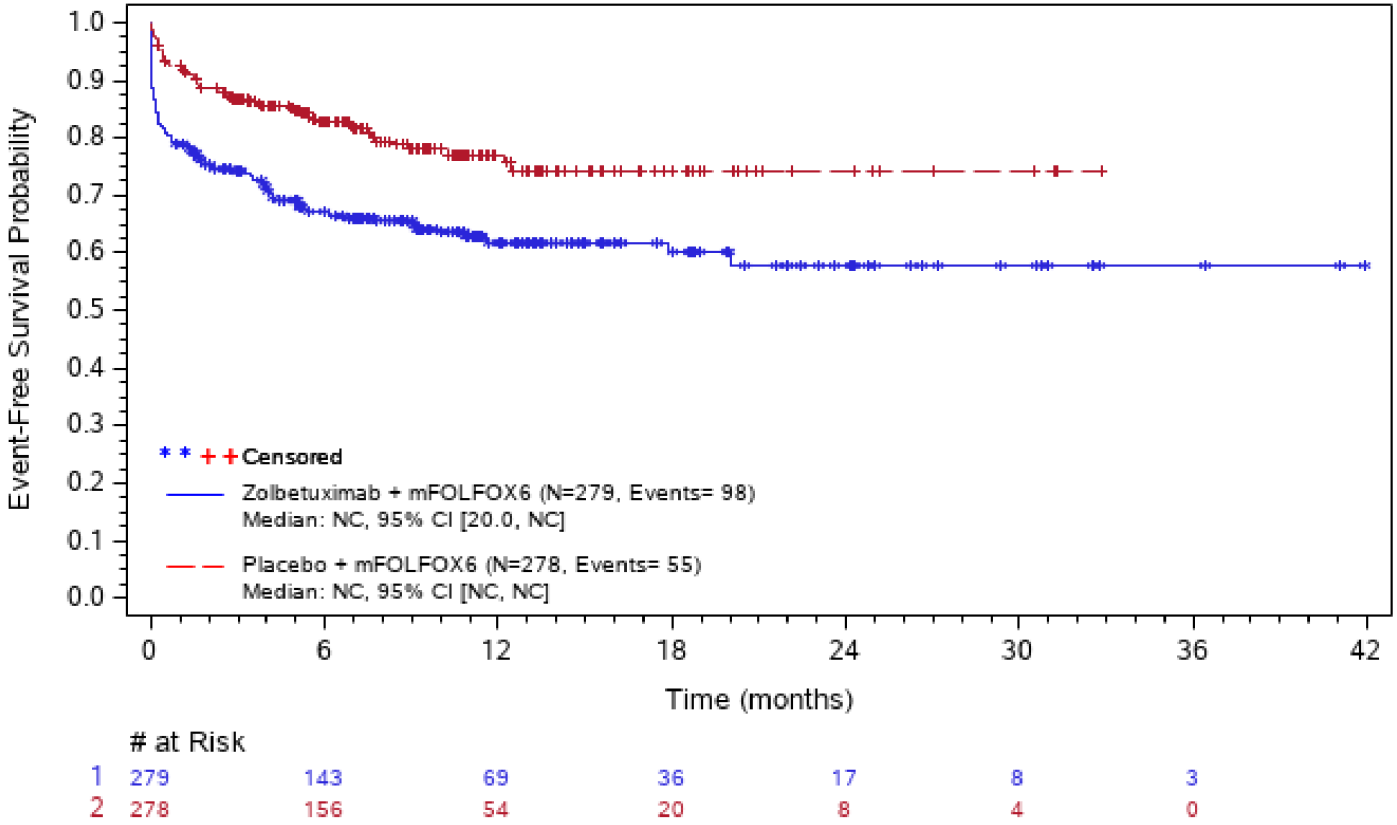
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.170: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (PT) - Safety Analysis Set



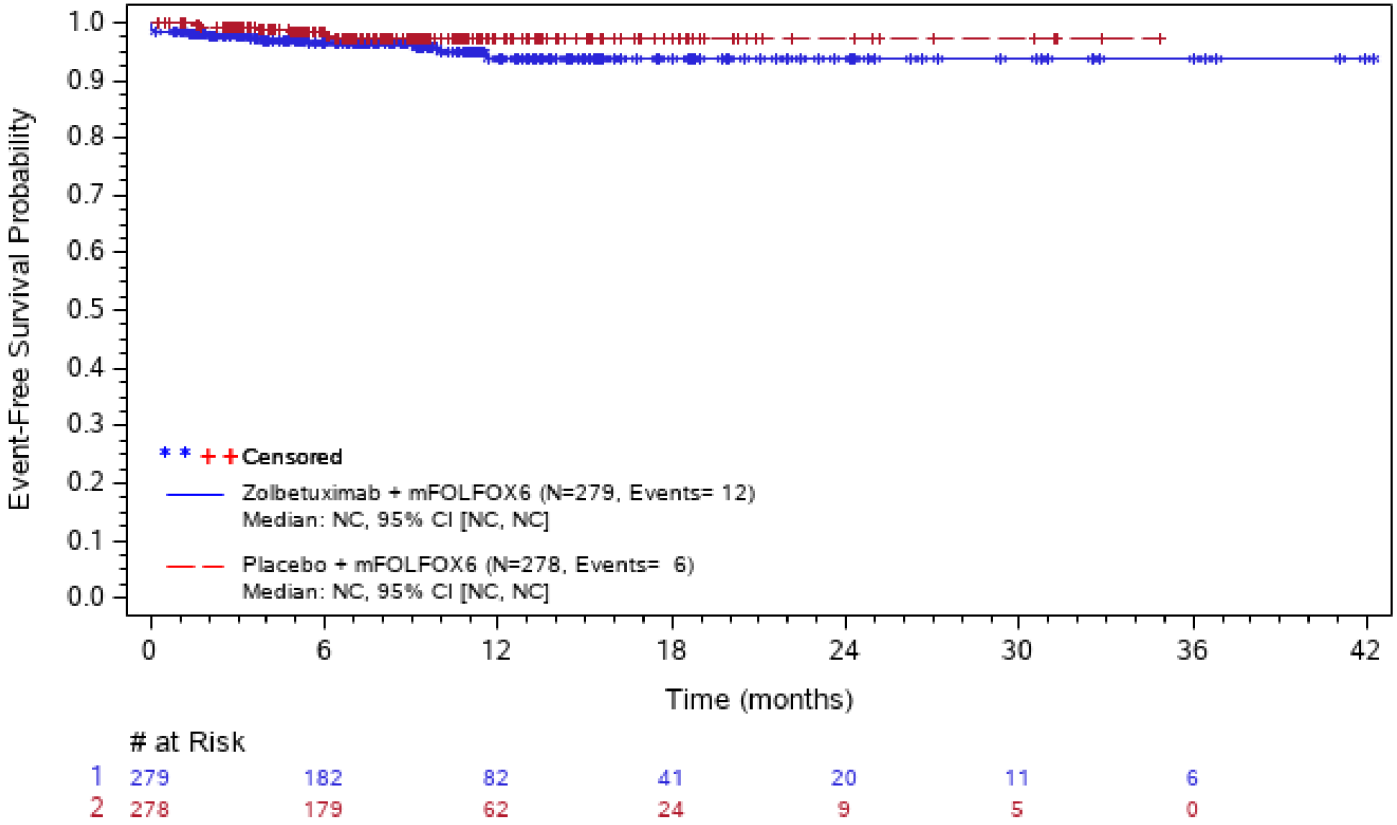
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.171: Kaplan-Meier Plot of Time to first Severe TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



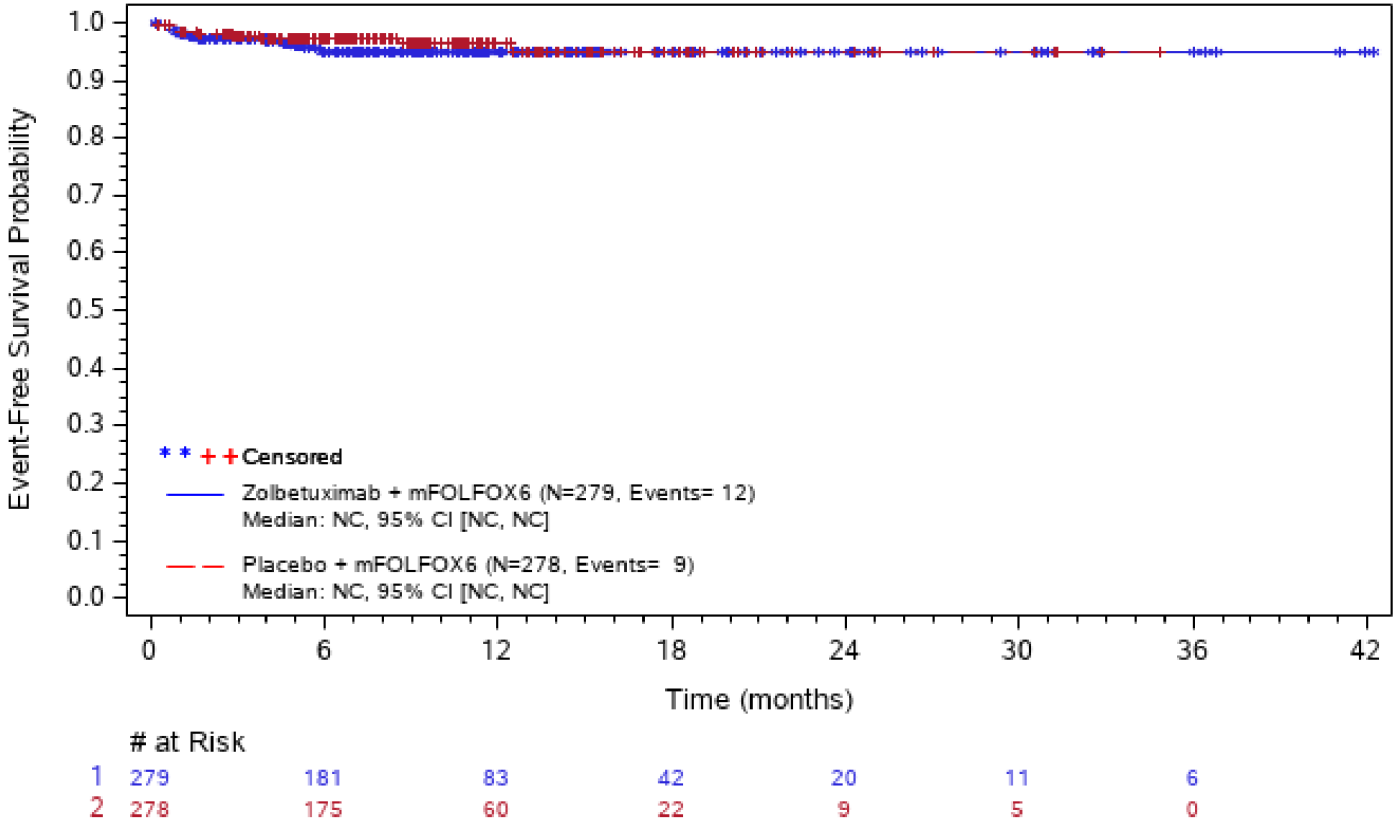
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.172: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (PT) - Safety Analysis Set



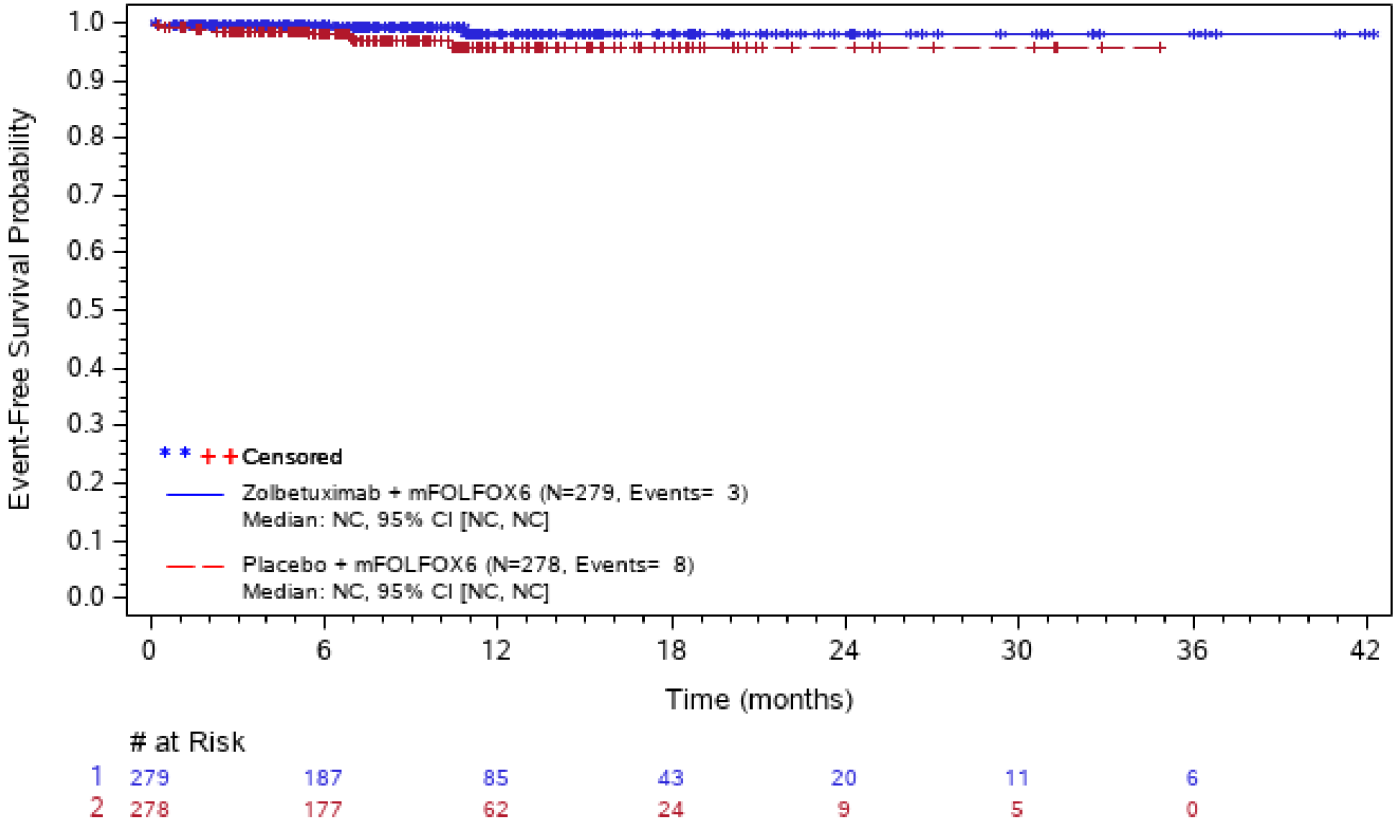
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.173: Kaplan-Meier Plot of Time to first Severe TEAE - Diarrhoea (PT) - Safety Analysis Set



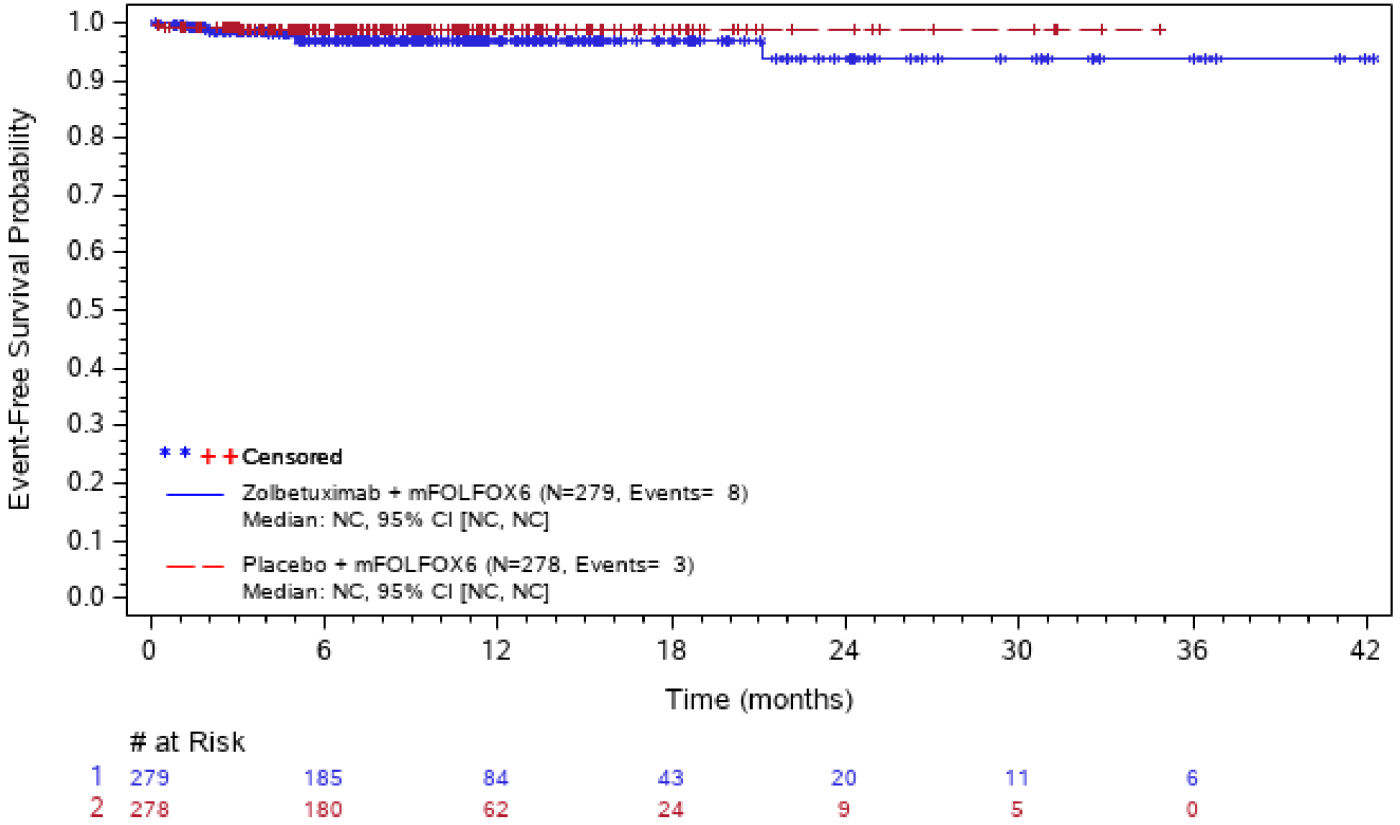
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.174: Kaplan-Meier Plot of Time to first Severe TEAE - Dysphagia (PT) - Safety Analysis Set



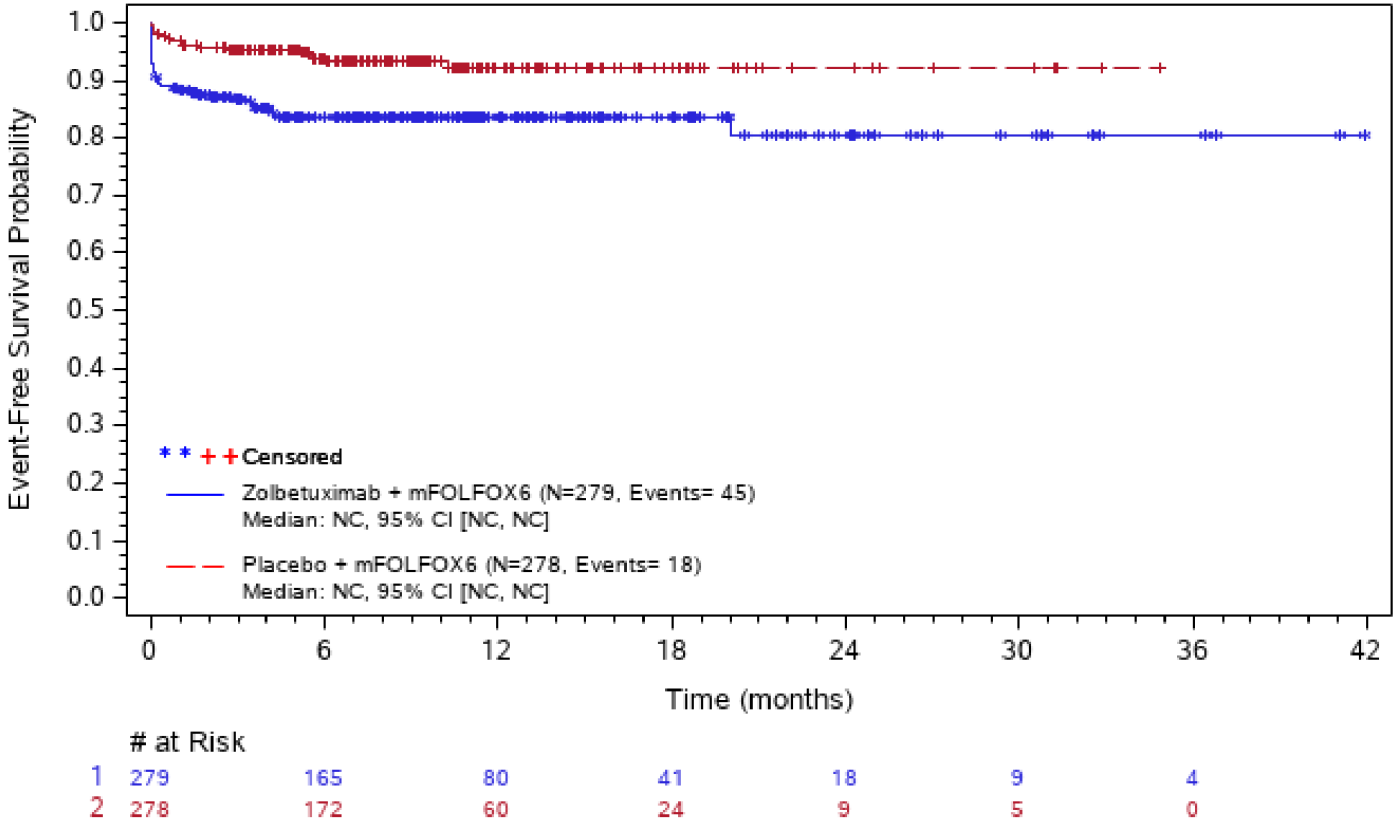
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.175: Kaplan-Meier Plot of Time to first Severe TEAE - Intestinal Obstruction (PT) - Safety Analysis Set



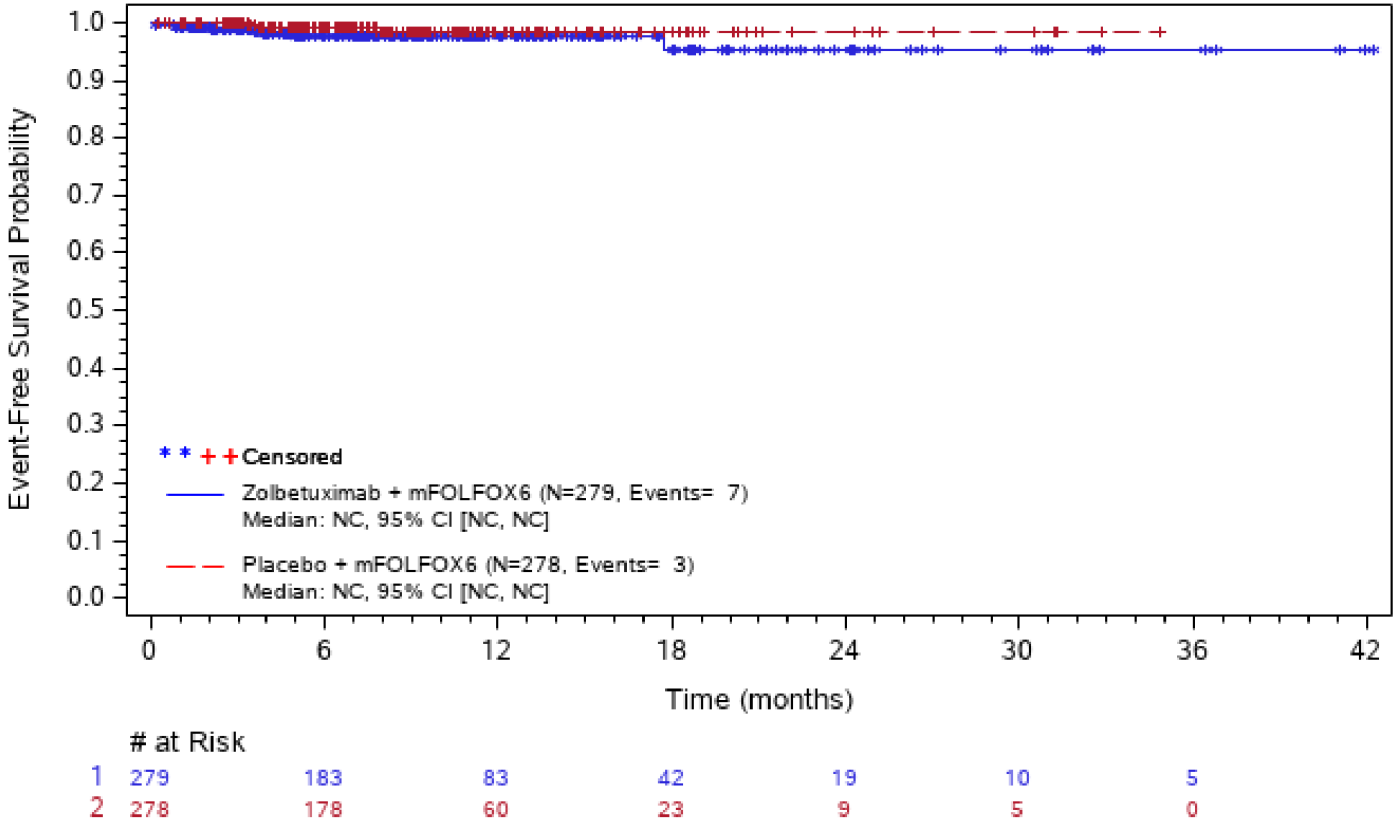
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.176: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (PT) - Safety Analysis Set



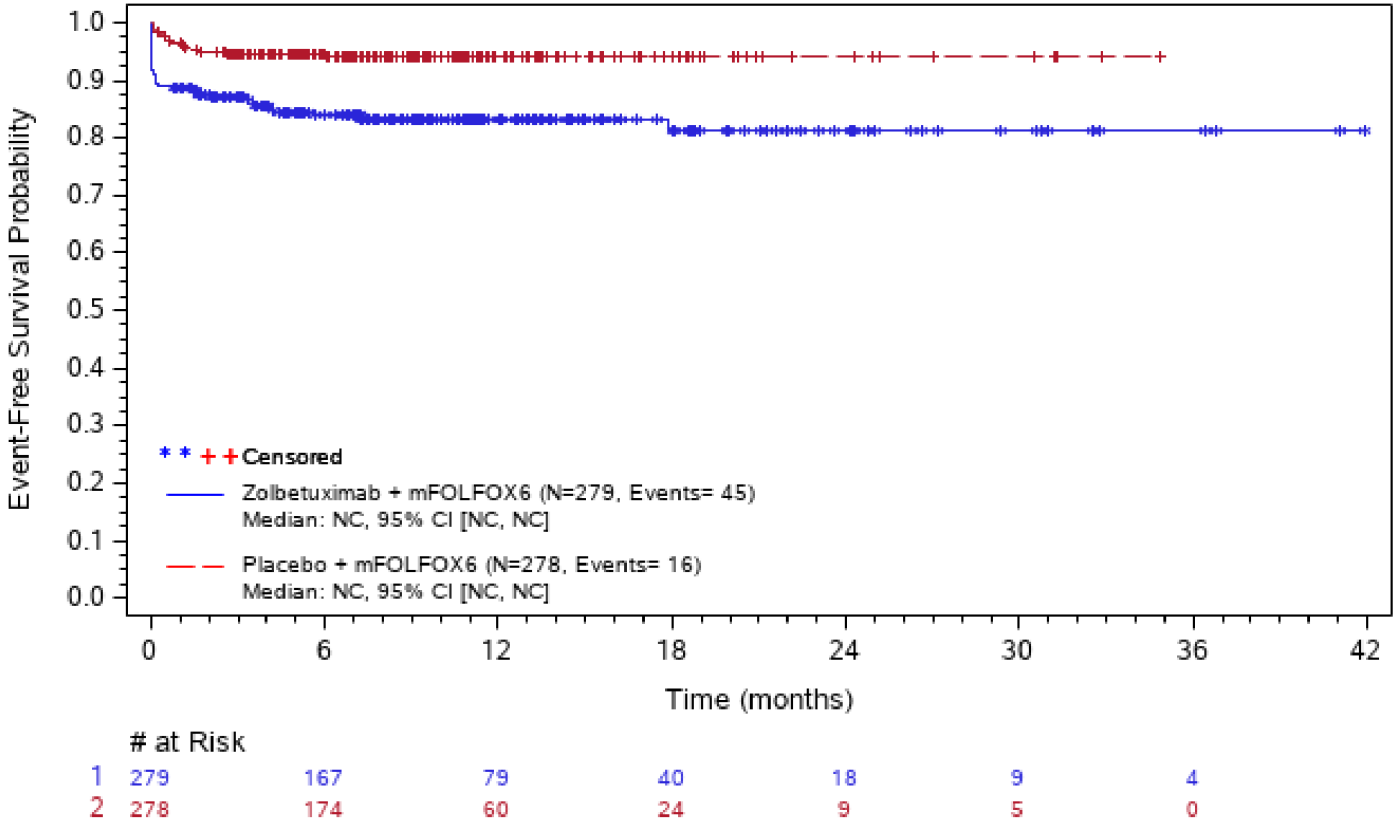
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.177: Kaplan-Meier Plot of Time to first Severe TEAE - Stomatitis (PT) - Safety Analysis Set



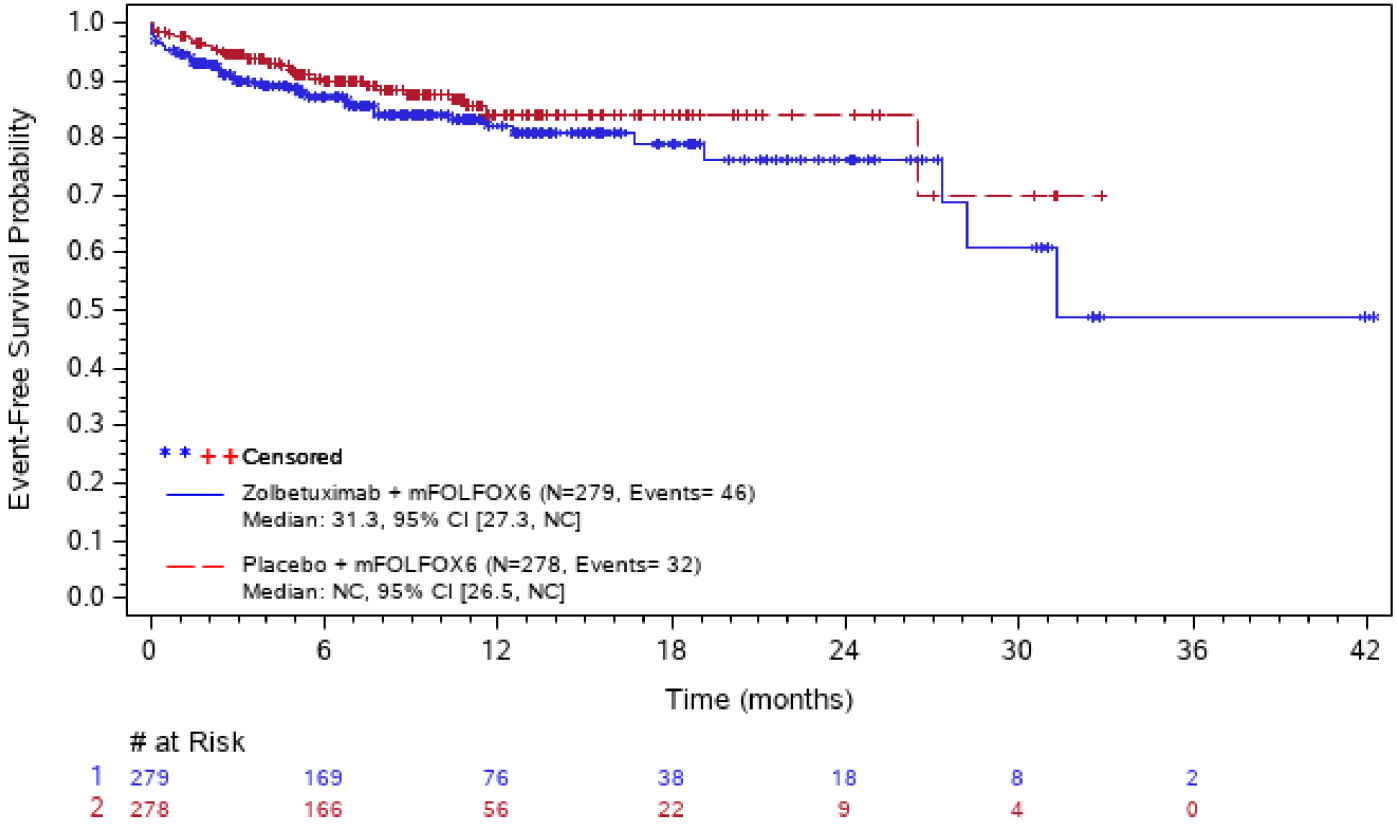
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.178: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (PT) - Safety Analysis Set



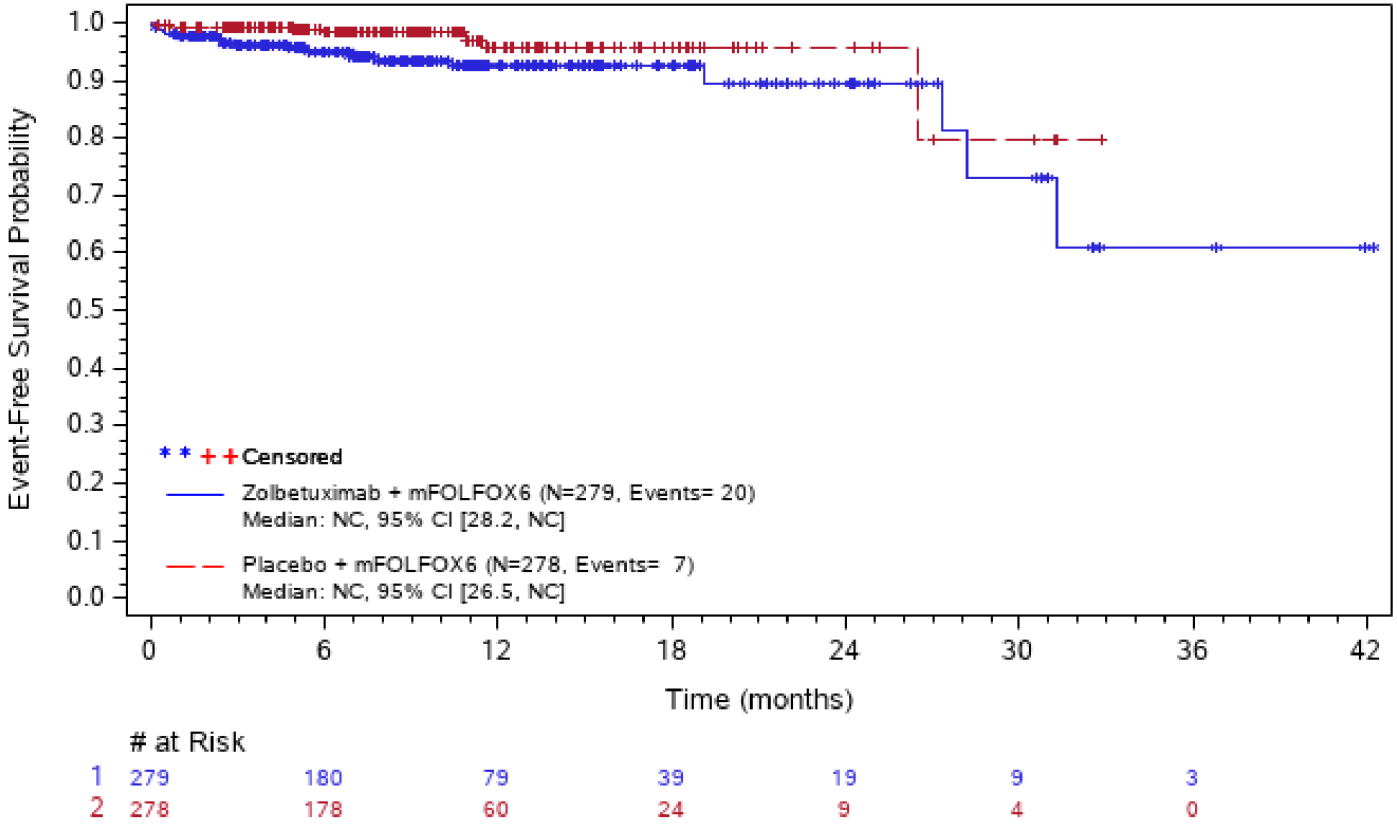
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.179: Kaplan-Meier Plot of Time to first Severe TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



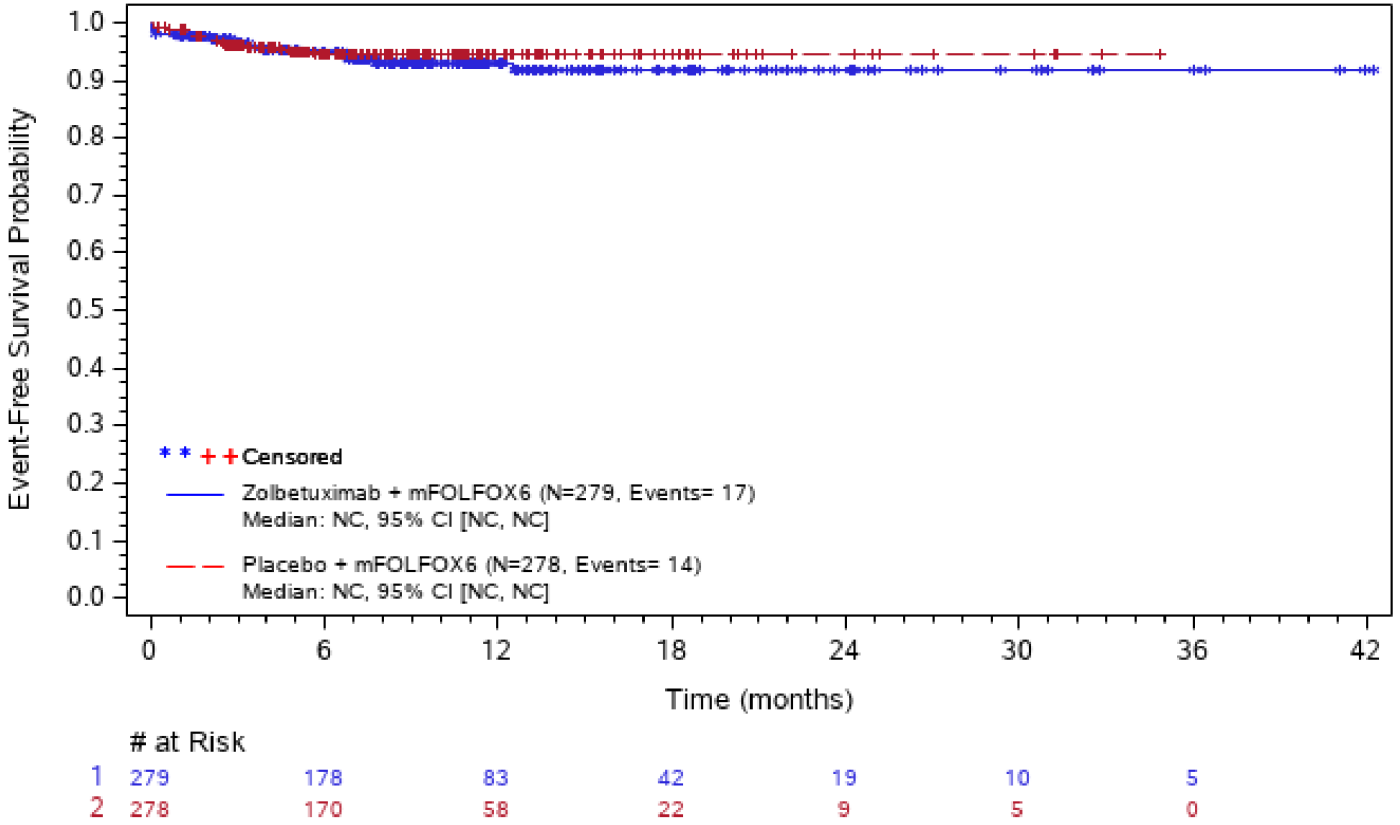
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.180: Kaplan-Meier Plot of Time to first Severe TEAE - Asthenia (PT) - Safety Analysis Set



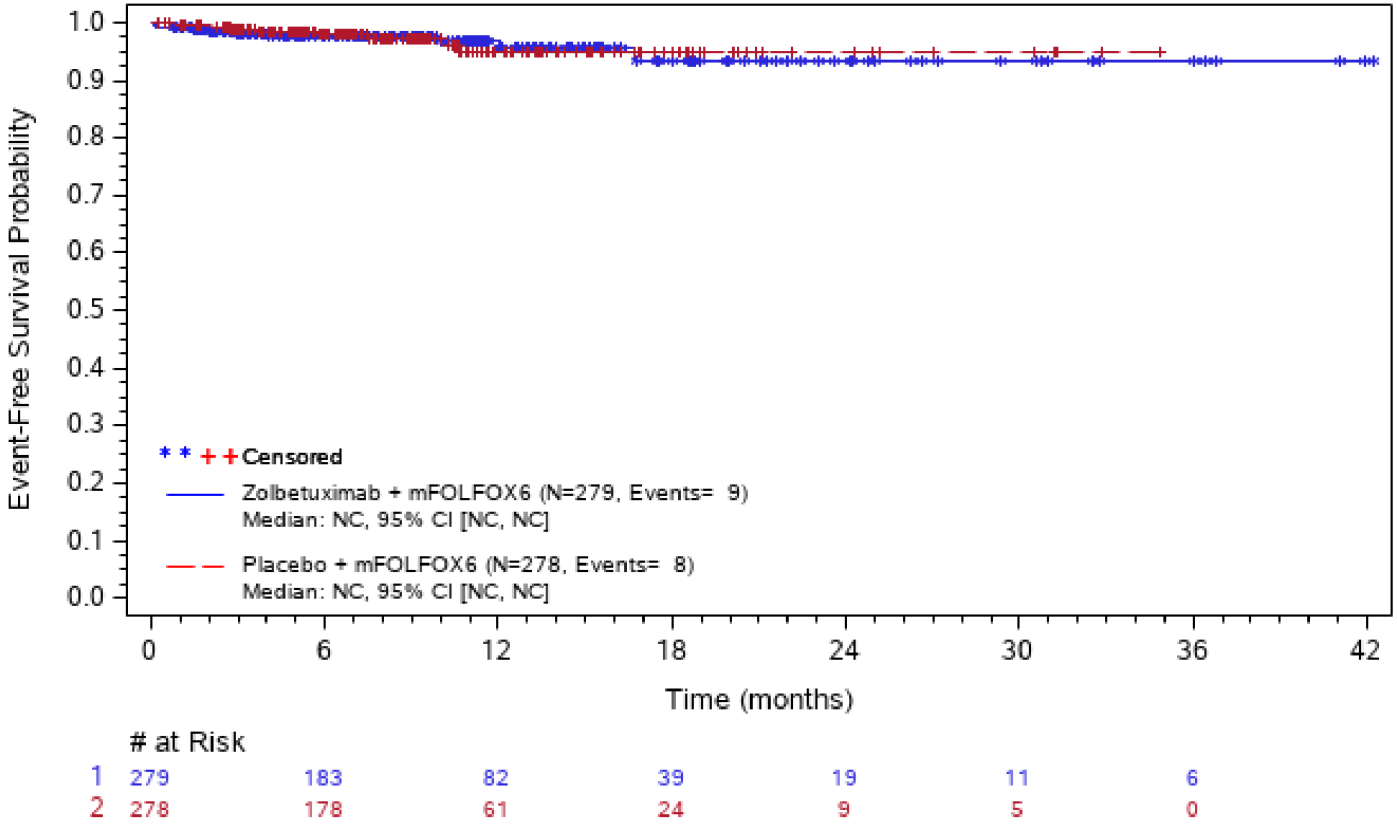
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.181: Kaplan-Meier Plot of Time to first Severe TEAE - Fatigue (PT) - Safety Analysis Set



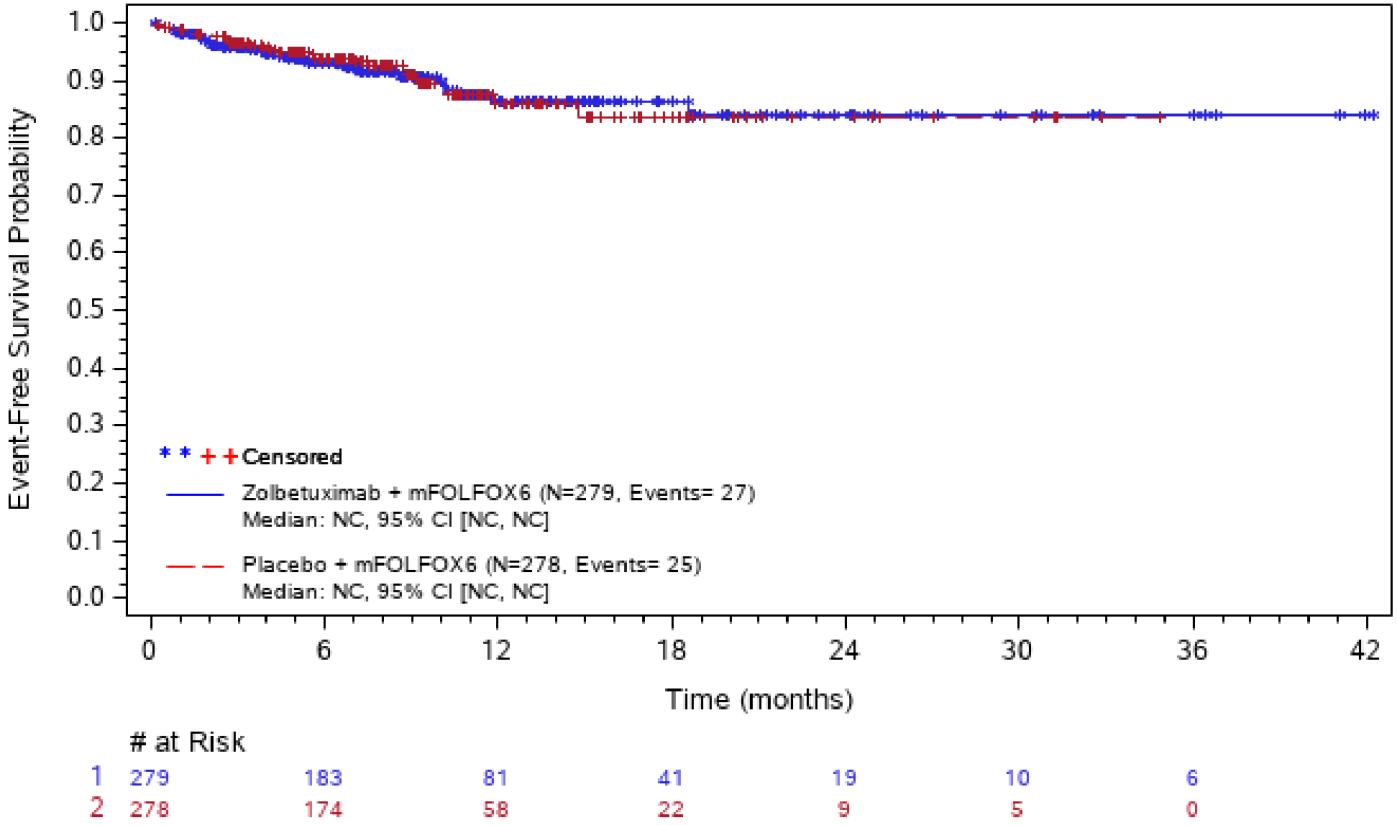
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.182: Kaplan-Meier Plot of Time to first Severe TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



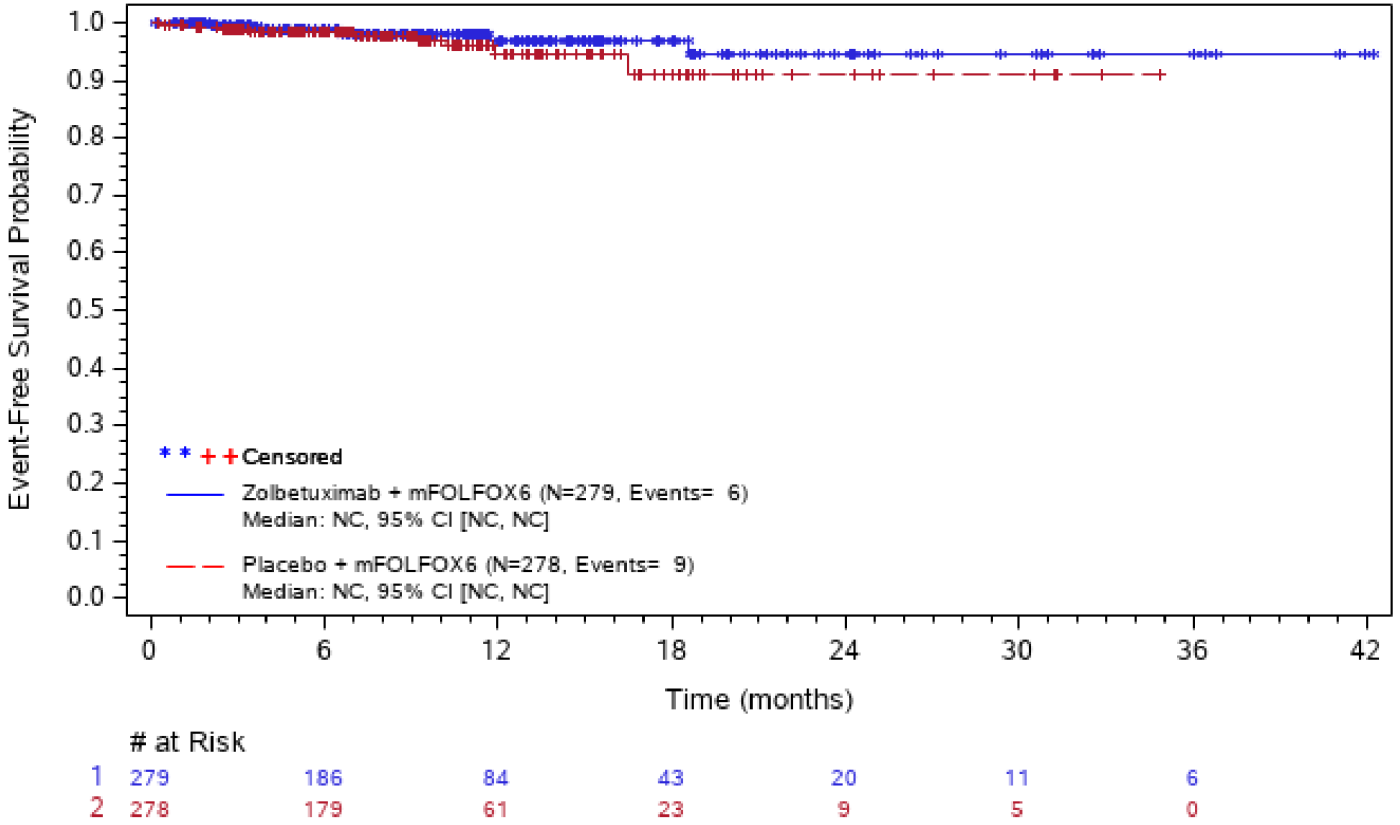
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.183: Kaplan-Meier Plot of Time to first Severe TEAE - Infections And Infestations (SOC) - Safety Analysis Set



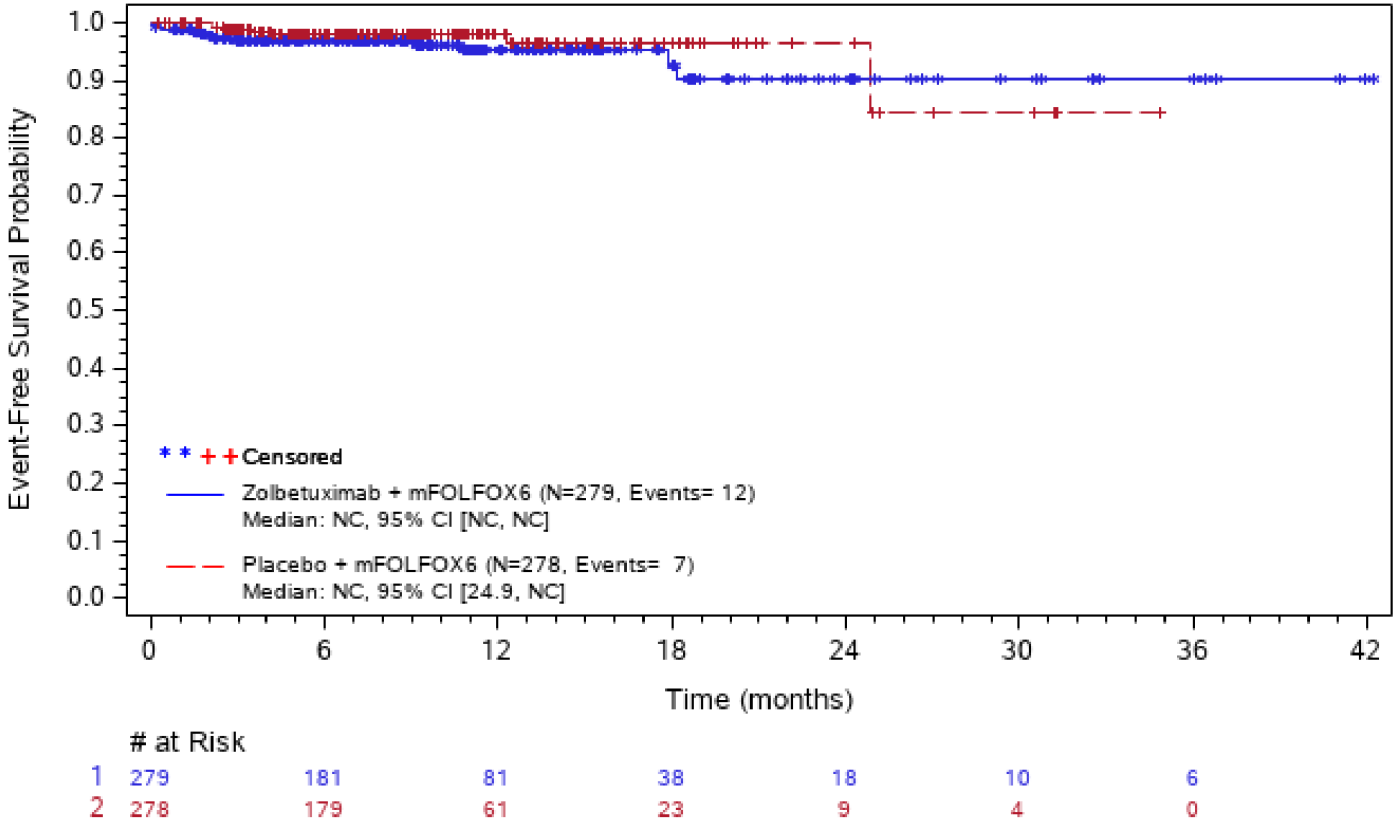
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.184: Kaplan-Meier Plot of Time to first Severe TEAE - Pneumonia (PT) - Safety Analysis Set



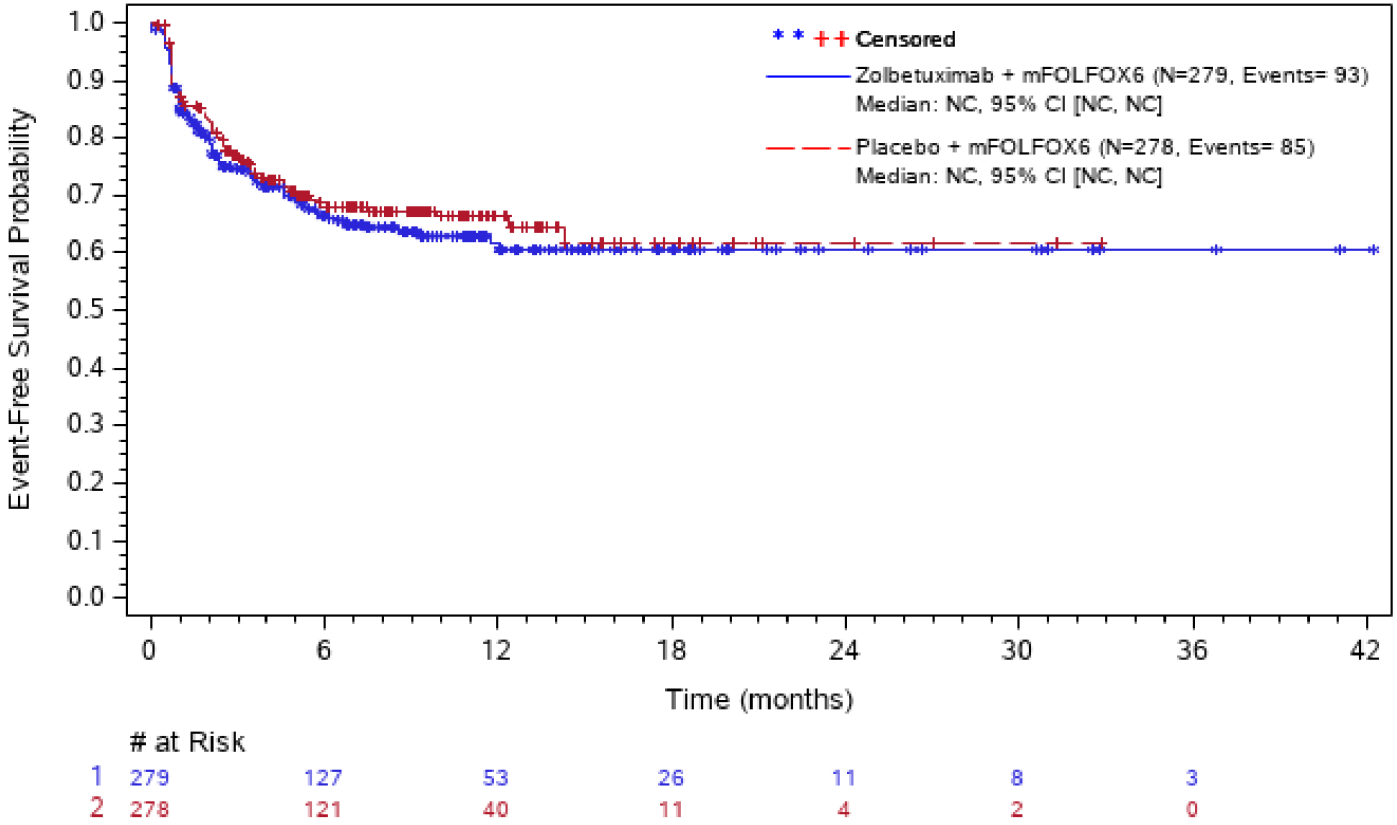
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.185: Kaplan-Meier Plot of Time to first Severe TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



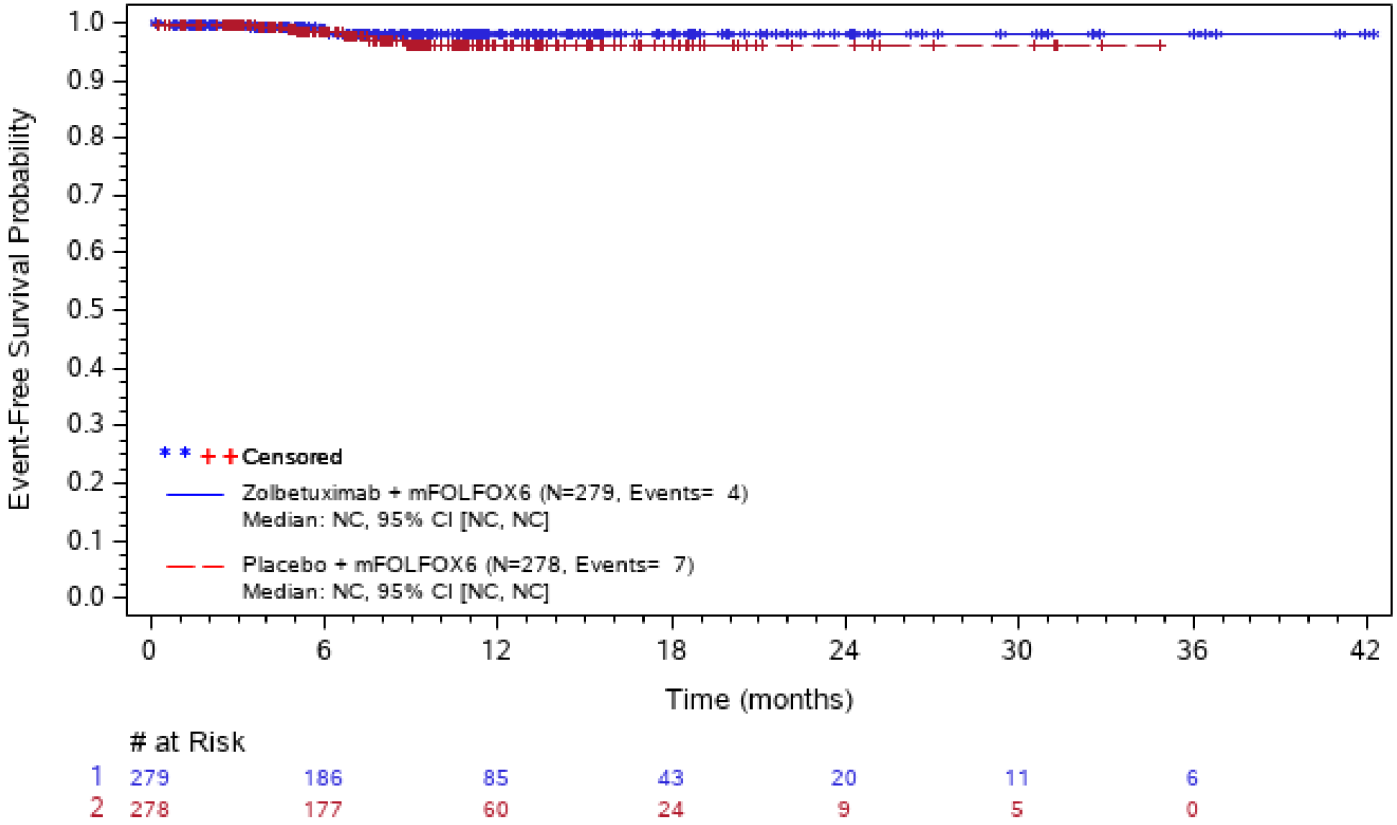
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.186: Kaplan-Meier Plot of Time to first Severe TEAE - Investigations (SOC) - Safety Analysis Set



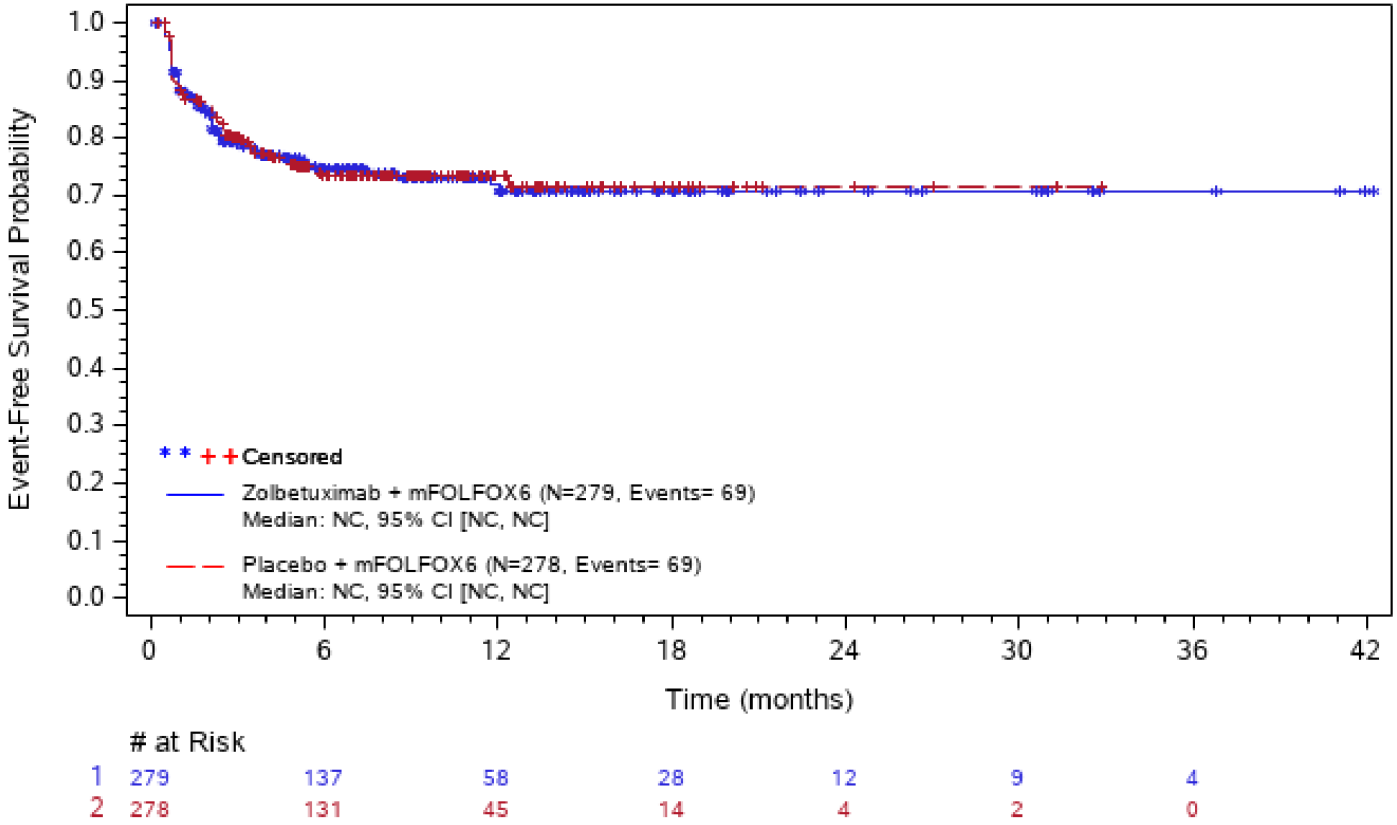
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.187: Kaplan-Meier Plot of Time to first Severe TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



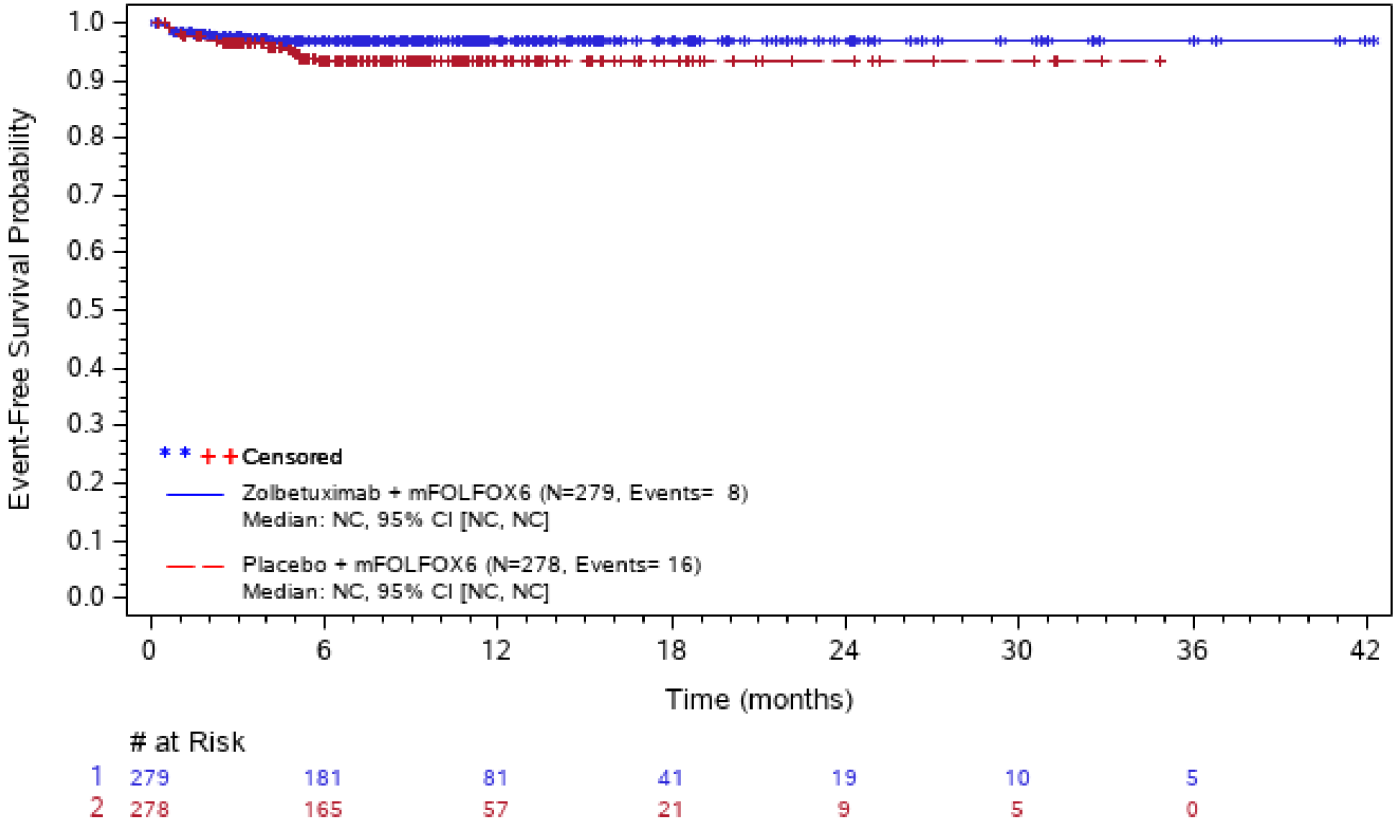
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.188: Kaplan-Meier Plot of Time to first Severe TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set



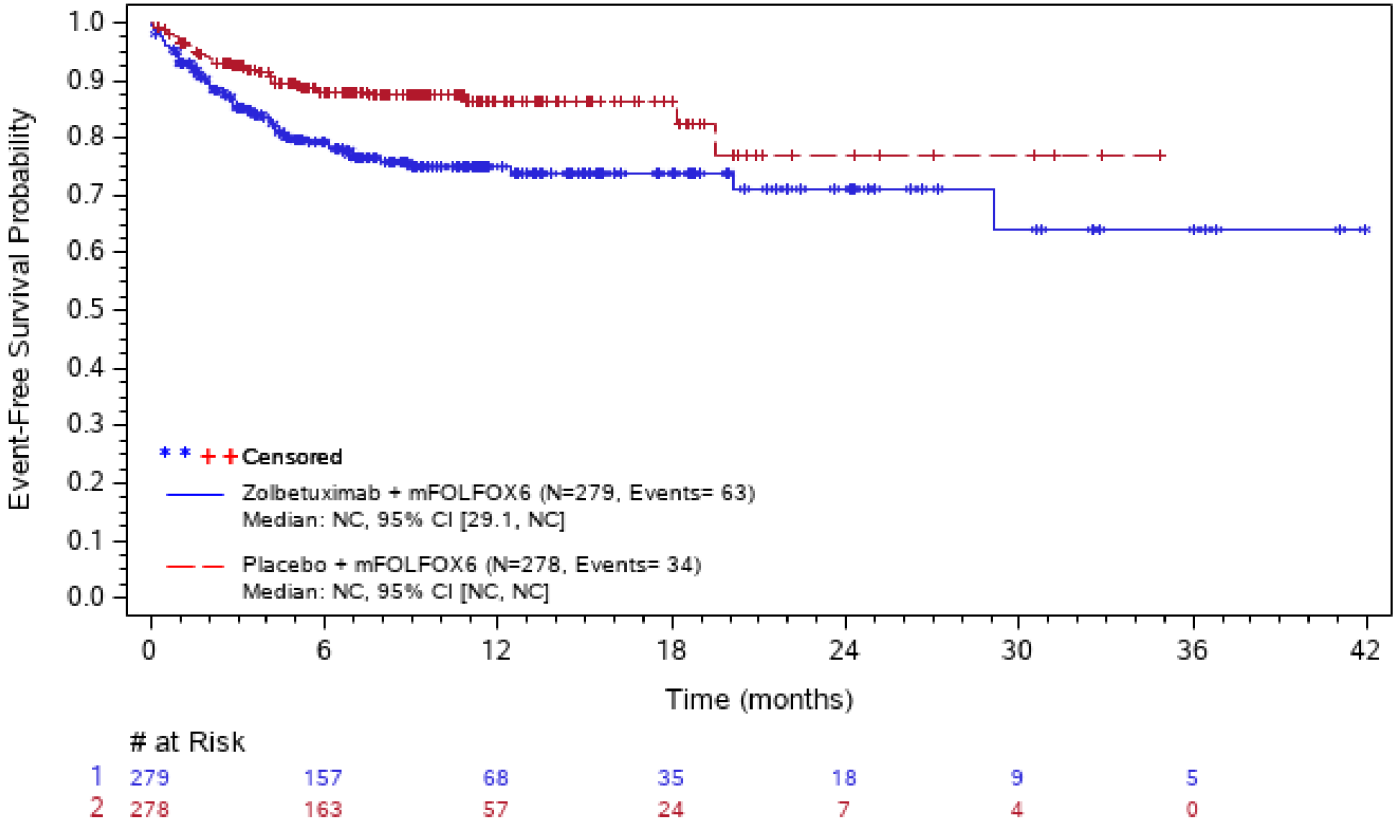
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.189: Kaplan-Meier Plot of Time to first Severe TEAE - White Blood Cell Count 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: 09SEP22

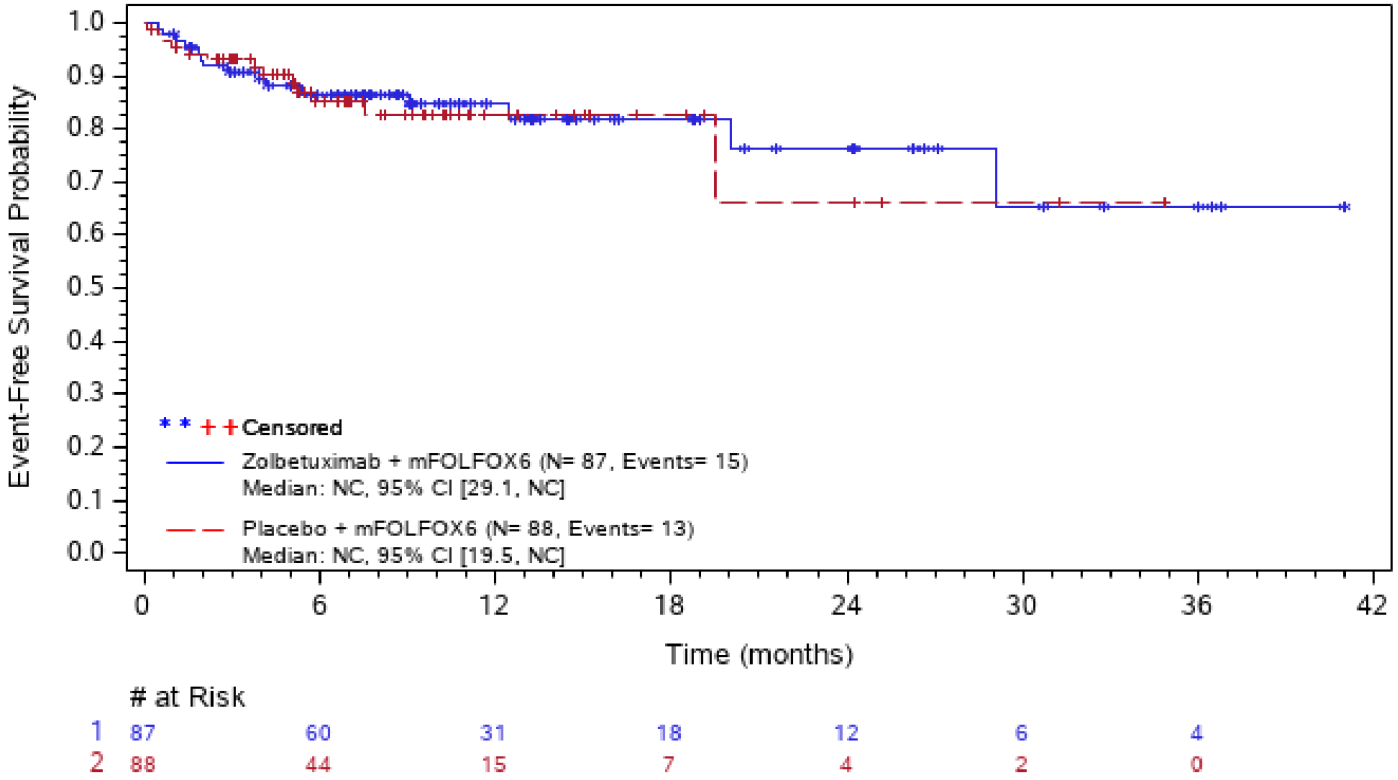
Figure 301.1.2001.190: Kaplan-Meier Plot of Time to first Severe TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 09SEP22

Figure 301.1.2001.190.3: Kaplan-Meier Plot of Time to first Severe TEAE by Region - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

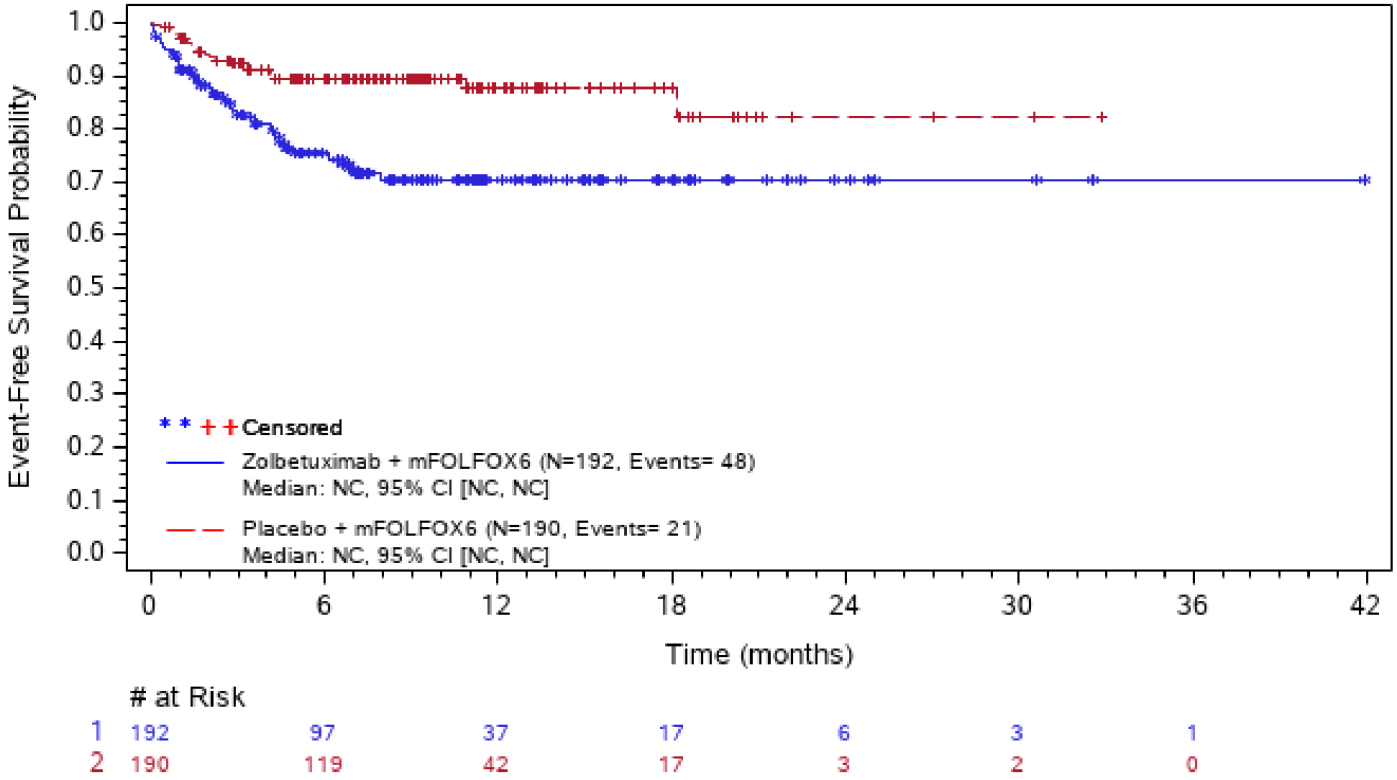
Region: Asia



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.

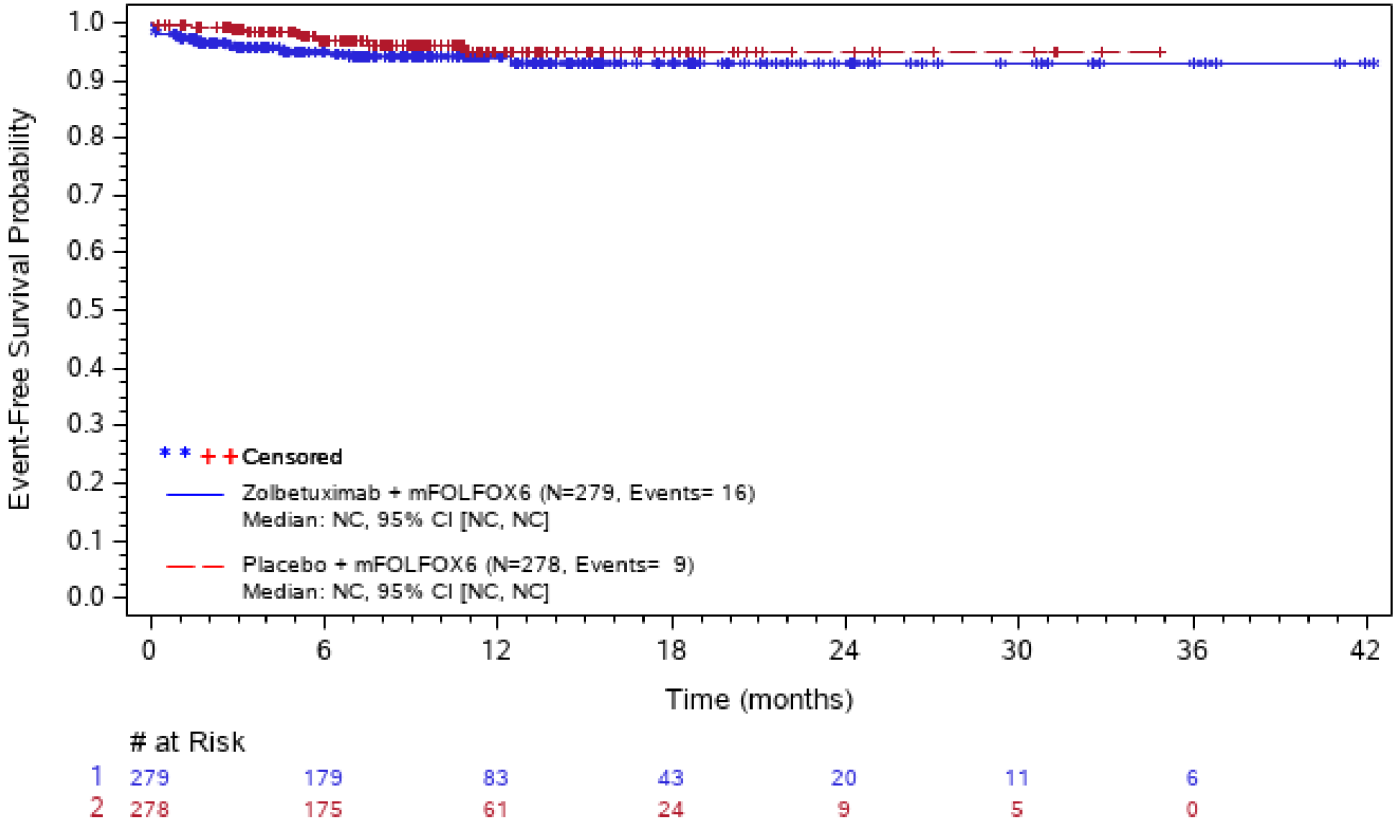
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.190.3: Kaplan-Meier Plot of Time to first Severe TEAE by Region - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set
Region: Non-Asia



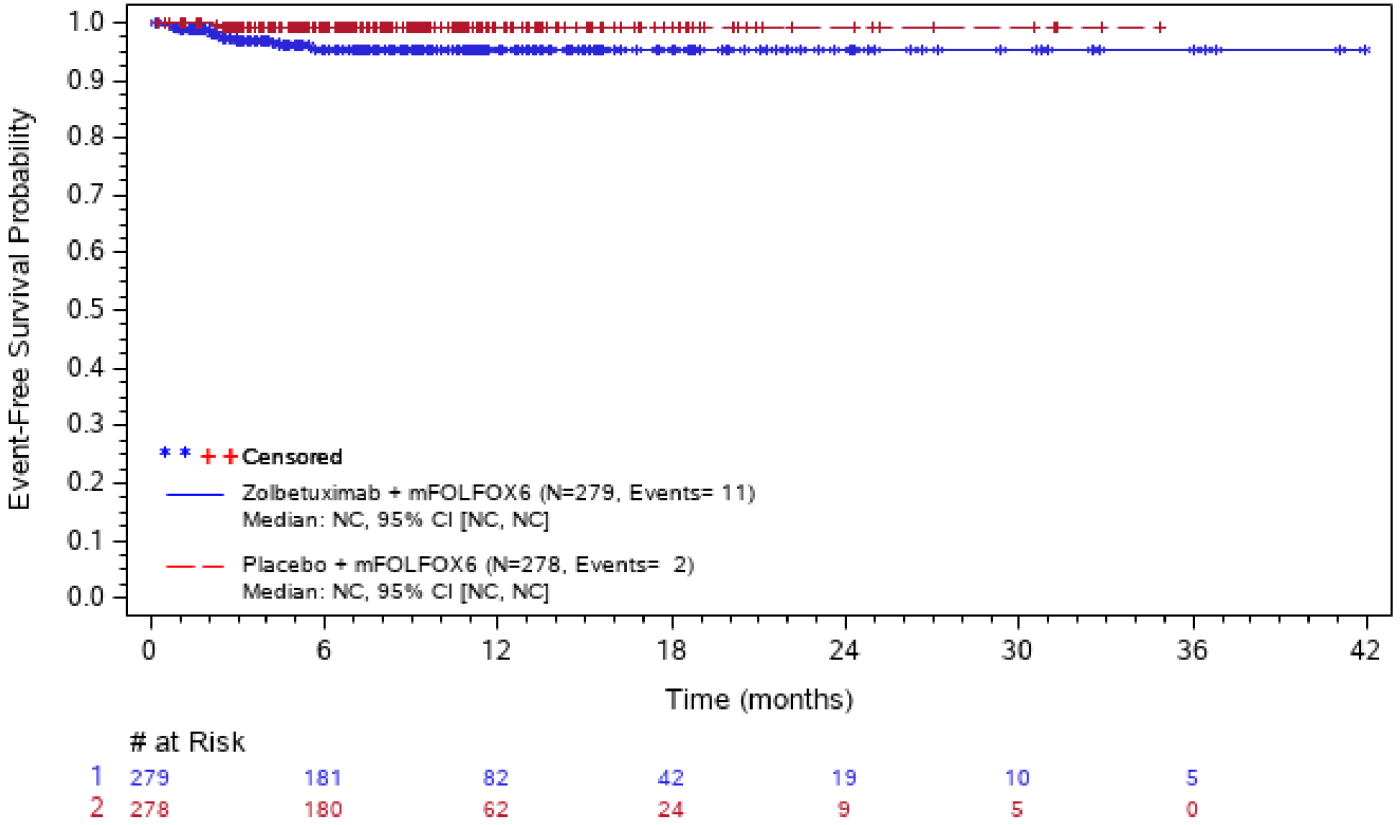
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.191: Kaplan-Meier Plot of Time to first Severe TEAE - Decreased Appetite (PT) - Safety Analysis Set



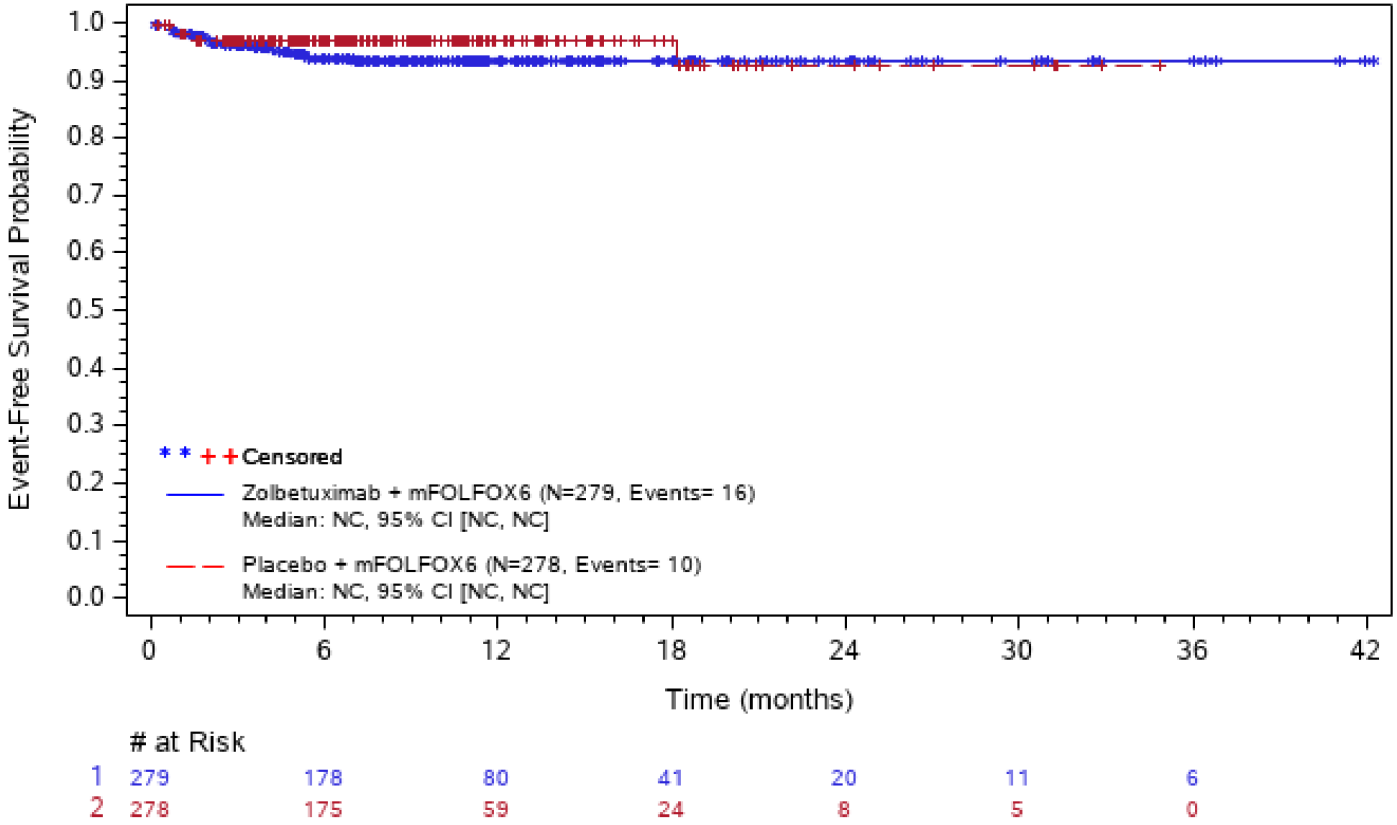
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.192: Kaplan-Meier Plot of Time to first Severe TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



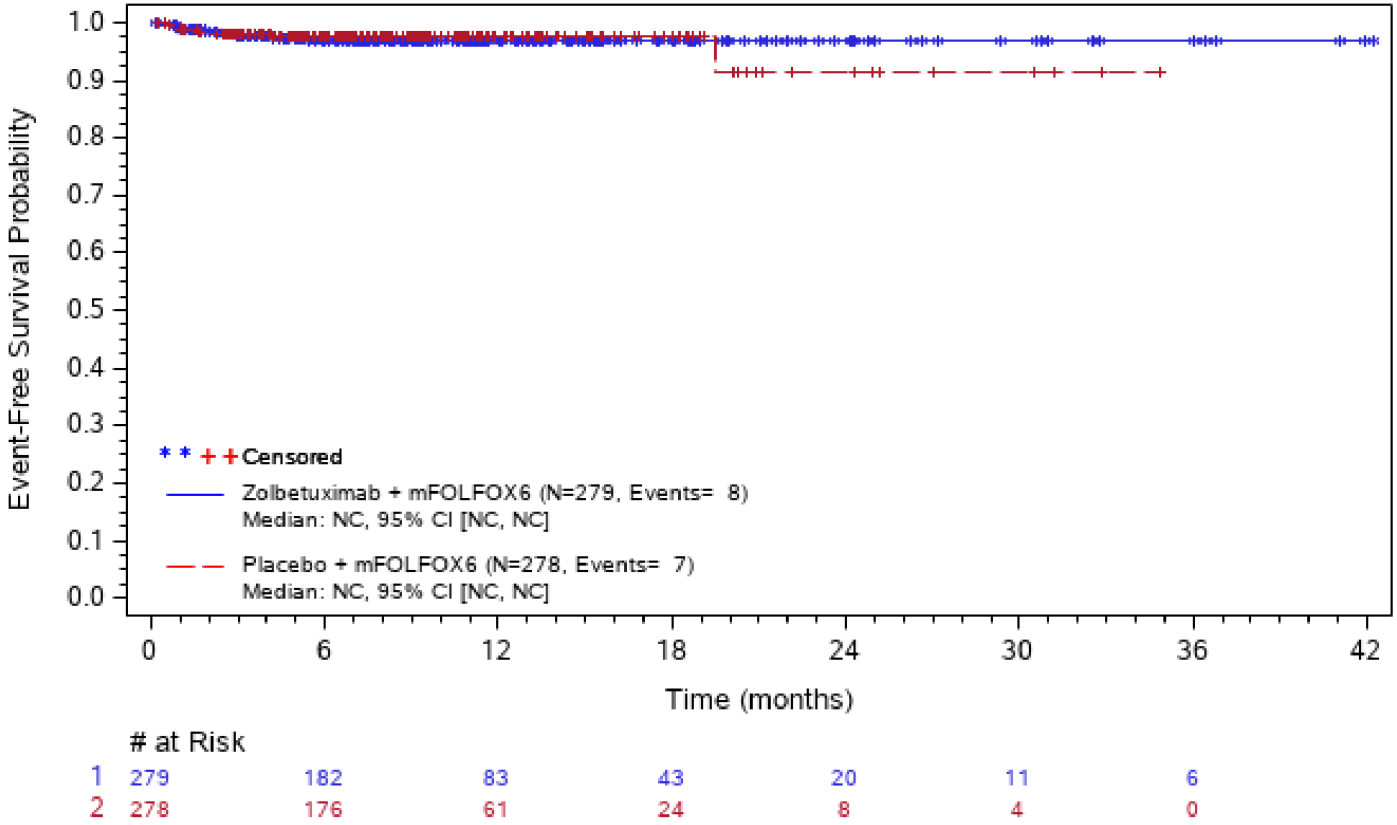
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.193: Kaplan-Meier Plot of Time to first Severe TEAE - Hypokalaemia (PT) - Safety Analysis Set



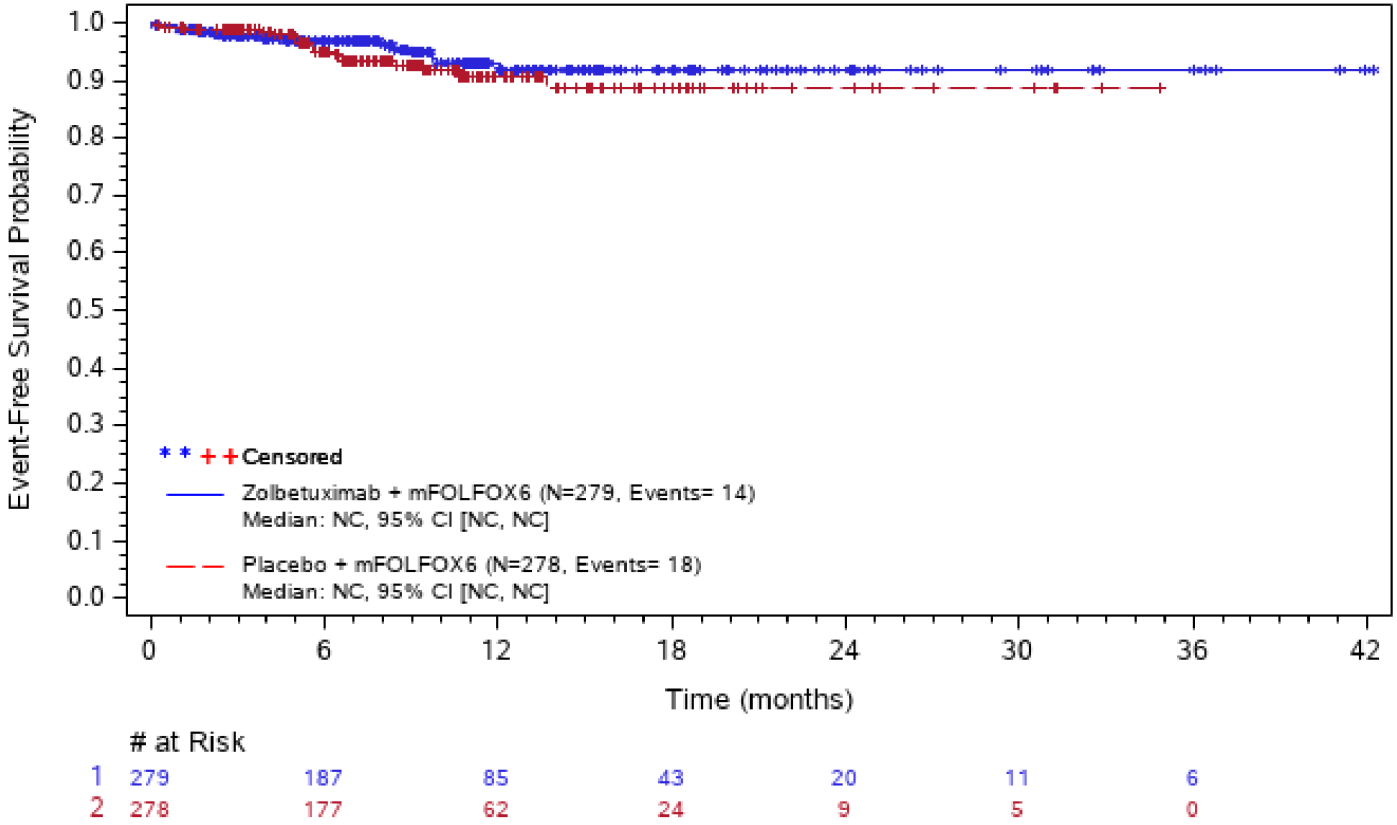
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.194: Kaplan-Meier Plot of Time to first Severe TEAE - Hypophosphataemia (PT) - Safety Analysis Set



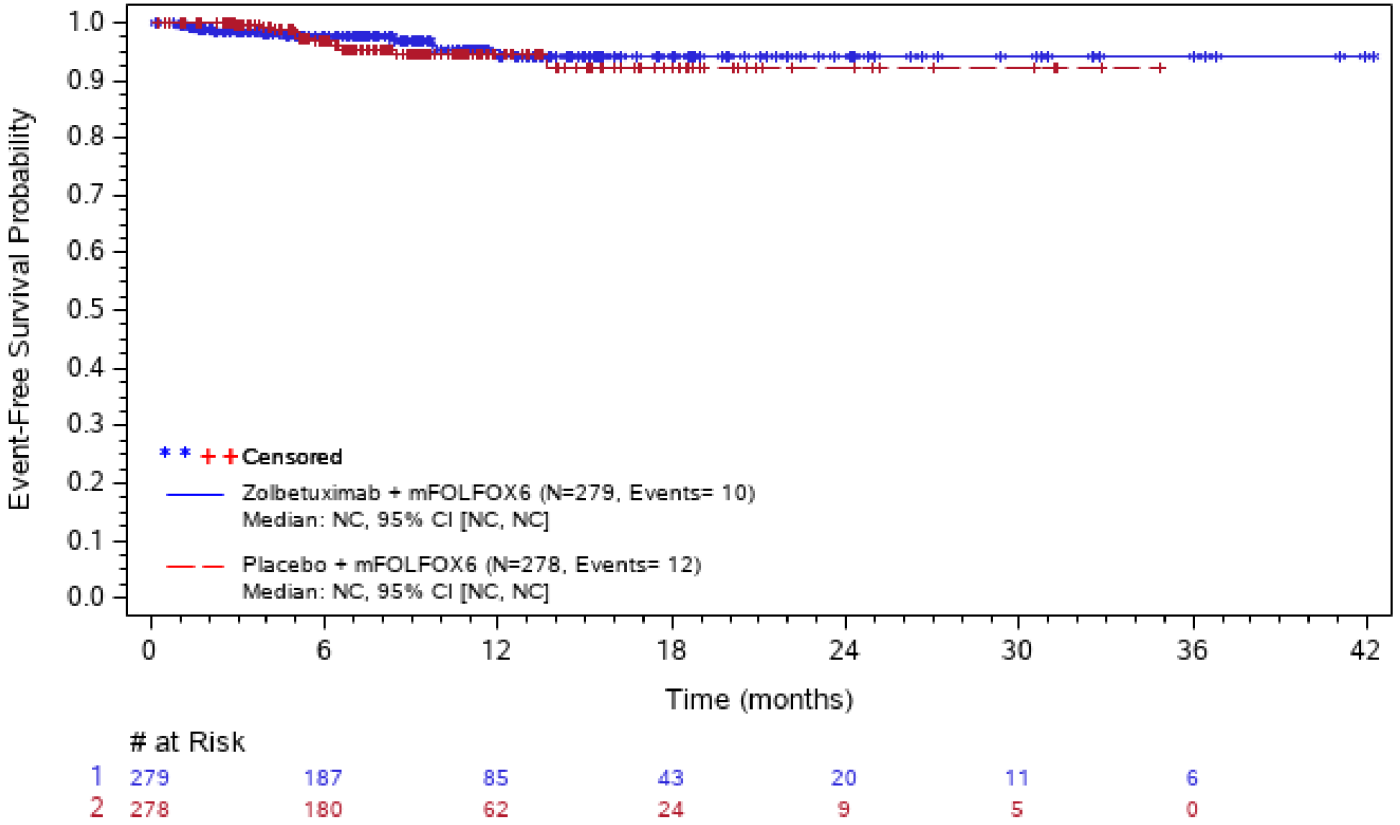
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.195: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



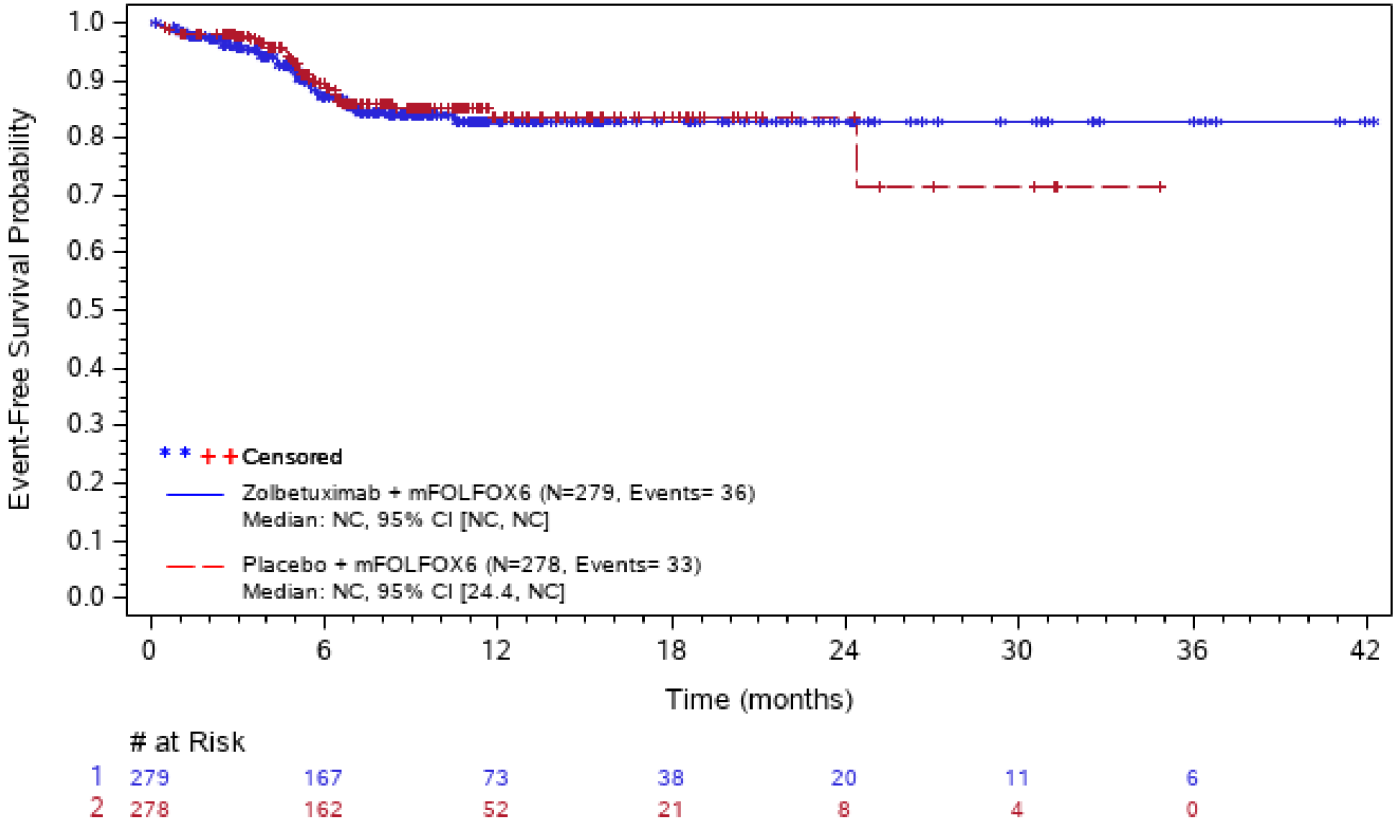
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.196: Kaplan-Meier Plot of Time to first Severe TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



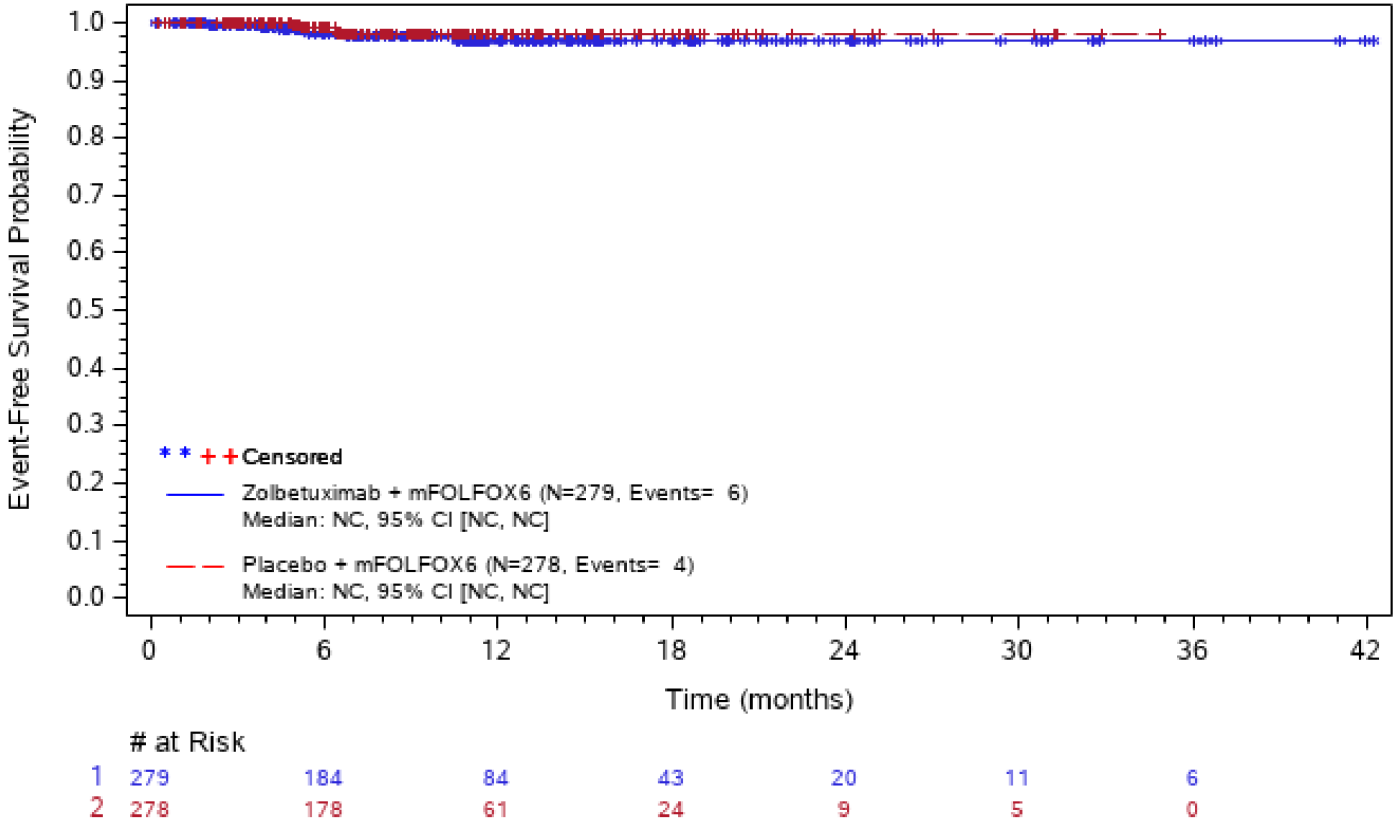
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.197: Kaplan-Meier Plot of Time to first Severe TEAE - Nervous System Disorders (SOC) - Safety Analysis Set



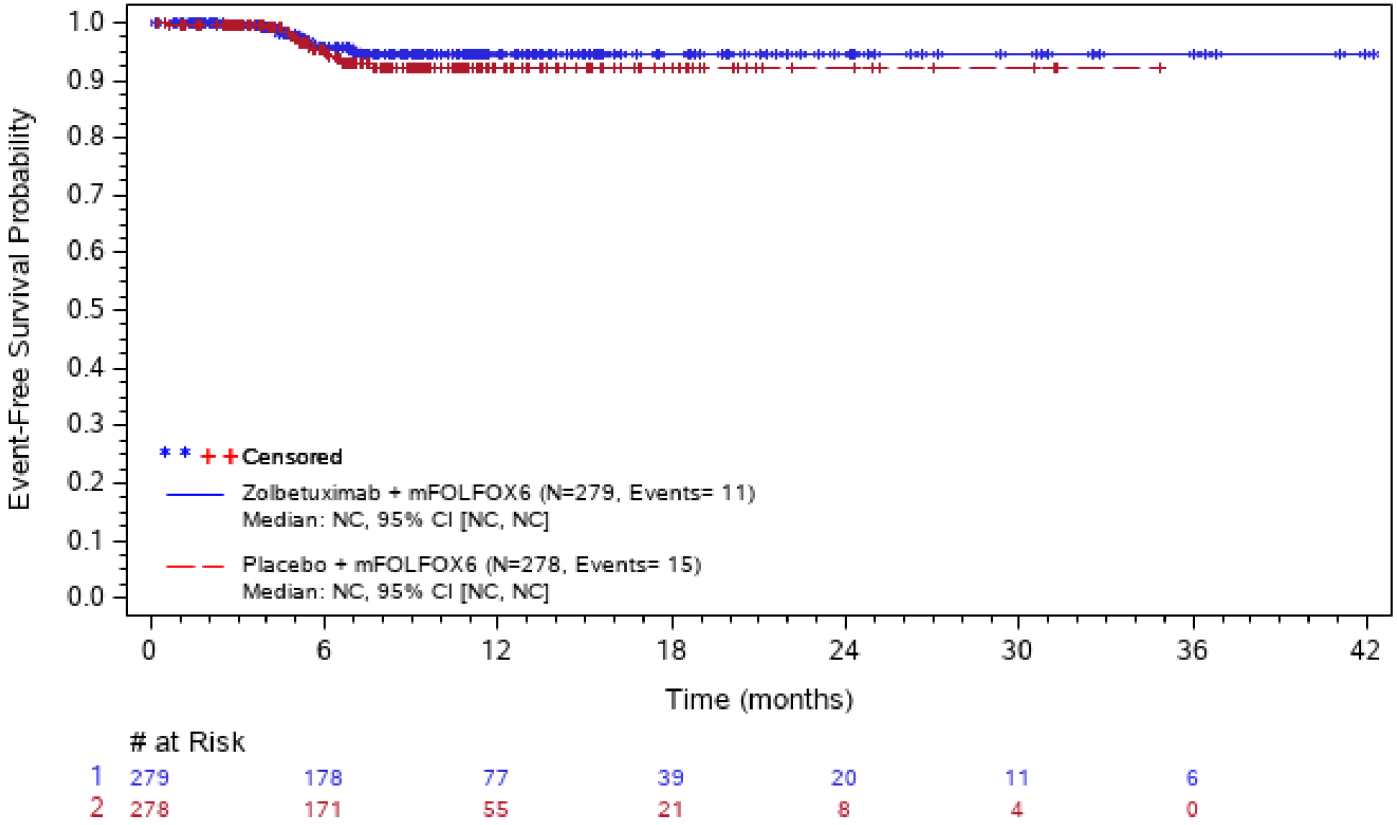
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.198: Kaplan-Meier Plot of Time to first Severe TEAE - Paraesthesia (PT) - Safety Analysis Set



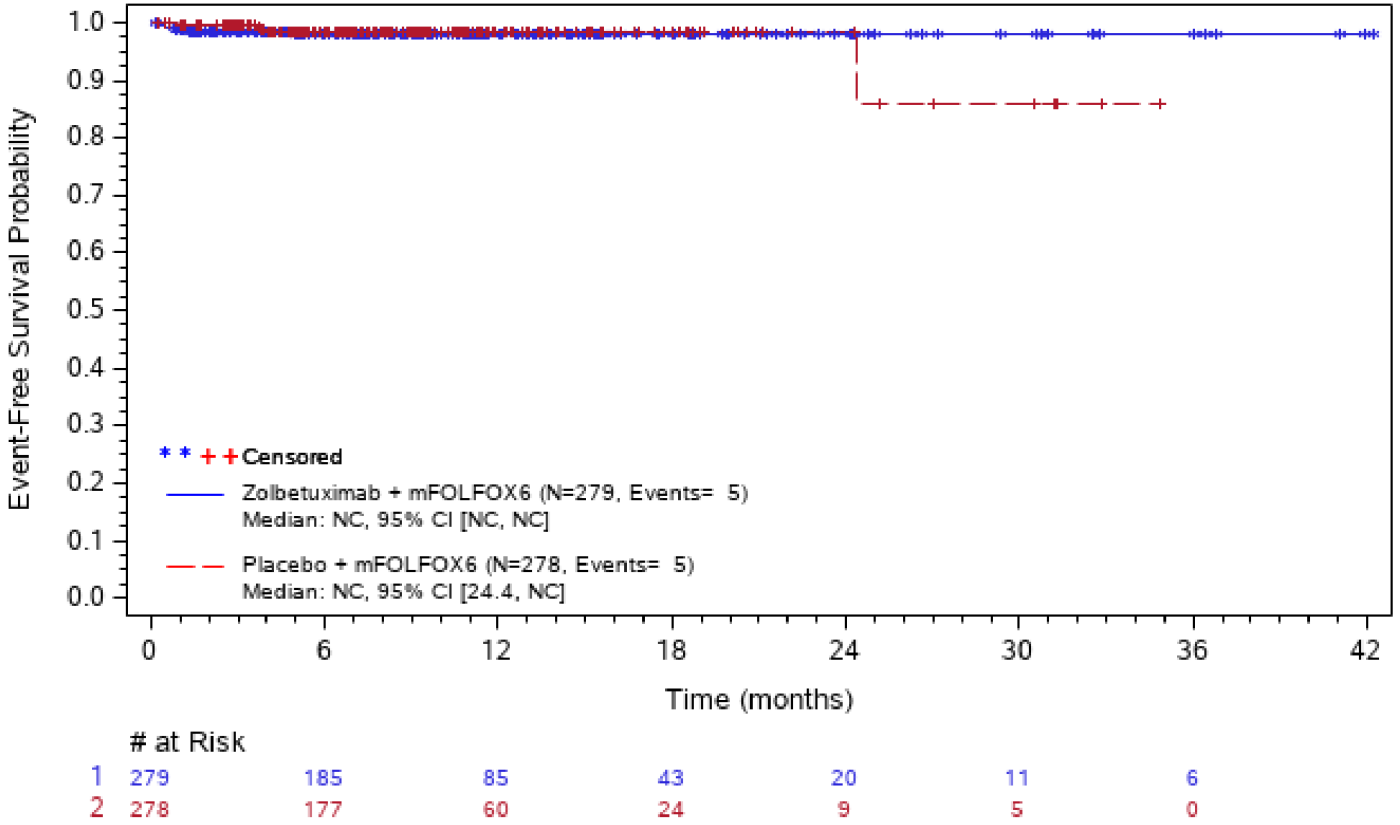
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.199: Kaplan-Meier Plot of Time to first Severe TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set



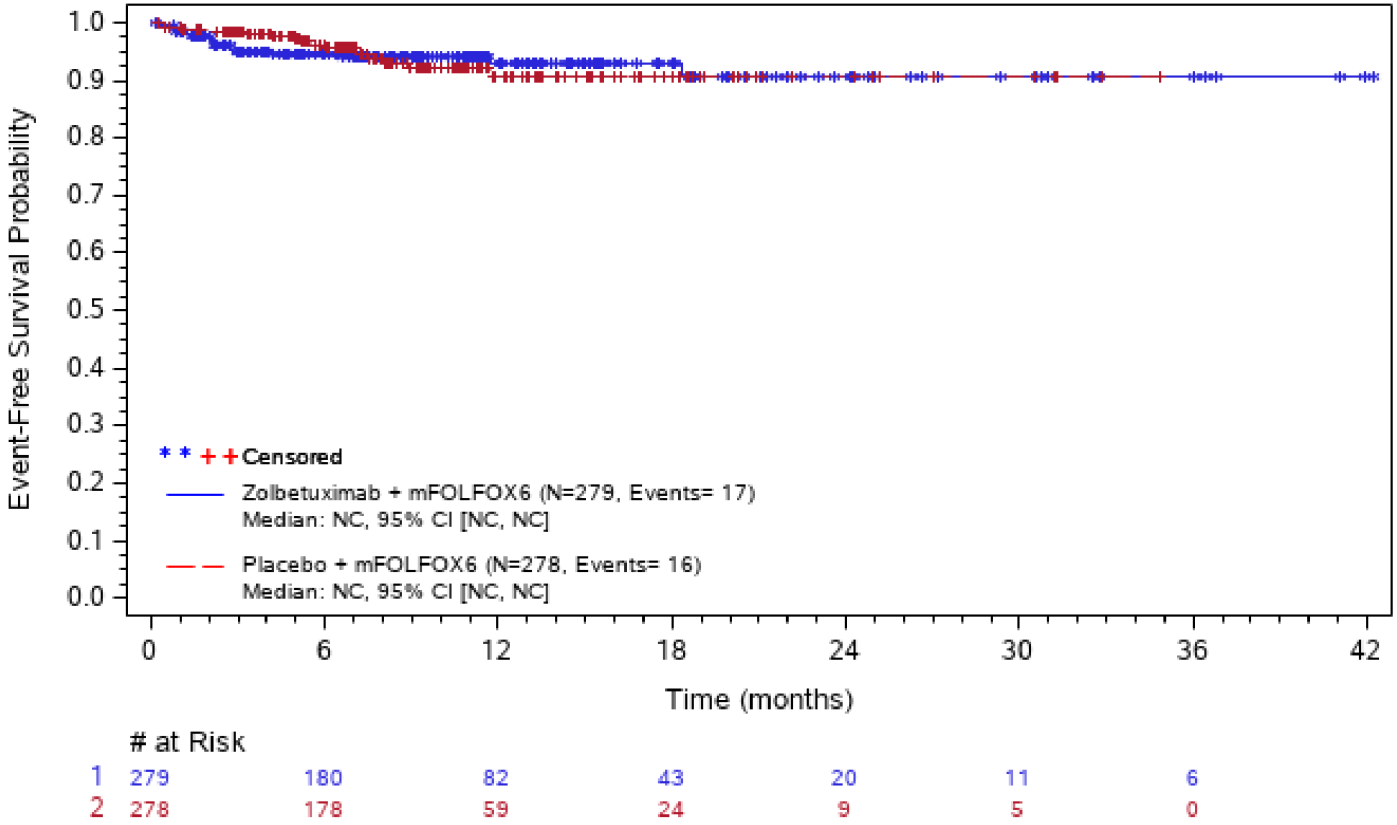
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.200: Kaplan-Meier Plot of Time to first Severe TEAE - Syncope (PT) - Safety Analysis Set



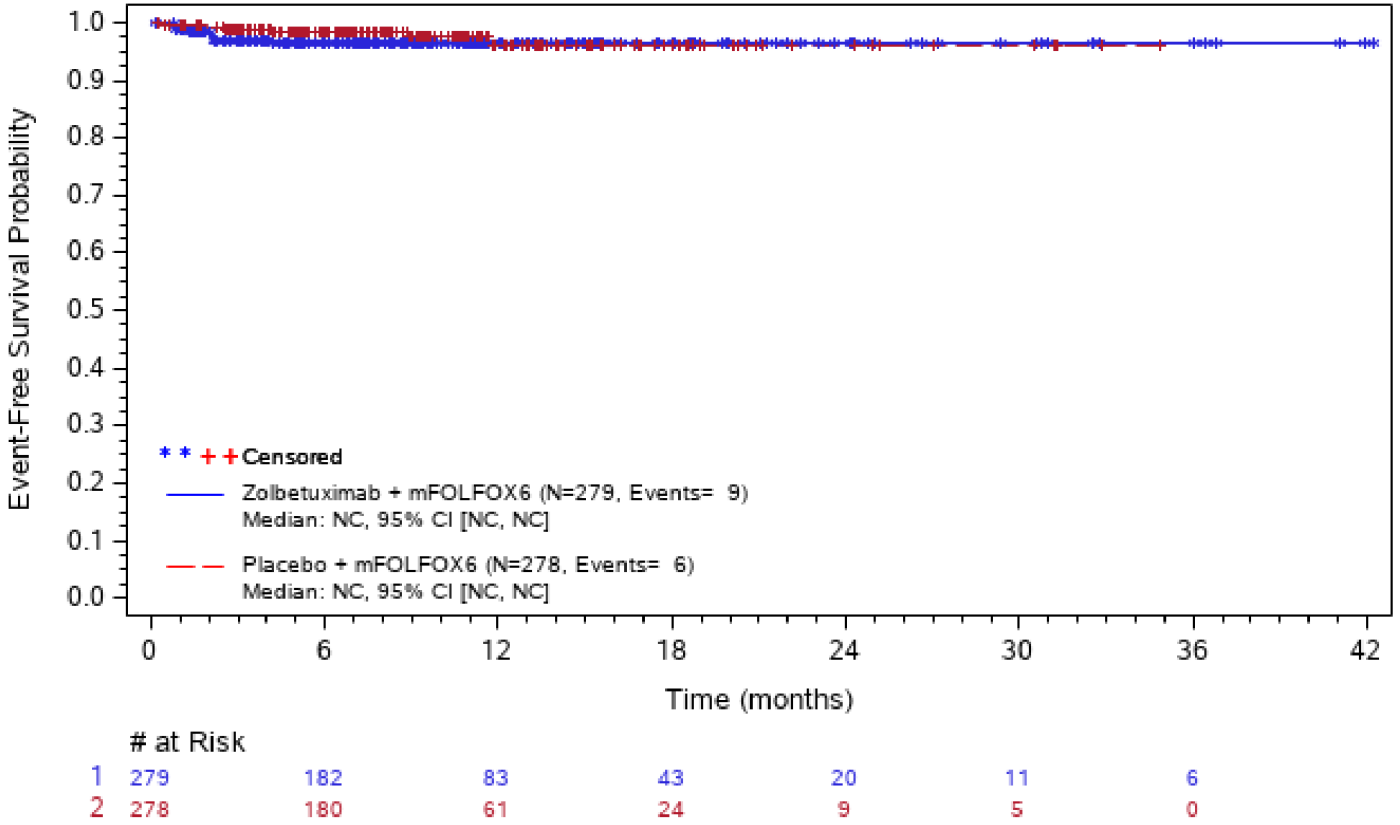
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.201: Kaplan-Meier Plot of Time to first Severe TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



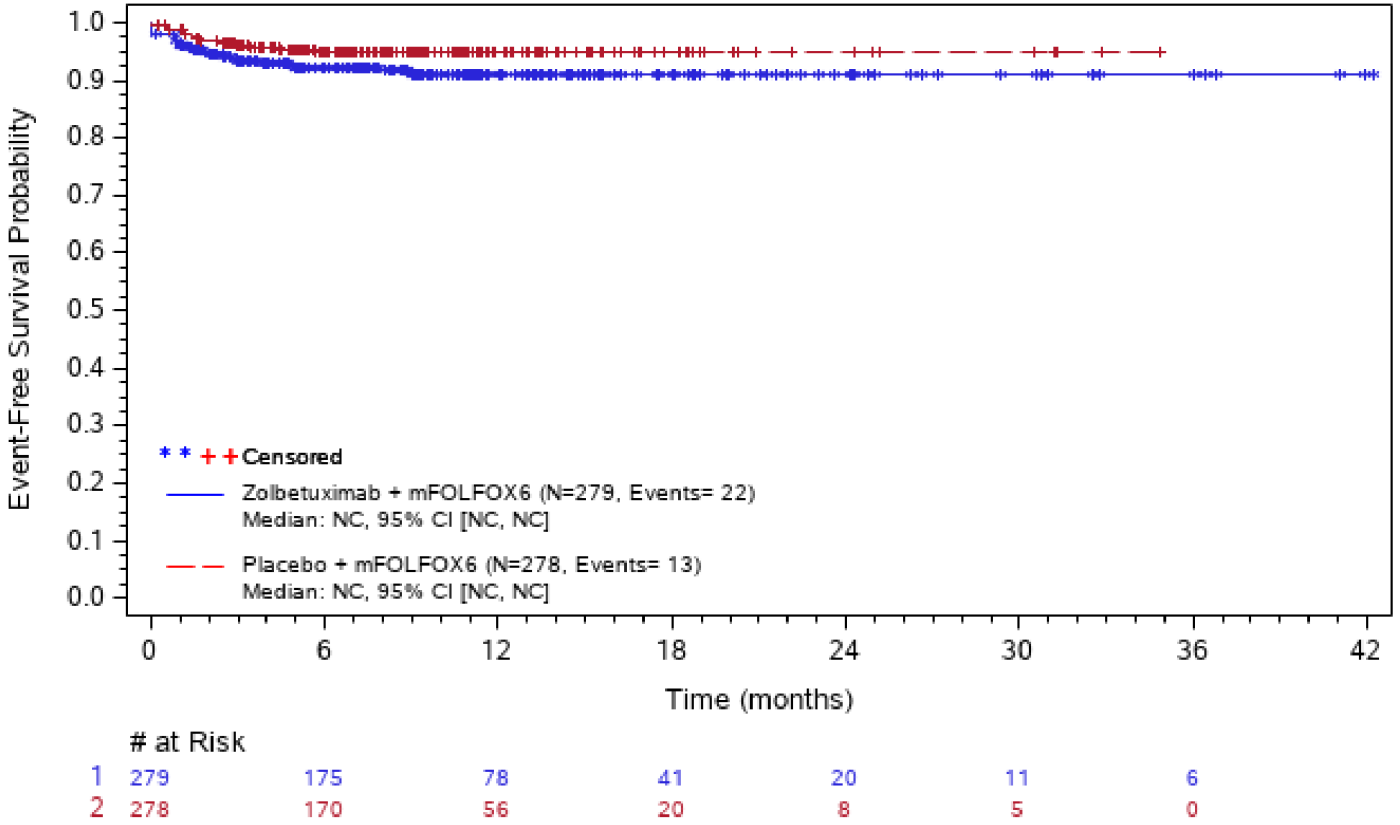
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.202: Kaplan-Meier Plot of Time to first Severe TEAE - Pulmonary Embolism (PT) - Safety Analysis Set



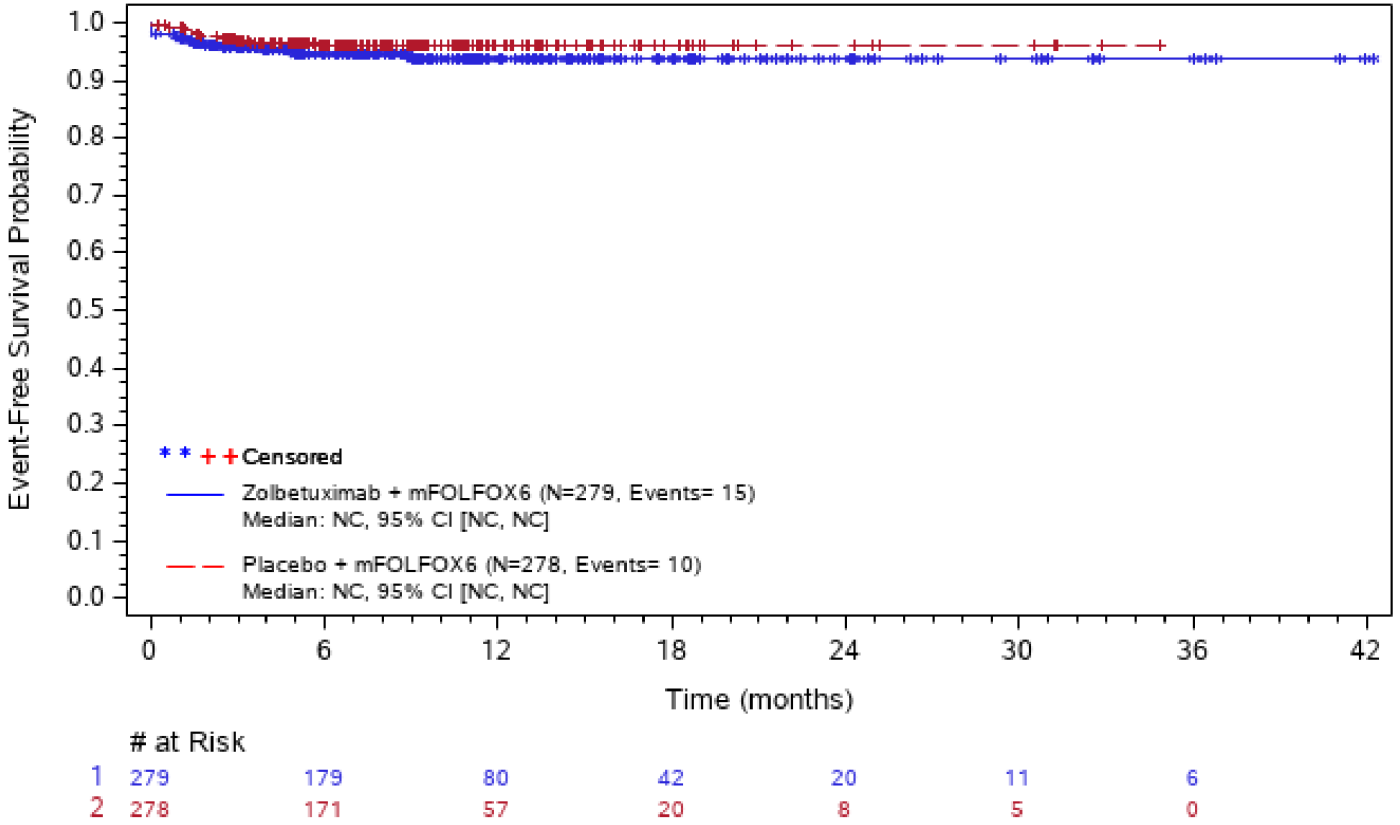
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.203: Kaplan-Meier Plot of Time to first Severe 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: 09SEP22

Figure 301.1.2001.204: Kaplan-Meier Plot of Time to first Severe 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.1.2001.144.1: Summary and Results of TESAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	9 (3.2%)	
Number of patients censored	262 (93.9%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.937 [0.863, 4.349]
Log-rank test			
Two-sided stratified log-rank p-value			0.1030

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.145.1: Summary and Results of TESAEs - Cardiac Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	8 (2.9%)	
Number of patients censored	274 (98.2%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.665 [0.217, 2.037]
Log-rank test			
Two-sided stratified log-rank p-value			0.4721

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.146.1: Summary and Results of TESAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	52 (18.6%)	42 (15.1%)	
Number of patients censored	227 (81.4%)	236 (84.9%)	
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			1.283 [0.853, 1.929]
Log-rank test			
Two-sided stratified log-rank p-value			0.2341

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.147.1: Summary and Results of TESAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	9 (3.2%)	
Number of patients censored	274 (98.2%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.568 [0.190, 1.699]
Log-rank test			
Two-sided stratified log-rank p-value			0.3055

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.148.1: Summary and Results of TESAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	4 (1.4%)	
Number of patients censored	271 (97.1%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.012 [0.604, 6.701]
Log-rank test			
Two-sided stratified log-rank p-value			0.2454

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.149.1: Summary and Results of TESAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.108 [0.532, 8.353]
Log-rank test			
Two-sided stratified log-rank p-value			0.2776

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.150.1: Summary and Results of TESAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	19 (6.8%)	11 (4.0%)	
Number of patients censored	260 (93.2%)	267 (96.0%)	
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			1.768 [0.840, 3.724]
Log-rank test			
Two-sided stratified log-rank p-value			0.1293

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.151.1: Summary and Results of TESAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	23 (8.2%)	13 (4.7%)	
Number of patients censored	256 (91.8%)	265 (95.3%)	
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			1.886 [0.955, 3.723]
Log-rank test			
Two-sided stratified log-rank p-value			0.0647

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.152.1: Summary and Results of TESAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	22 (7.9%)	
Number of patients censored	255 (91.4%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.116 [0.623, 2.000]
Log-rank test			
Two-sided stratified log-rank p-value			0.7123

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.153.1: Summary and Results of TESAEs - Pyrexia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	6 (2.2%)	
Number of patients censored	272 (97.5%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.223 [0.411, 3.641]
Log-rank test			
Two-sided stratified log-rank p-value			0.7185

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.154.1: Summary and Results of TESAEs - Hepatobiliary Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	13 (4.7%)	
Number of patients censored	271 (97.1%)	265 (95.3%)	
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			0.573 [0.234, 1.403]
Log-rank test			
Two-sided stratified log-rank p-value			0.2176

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.155.1: Summary and Results of TESAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	29 (10.4%)	23 (8.3%)	
Number of patients censored	250 (89.6%)	255 (91.7%)	
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			1.198 [0.690, 2.080]
Log-rank test			
Two-sided stratified log-rank p-value			0.5205

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.156.1: Summary and Results of TESAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	8 (2.9%)	
Number of patients censored	273 (97.8%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.678 [0.230, 1.992]
Log-rank test			
Two-sided stratified log-rank p-value			0.4767

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.157.1: Summary and Results of TESAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	4 (1.4%)	
Number of patients censored	270 (96.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [24.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.614 [0.700, 9.765]
Log-rank test			
Two-sided stratified log-rank p-value			0.1383

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.158.1: Summary and Results of TESAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	9 (3.2%)	
Number of patients censored	273 (97.8%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.667 [0.237, 1.876]
Log-rank test			
Two-sided stratified log-rank p-value			0.4398

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.159.1: Summary and Results of TESAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	9 (3.2%)	
Number of patients censored	266 (95.3%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.397 [0.595, 3.283]
Log-rank test			
Two-sided stratified log-rank p-value			0.4406

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.160.1: Summary and Results of TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	17 (6.1%)	
Number of patients censored	265 (95.0%)	261 (93.9%)	
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			0.866 [0.426, 1.762]
Log-rank test			
Two-sided stratified log-rank p-value			0.6917

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.161.1: Summary and Results of TESAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.909 [0.392, 2.112]
Log-rank test			
Two-sided stratified log-rank p-value			0.8246

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.162.1: Summary and Results of TESAEs - Nervous System Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	13 (4.7%)	
Number of patients censored	269 (96.4%)	265 (95.3%)	
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			0.738 [0.319, 1.707]
Log-rank test			
Two-sided stratified log-rank p-value			0.4764

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.163.1: Summary and Results of TESAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	6 (2.2%)	
Number of patients censored	273 (97.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.935 [0.298, 2.932]
Log-rank test			
Two-sided stratified log-rank p-value			0.9078

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.164.1: Summary and Results of TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	15 (5.4%)	
Number of patients censored	265 (95.0%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.967 [0.464, 2.014]
Log-rank test			
Two-sided stratified log-rank p-value			0.9280

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.165.1: Summary and Results of TESAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.560 [0.440, 5.536]
Log-rank test			
Two-sided stratified log-rank p-value			0.4880

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.166.1: Summary and Results of TESAEs - Vascular Disorders (SOC)
- Safety Analysis Set

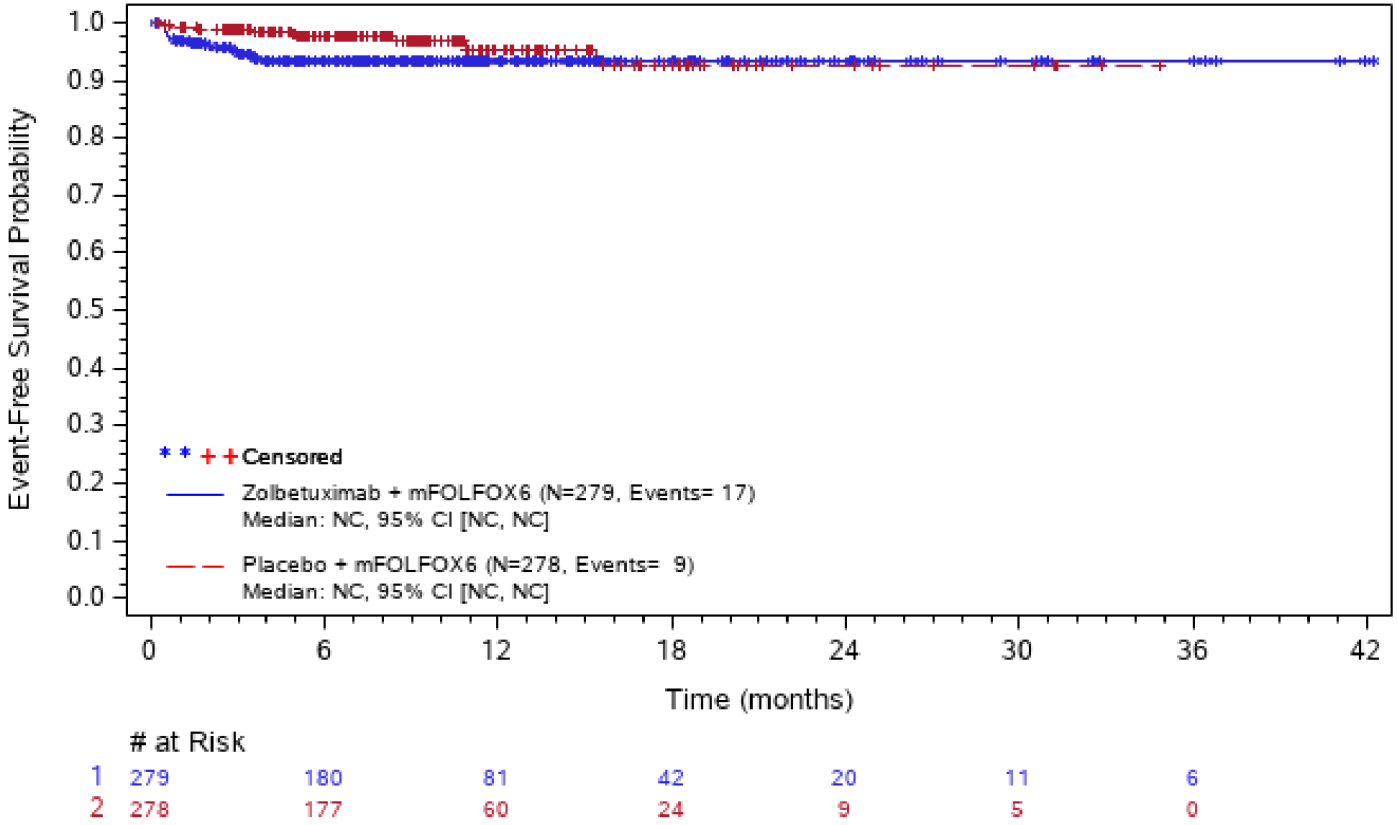
	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	5 (1.8%)	
Number of patients censored	270 (96.8%)	273 (98.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.970 [0.660, 5.884]
Log-rank test			
Two-sided stratified log-rank p-value			0.2159

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse - SOC und PT

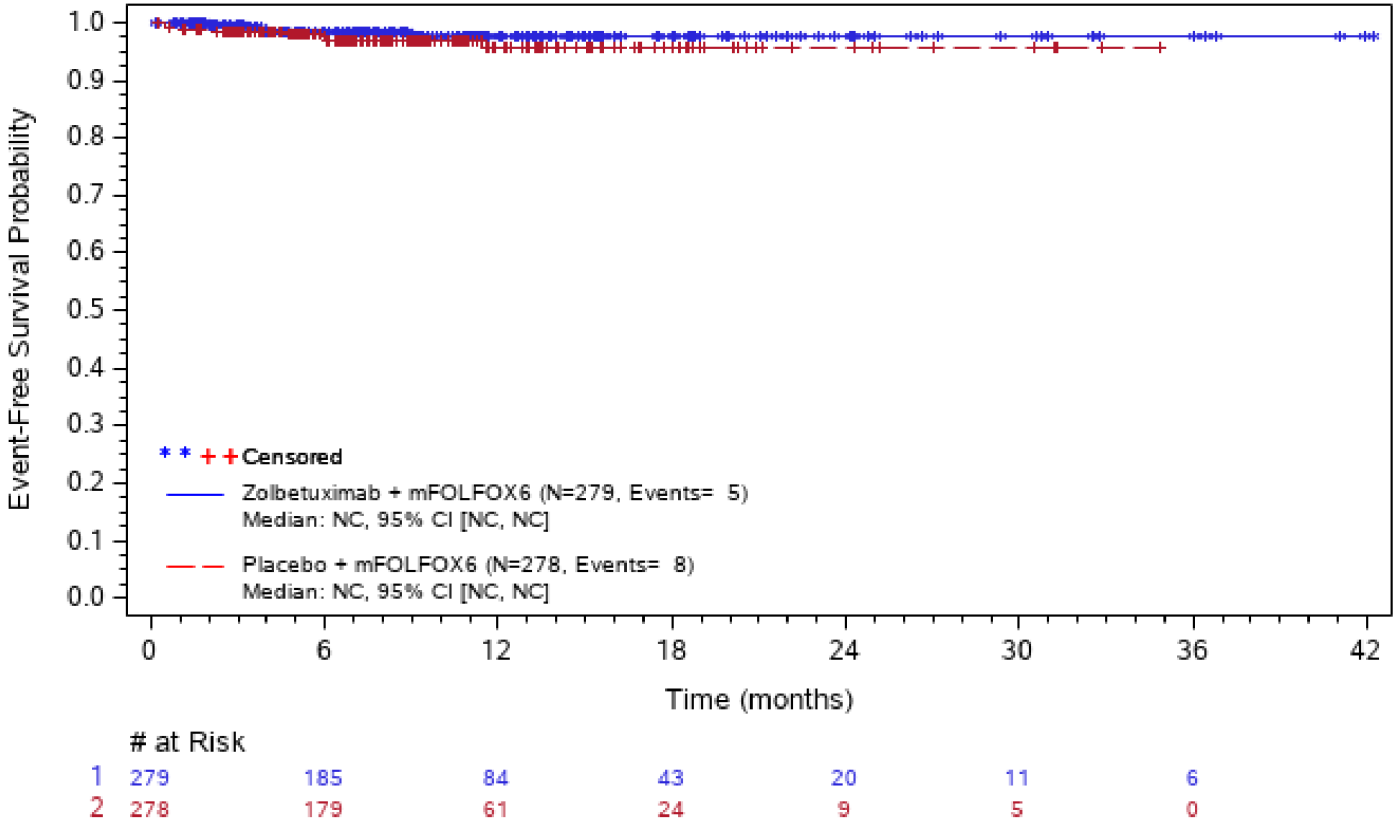
2. Kaplan-Meier-Plots

Figure 301.1.2001.144: Kaplan-Meier Plot of Time to first TESAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set



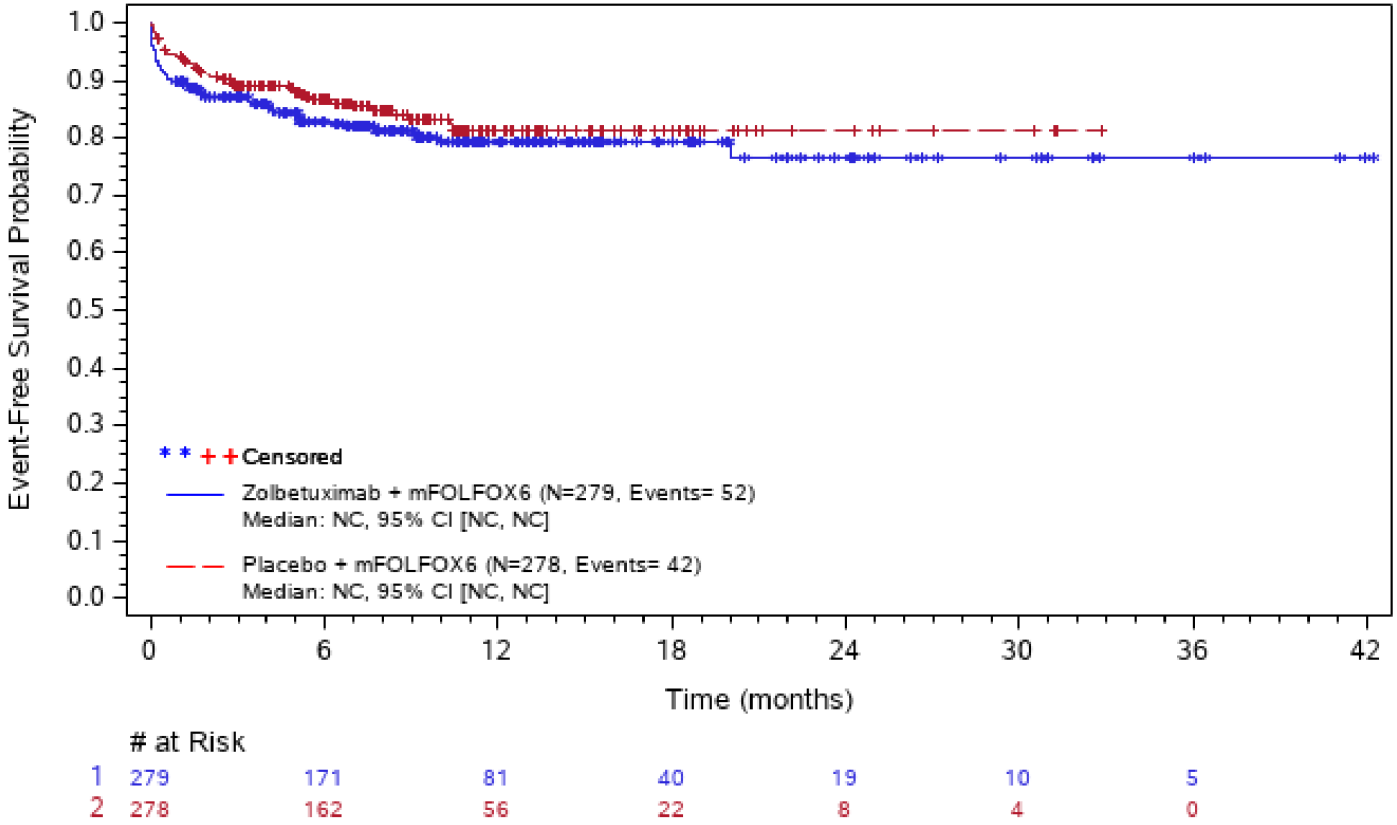
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.145: Kaplan-Meier Plot of Time to first TESAE - Cardiac Disorders (SOC) - Safety Analysis Set



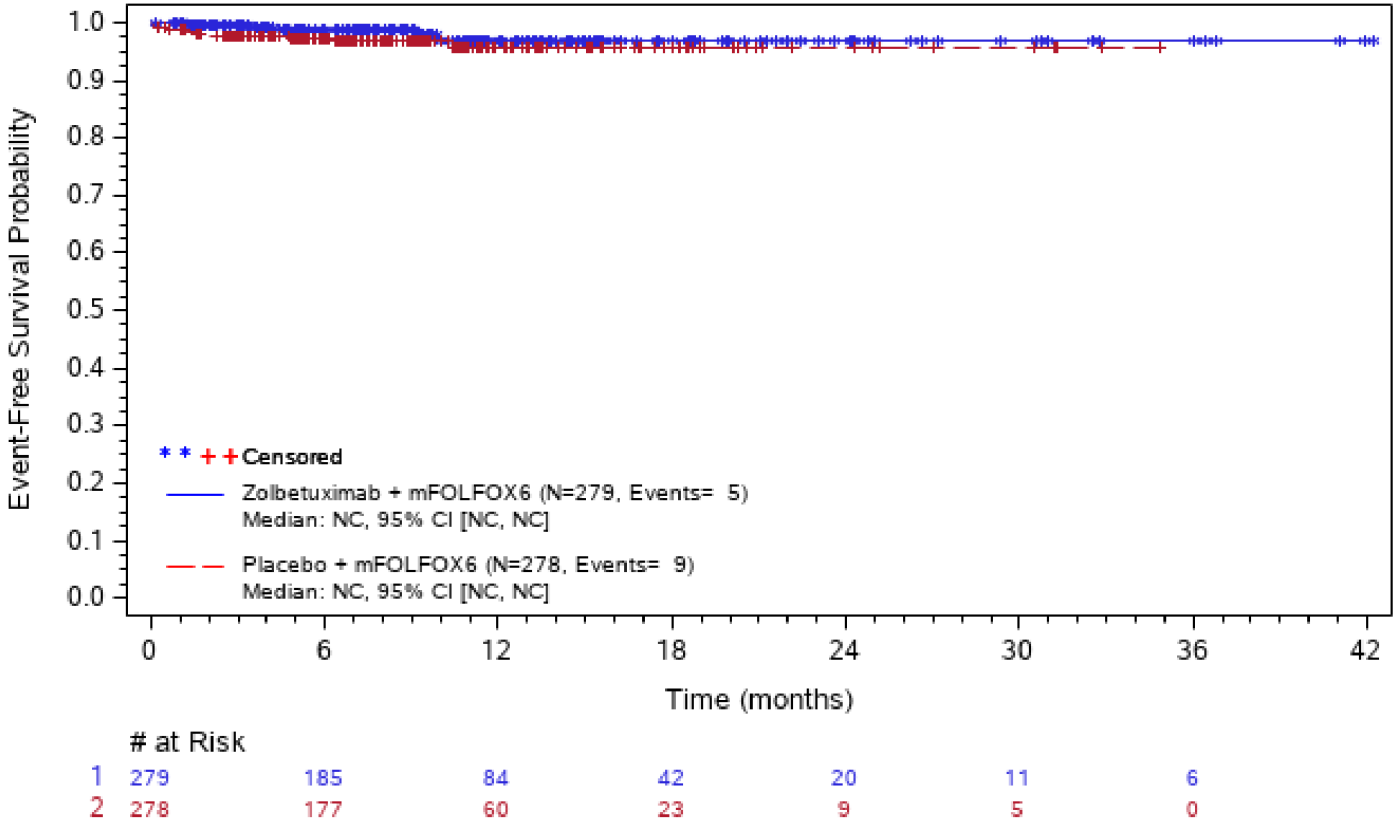
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.146: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set



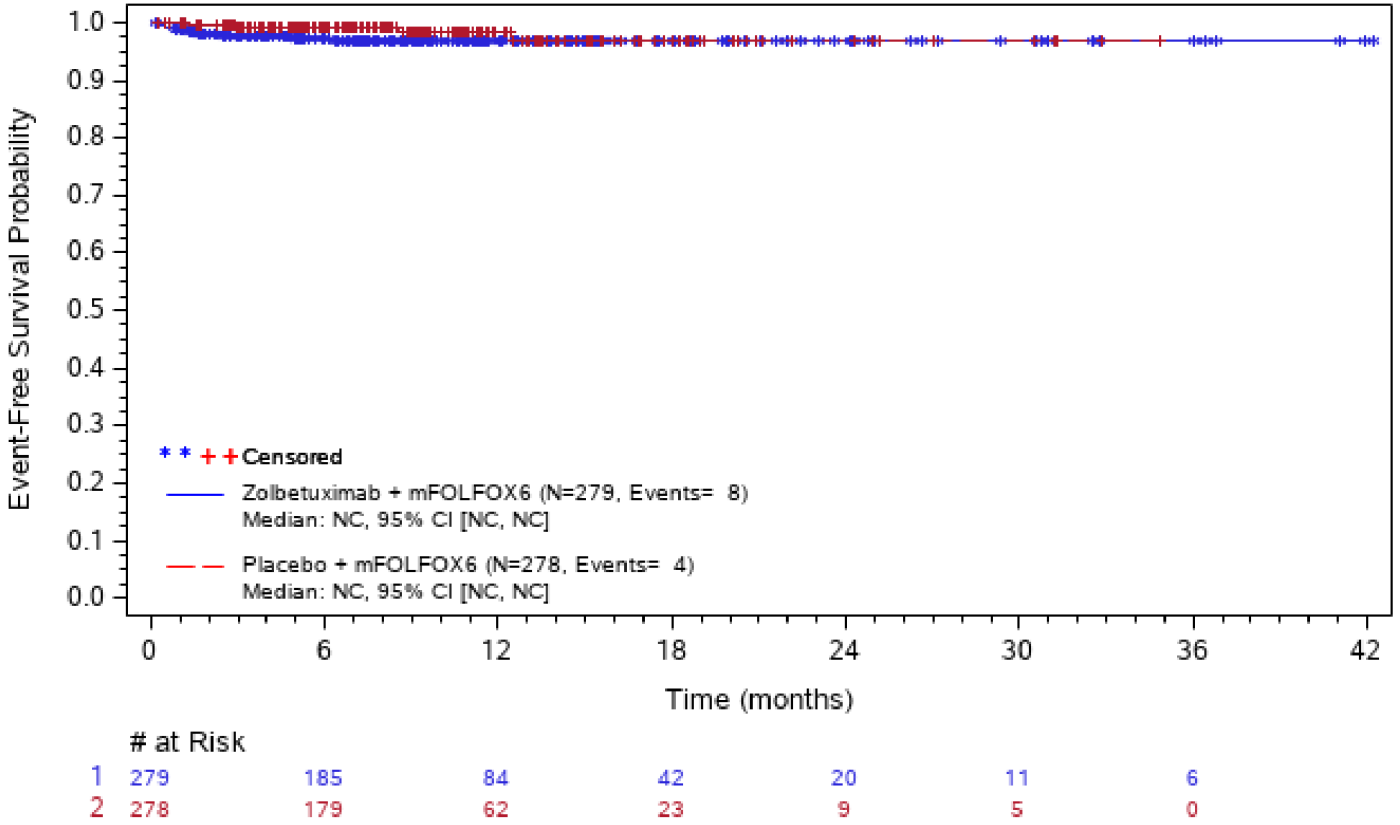
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.147: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (PT) - Safety Analysis Set



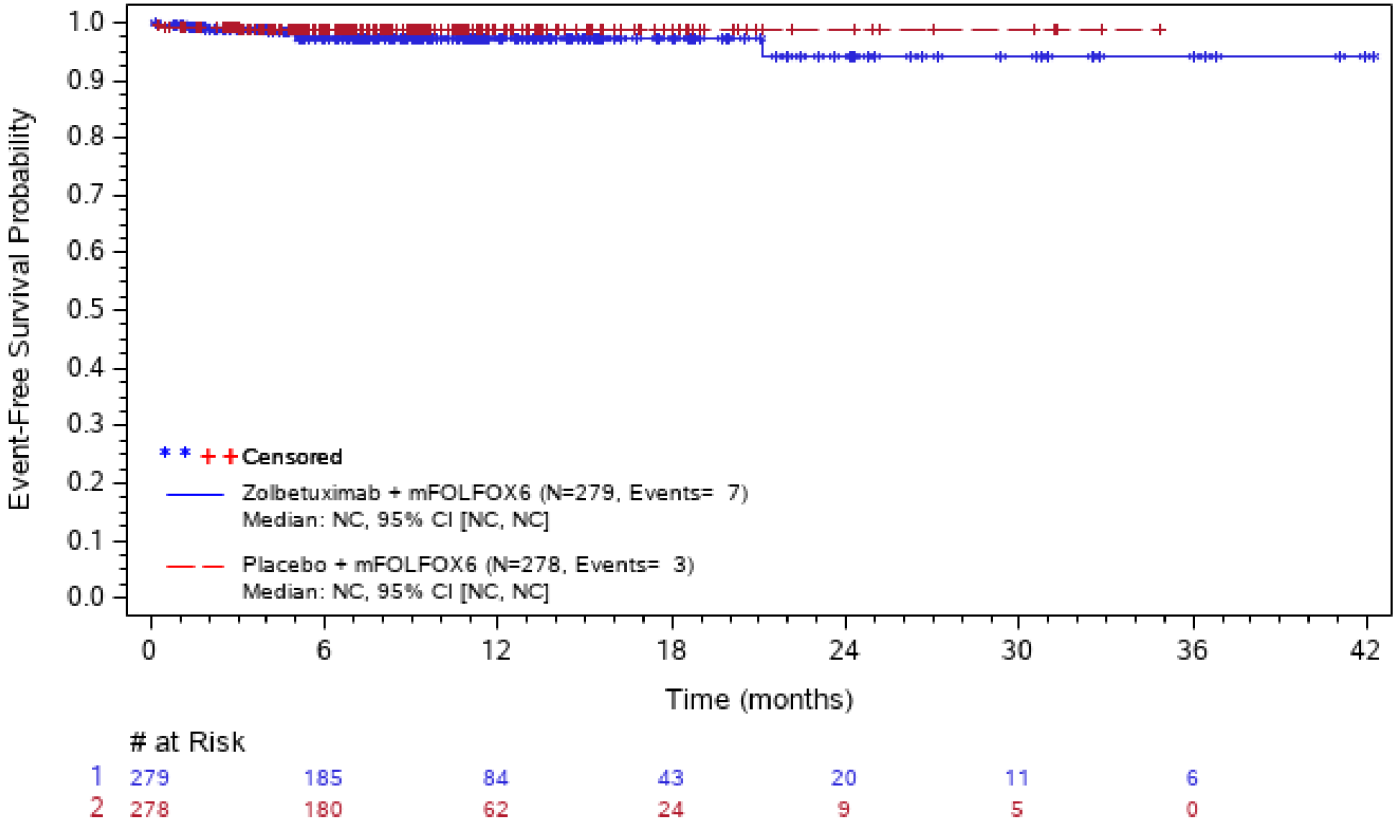
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.148: Kaplan-Meier Plot of Time to first TESAE - Diarrhoea (PT) - Safety Analysis Set



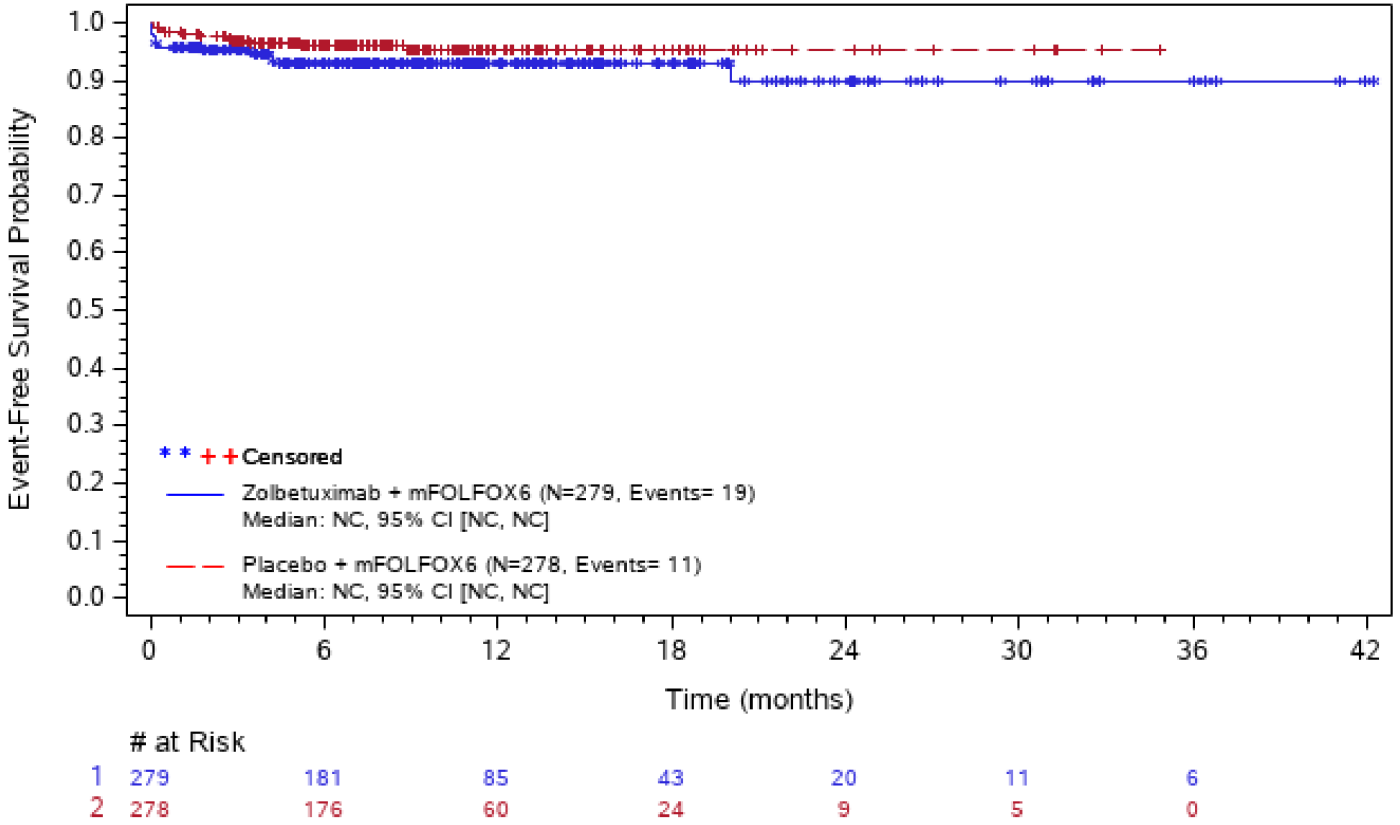
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.149: Kaplan-Meier Plot of Time to first TESAE - Intestinal Obstruction (PT) - Safety Analysis Set



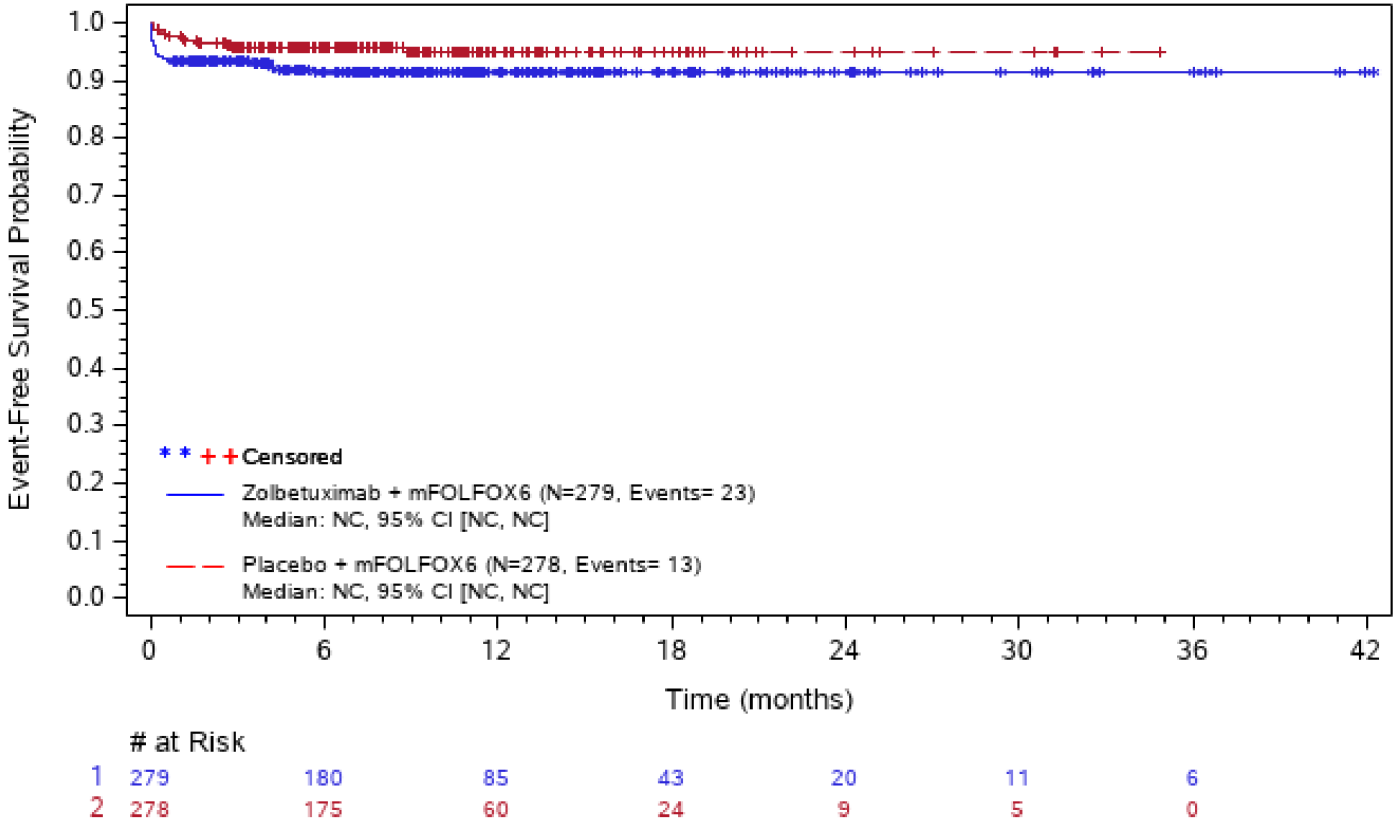
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.150: Kaplan-Meier Plot of Time to first TESAE - Nausea (PT) - Safety Analysis Set



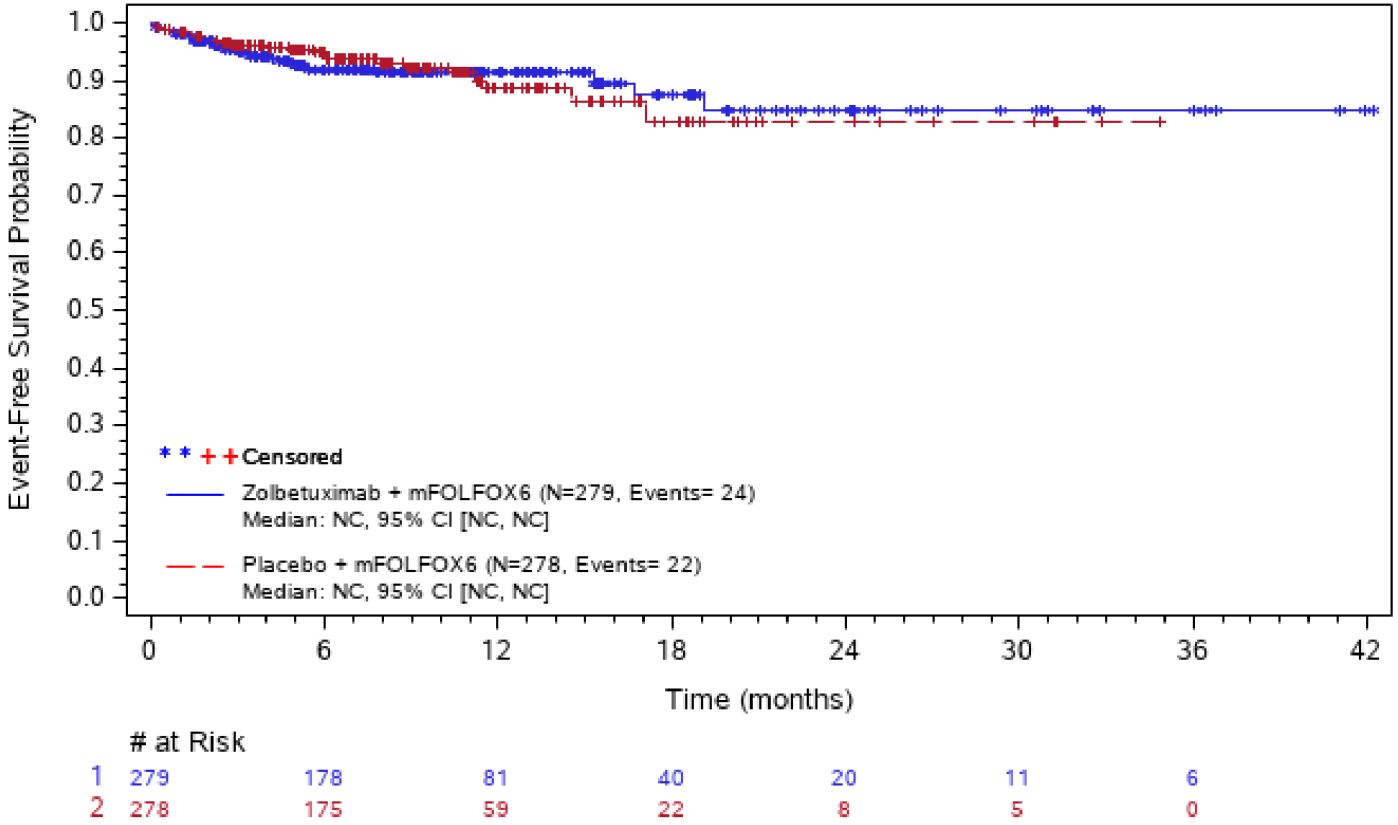
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.151: Kaplan-Meier Plot of Time to first TESAE - Vomiting (PT) - Safety Analysis Set



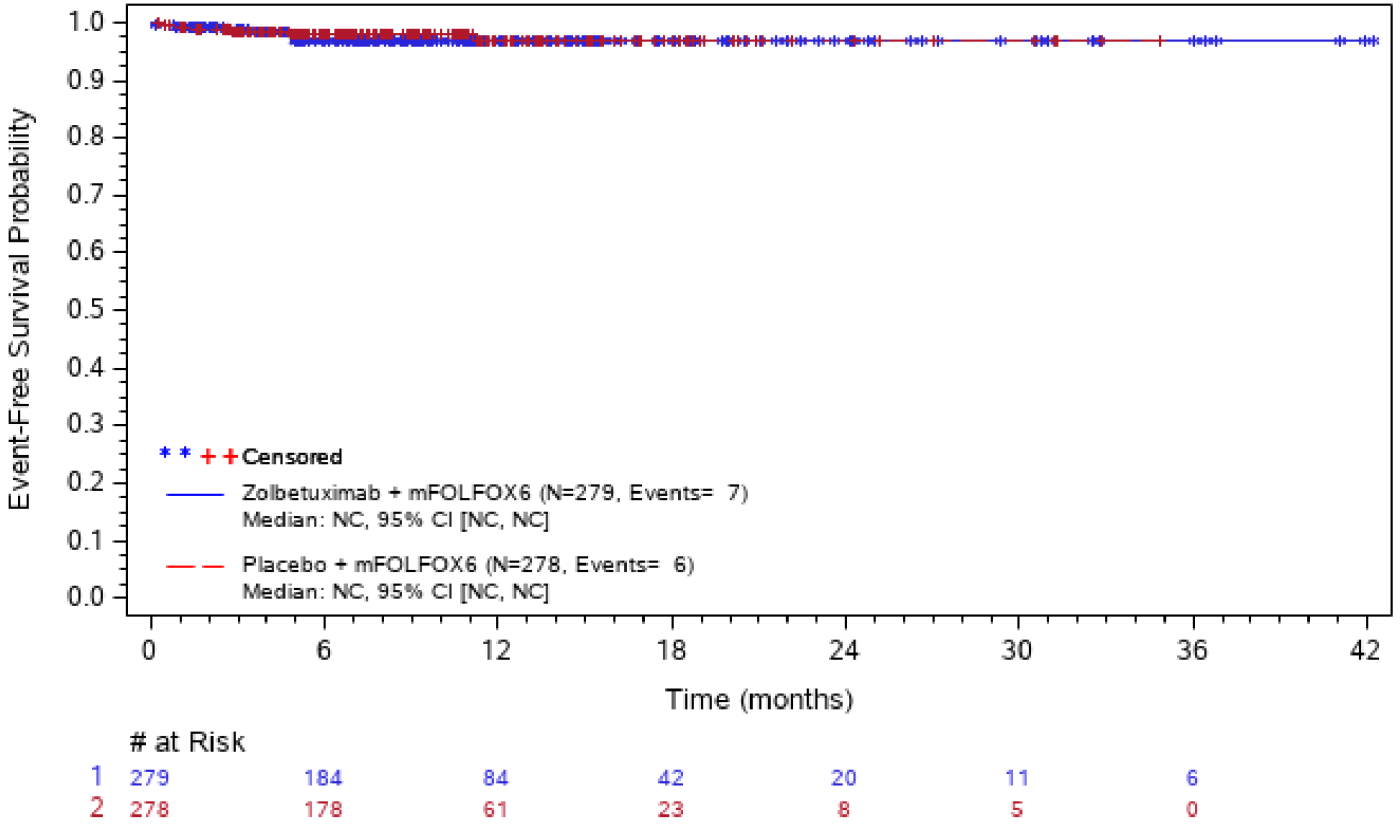
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.152: Kaplan-Meier Plot of Time to first TESAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



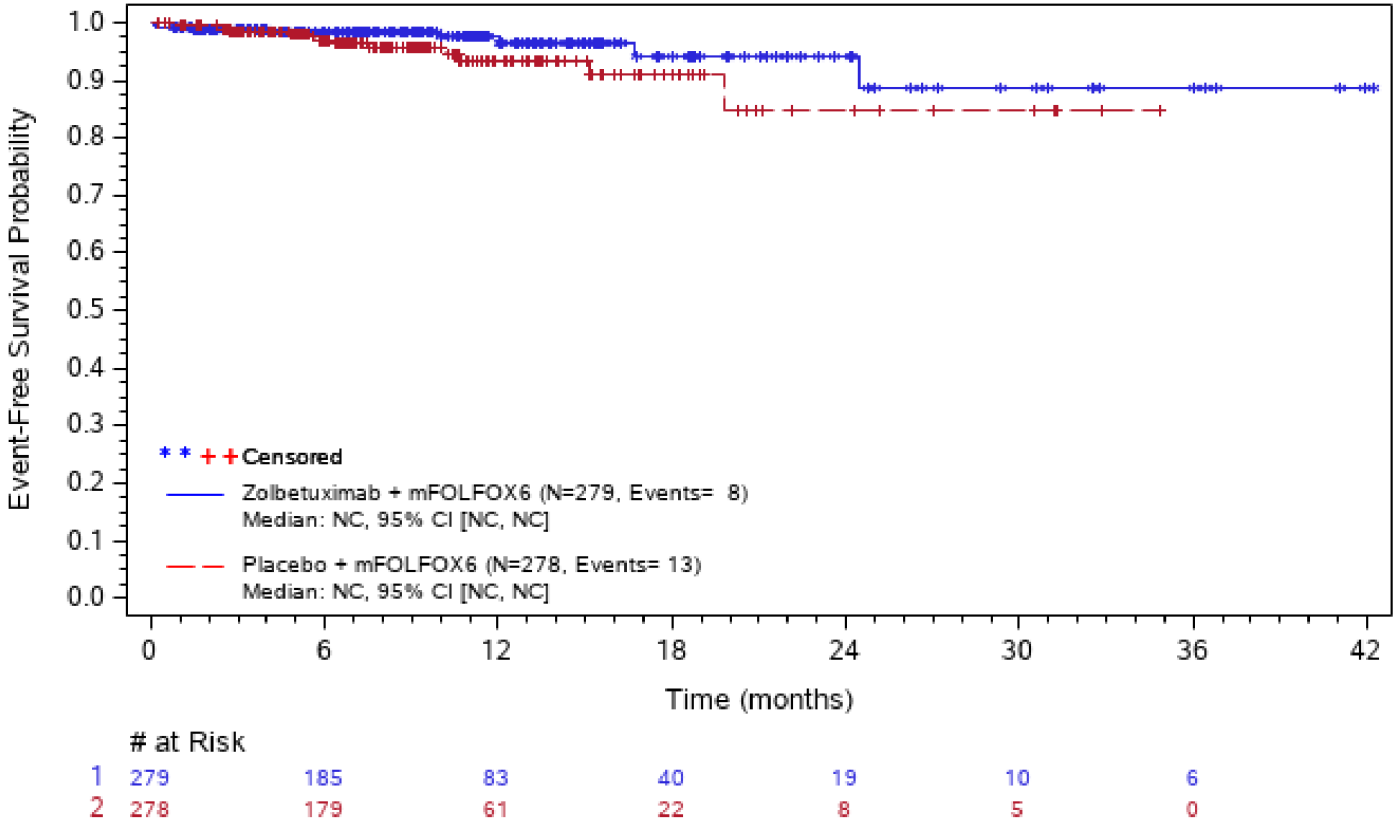
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.153: Kaplan-Meier Plot of Time to first TESAE - Pyrexia (PT) - Safety Analysis Set



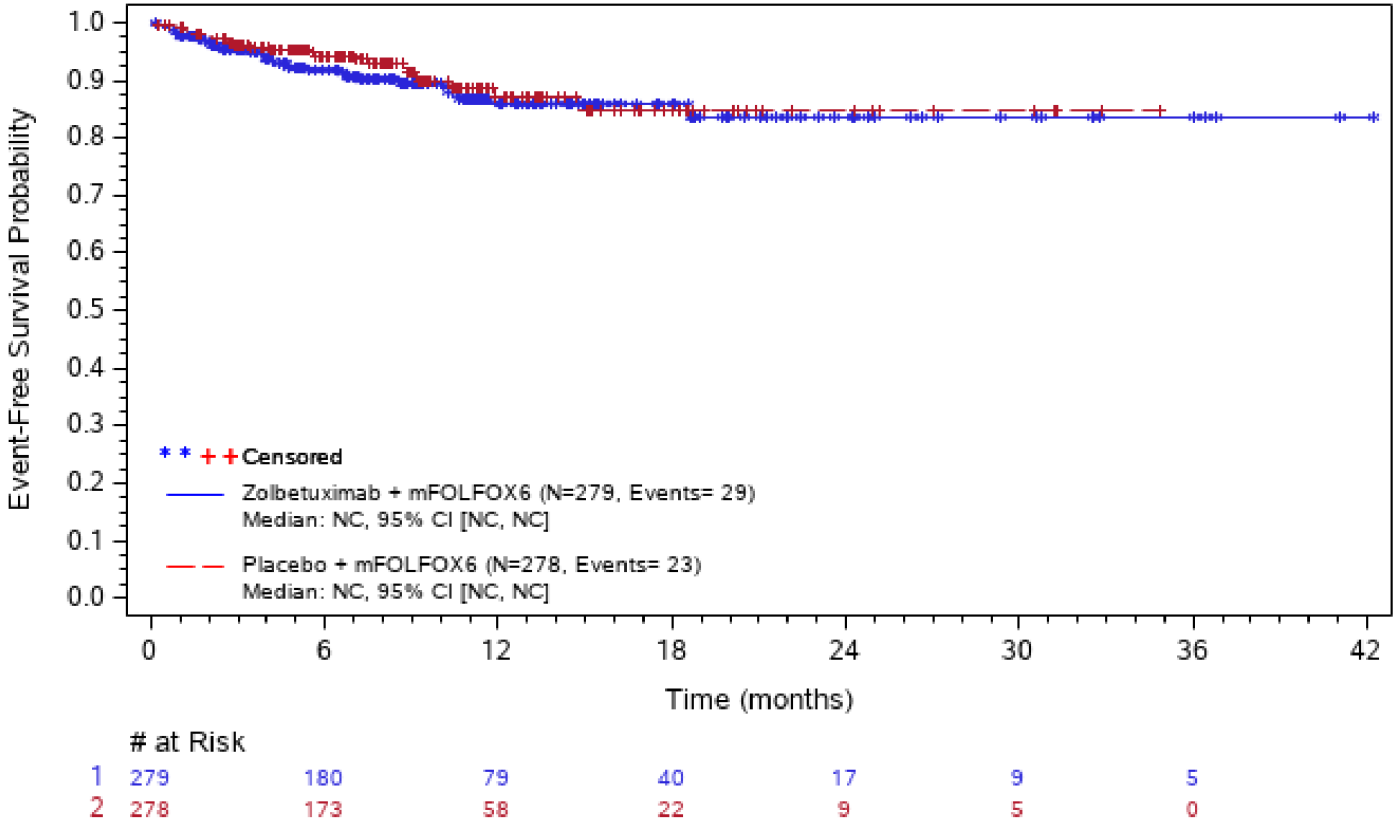
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.154: Kaplan-Meier Plot of Time to first TESAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



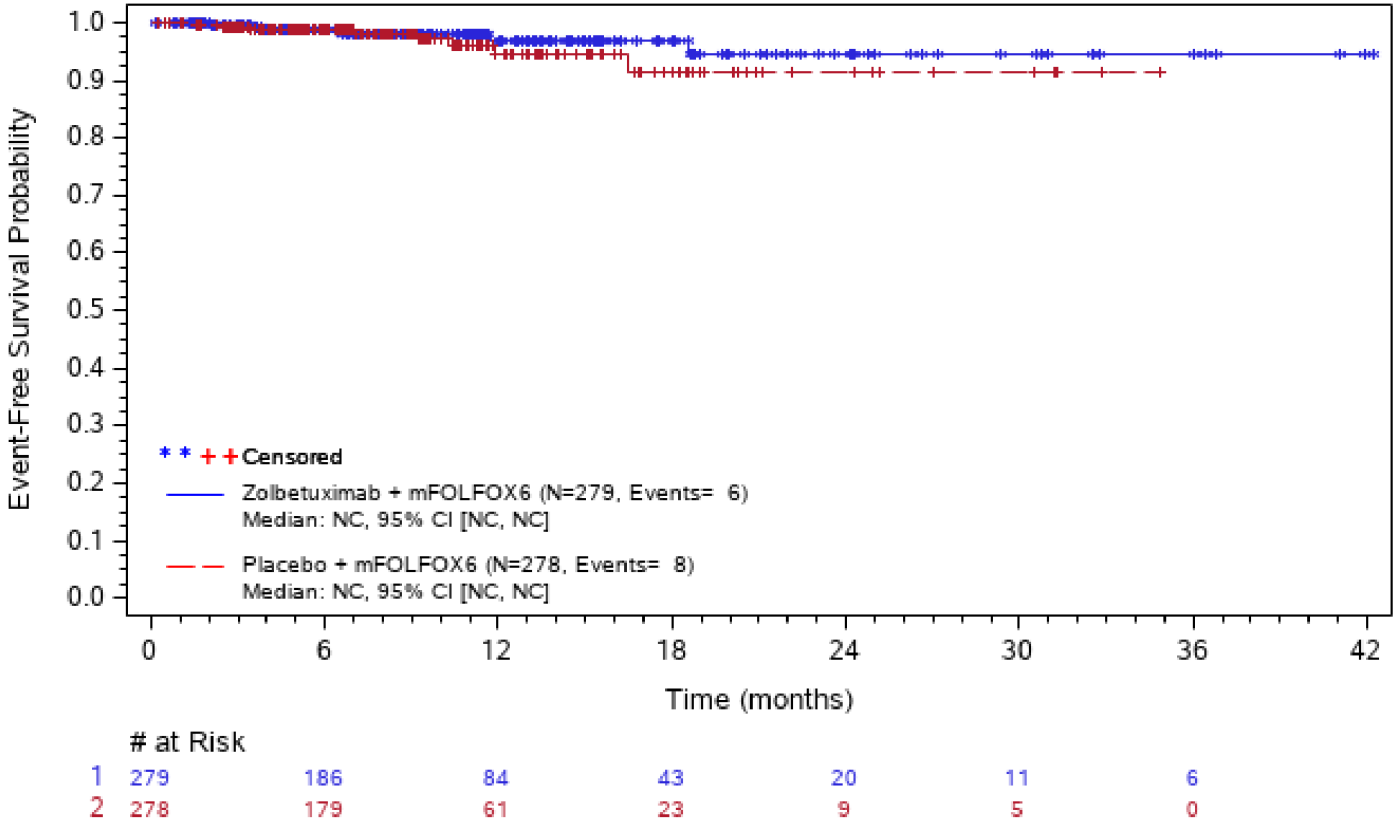
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.155: Kaplan-Meier Plot of Time to first TESAE - Infections And Infestations (SOC) - Safety Analysis Set



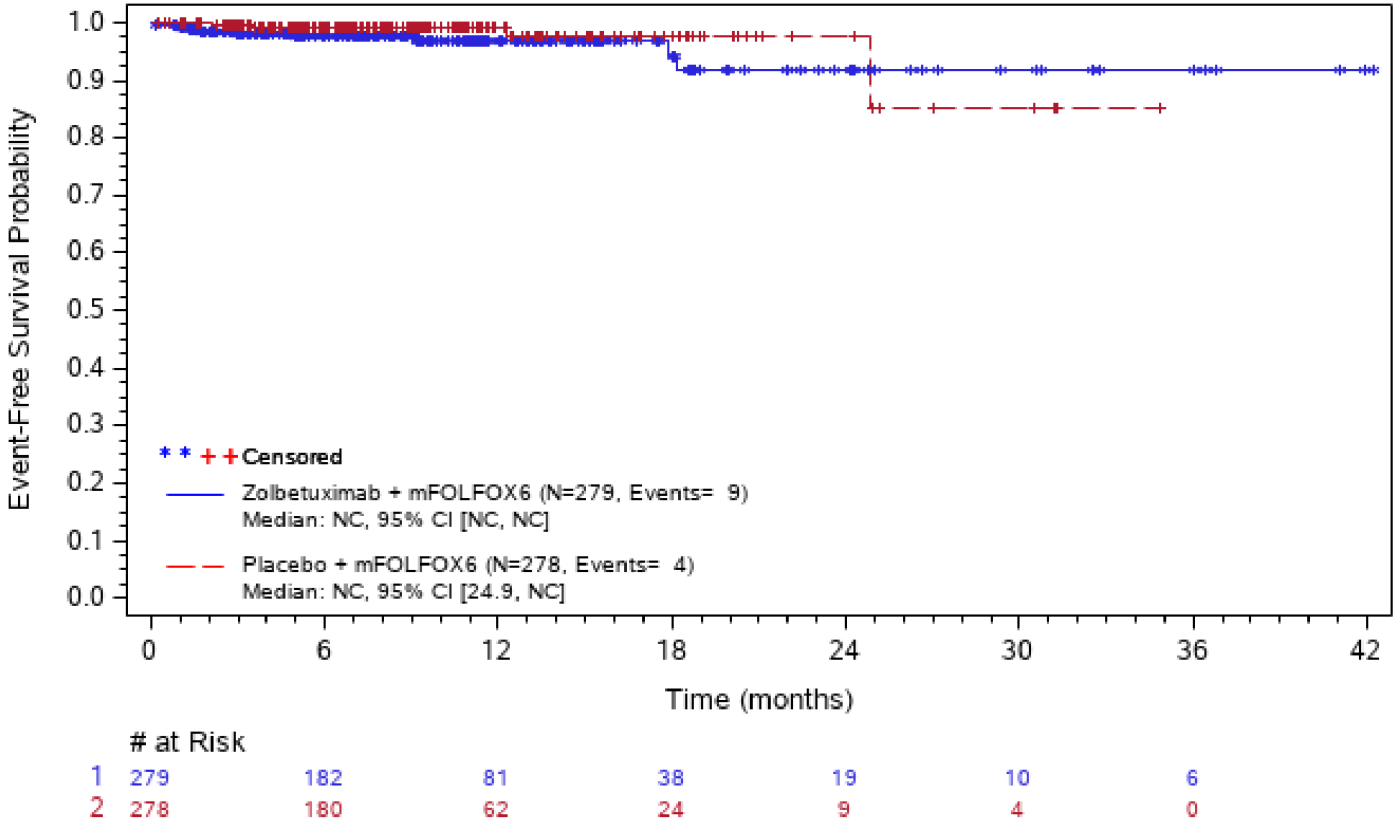
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.156: Kaplan-Meier Plot of Time to first TESAE - Pneumonia (PT) - Safety Analysis Set



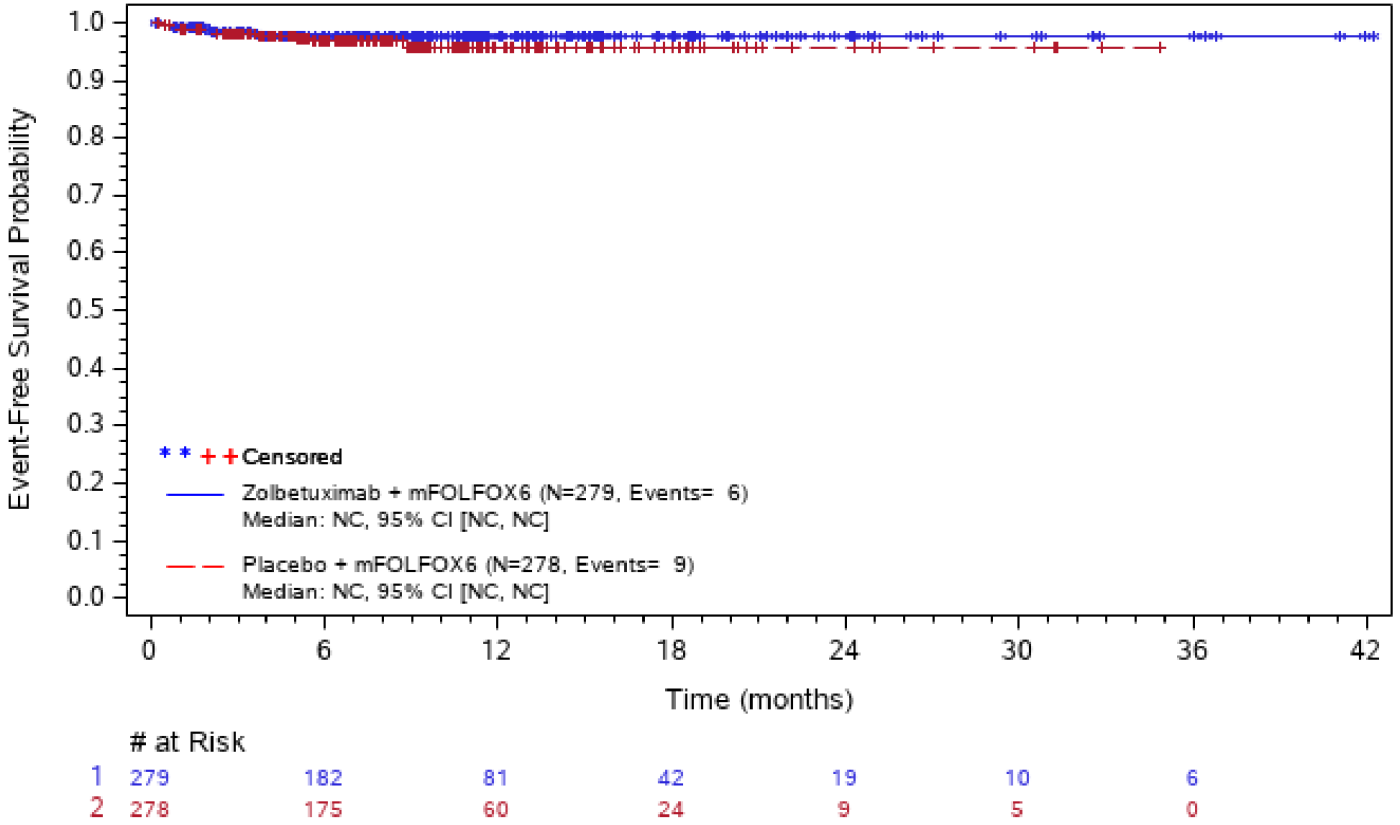
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.157: Kaplan-Meier Plot of Time to first TESAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set



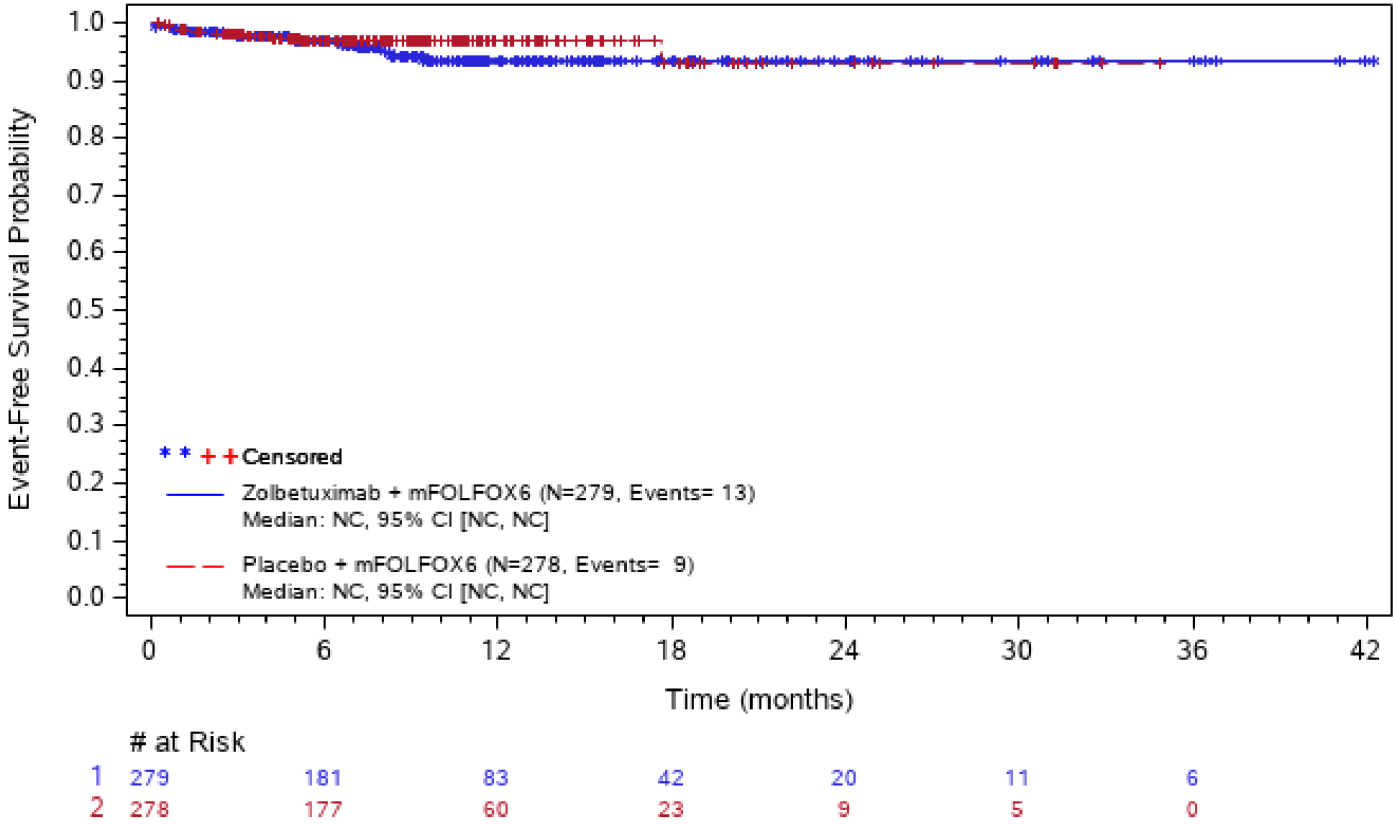
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.158: Kaplan-Meier Plot of Time to first TESAE - Investigations (SOC) - Safety Analysis Set



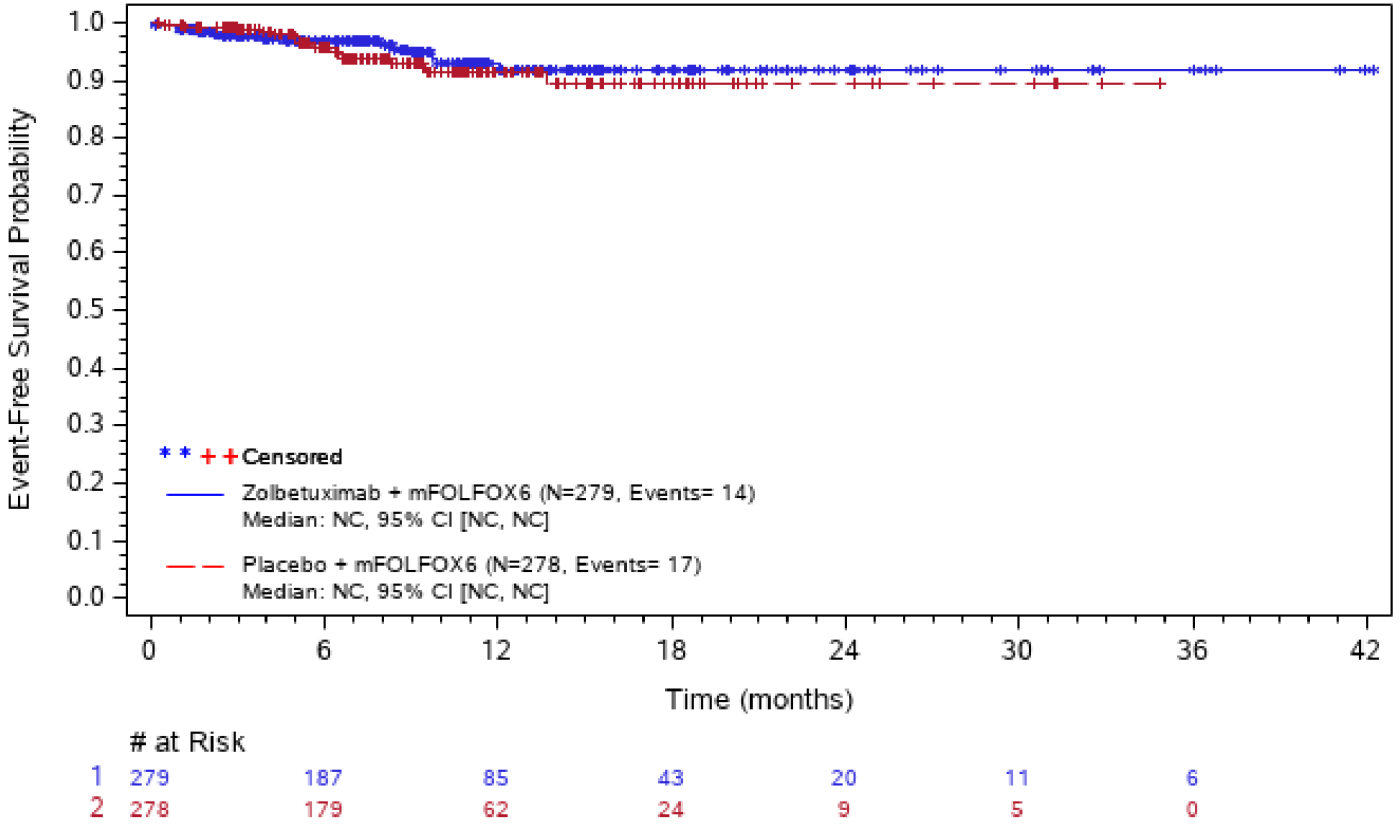
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.159: Kaplan-Meier Plot of Time to first TESAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



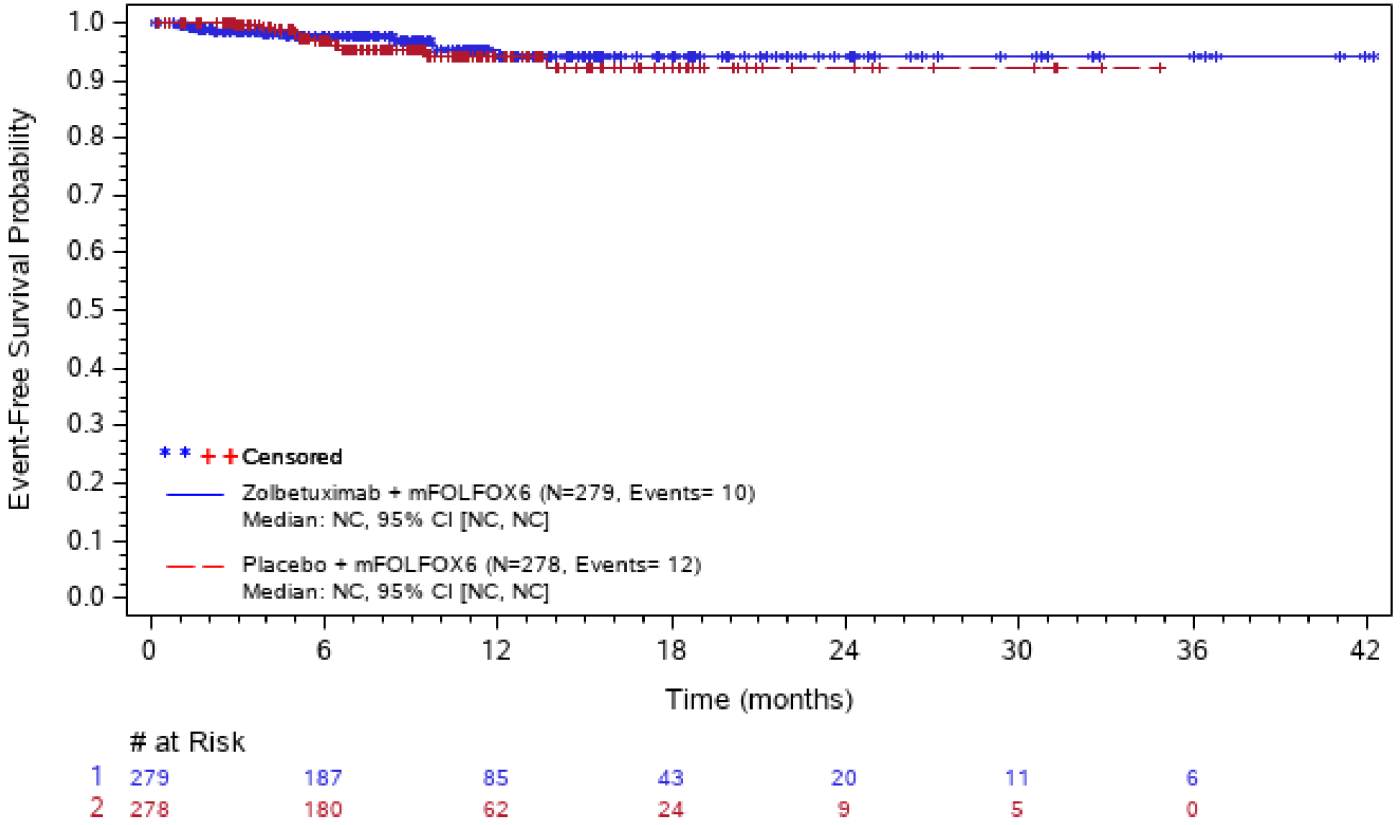
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.160: Kaplan-Meier Plot of Time to first TESAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set



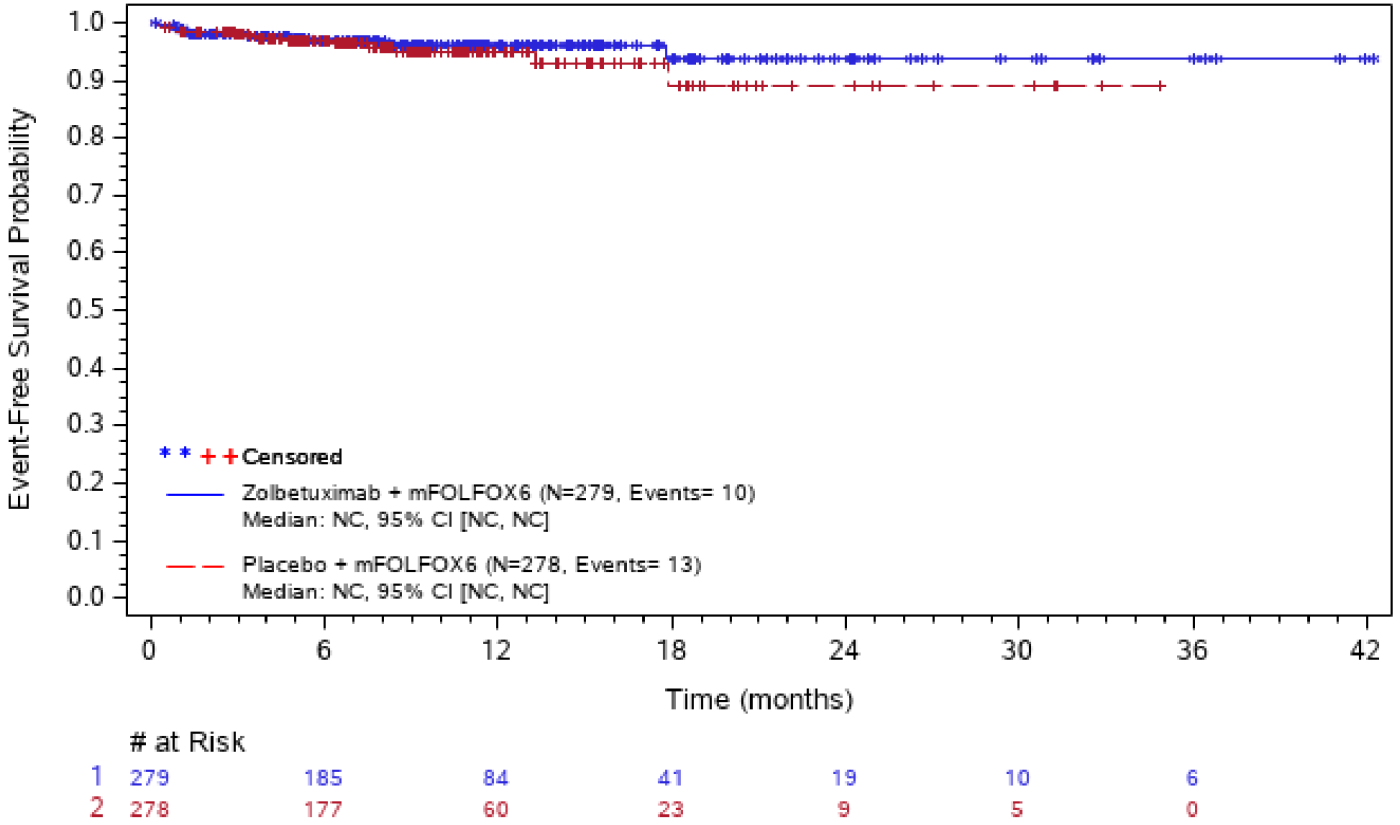
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.161: Kaplan-Meier Plot of Time to first TESAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set



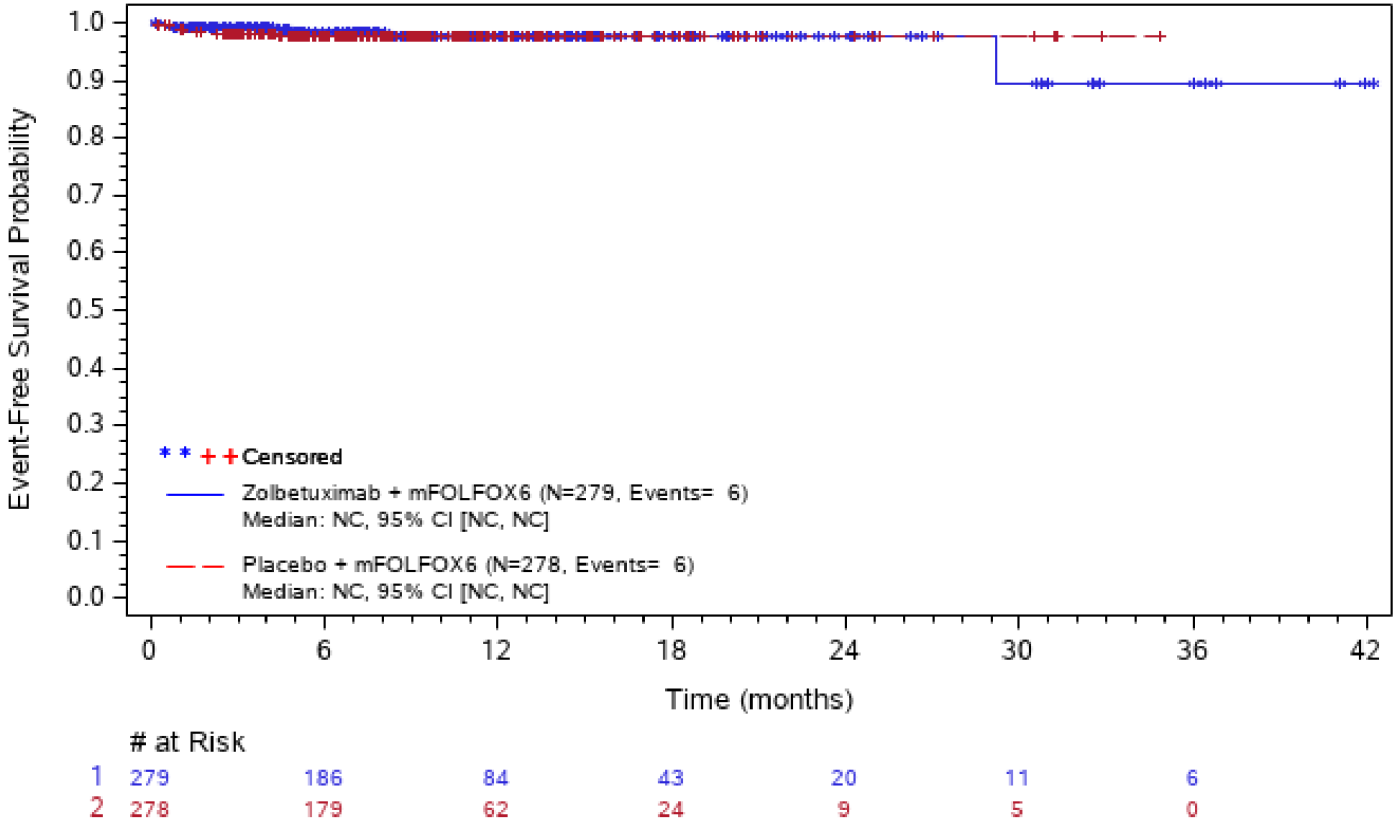
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.162: Kaplan-Meier Plot of Time to first TESAE - Nervous System Disorders (SOC) - Safety Analysis Set



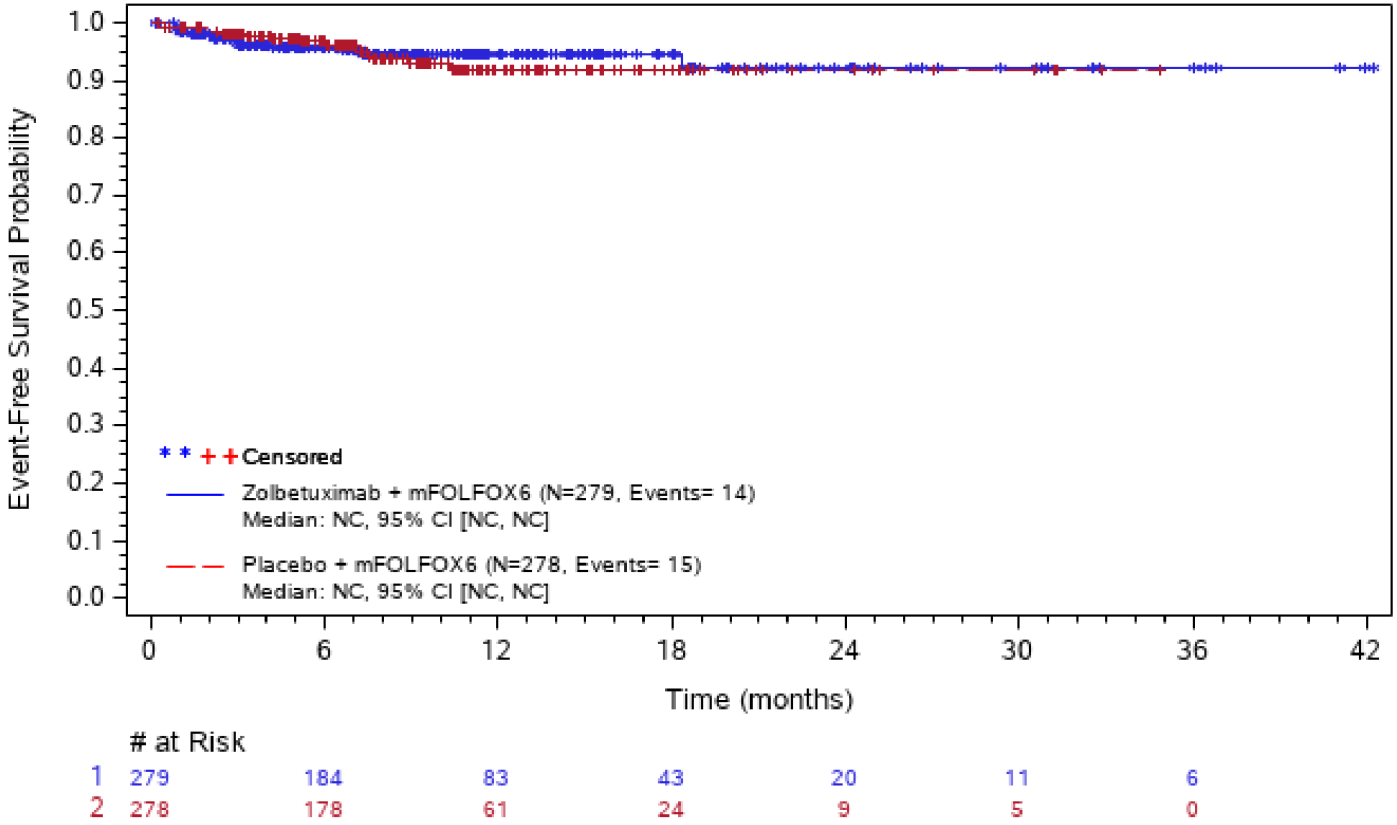
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.163: Kaplan-Meier Plot of Time to first TESAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set



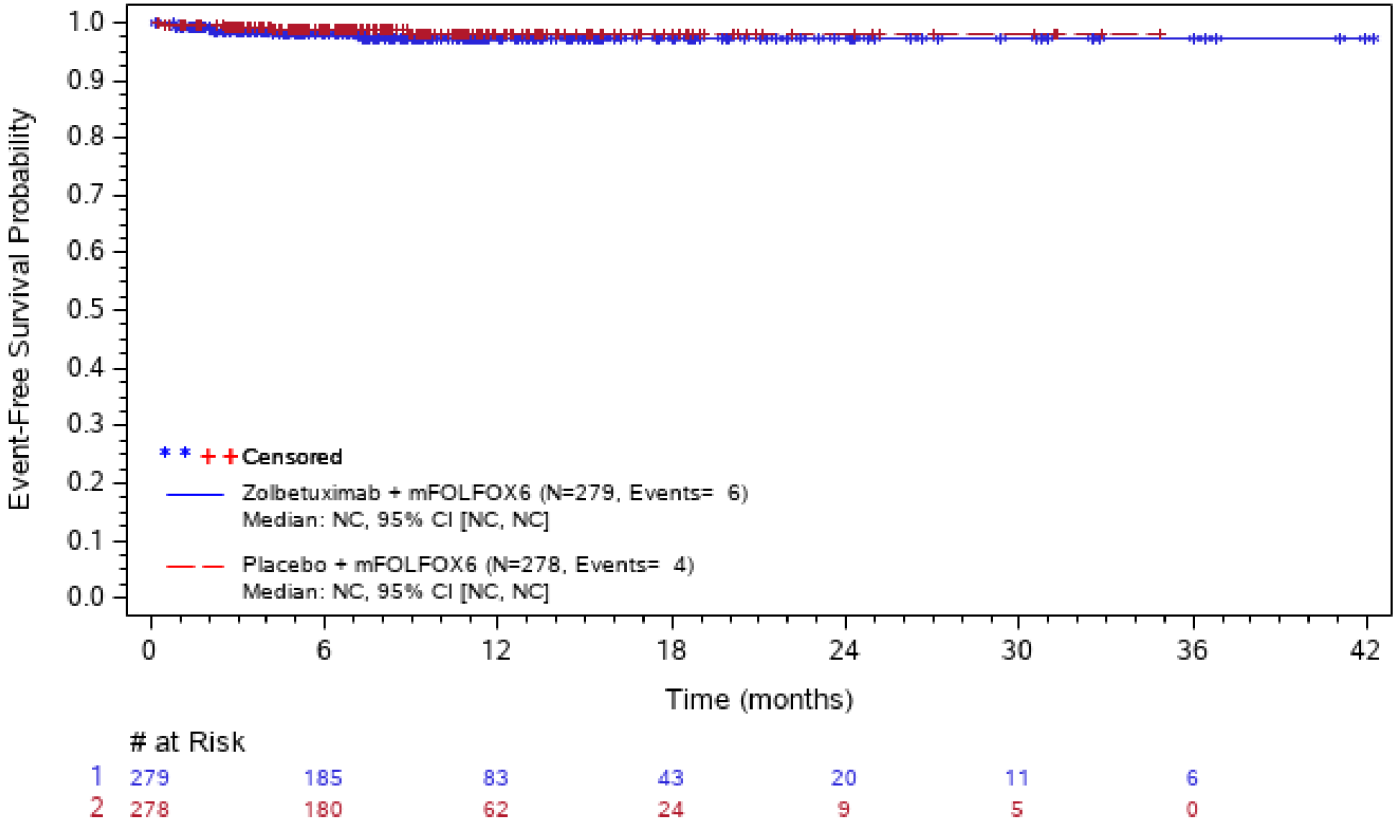
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.164: Kaplan-Meier Plot of Time to first TESAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set



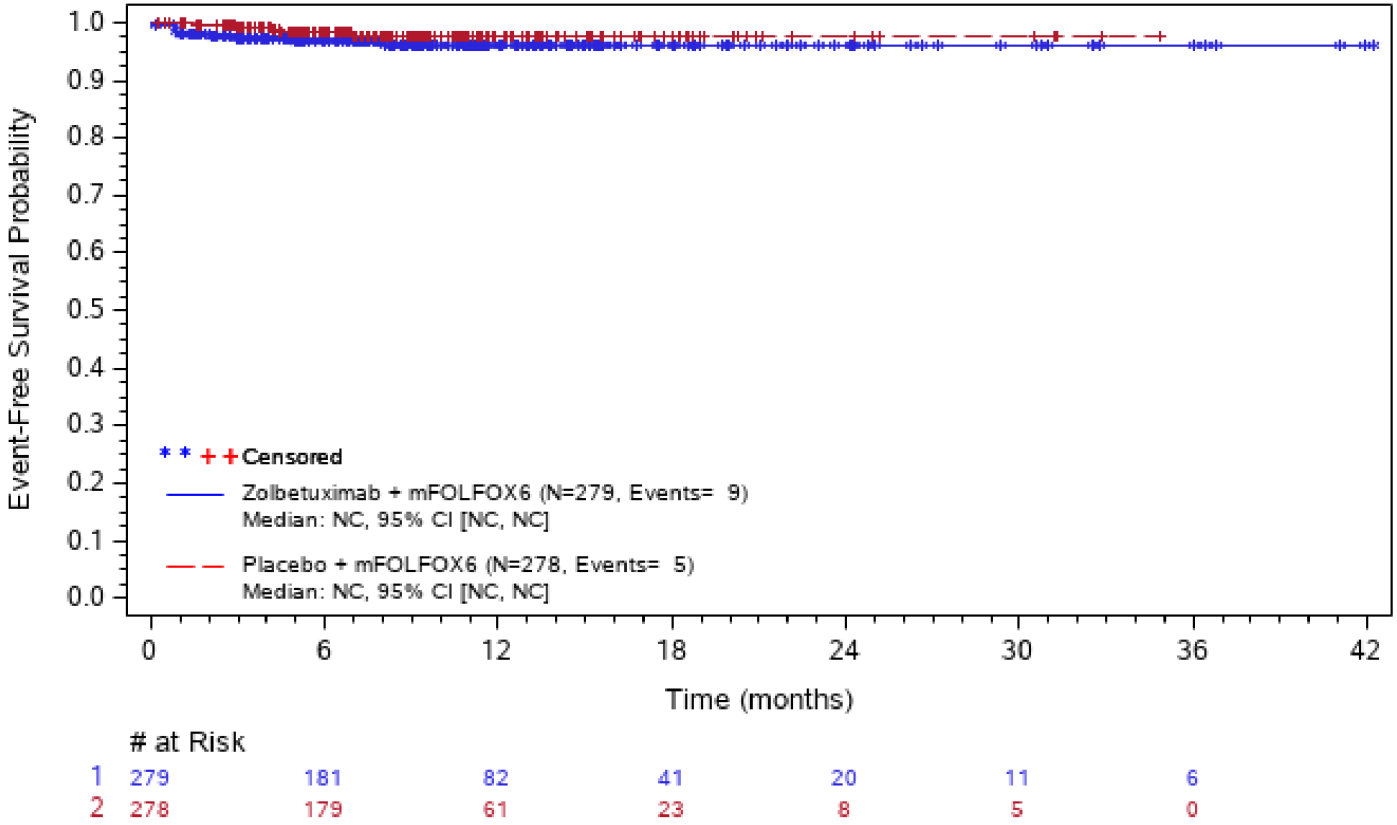
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.165: Kaplan-Meier Plot of Time to first TESAE - Pulmonary Embolism (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: 09SEP22

Figure 301.1.2001.166: Kaplan-Meier Plot of Time to first TESAE - 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruchgründe – SOC und PT

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Overall	120 (43.0%)	106 (38.1%)	226 (40.6%)
Nervous System Disorders	33 (11.8%)	35 (12.6%)	68 (12.2%)
Peripheral Sensory Neuropathy	19 (6.8%)	21 (7.6%)	40 (7.2%)
Neuropathy Peripheral	4 (1.4%)	4 (1.4%)	8 (1.4%)
Paraesthesia	3 (1.1%)	5 (1.8%)	8 (1.4%)
Neurotoxicity	2 (0.7%)	0	2 (0.4%)
Peripheral Motor Neuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyneuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebral Haemorrhage	0	1 (0.4%)	1 (0.2%)
Cerebral Ischaemia	1 (0.4%)	0	1 (0.2%)
Cerebrovascular Accident	0	1 (0.4%)	1 (0.2%)
Intracranial Pressure Increased	1 (0.4%)	0	1 (0.2%)
Seizure	0	1 (0.4%)	1 (0.2%)
Slow Speech	0	1 (0.4%)	1 (0.2%)
Wernicke's Encephalopathy	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorders	36 (12.9%)	12 (4.3%)	48 (8.6%)
Nausea	18 (6.5%)	3 (1.1%)	21 (3.8%)
Vomiting	20 (7.2%)	1 (0.4%)	21 (3.8%)
Abdominal Pain	2 (0.7%)	1 (0.4%)	3 (0.5%)
Dysphagia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Diarrhoea	2 (0.7%)	0	2 (0.4%)
Intestinal Obstruction	2 (0.7%)	0	2 (0.4%)
Stomatitis	2 (0.7%)	0	2 (0.4%)
Upper Gastrointestinal Haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ascites	0	1 (0.4%)	1 (0.2%)
Constipation	1 (0.4%)	0	1 (0.2%)

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: 09SEP22

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Enteritis	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Obstruction	0	1 (0.4%)	1 (0.2%)
Haematemesis	0	1 (0.4%)	1 (0.2%)
Lip Ulceration	0	1 (0.4%)	1 (0.2%)
Retching	1 (0.4%)	0	1 (0.2%)
Salivary Hypersecretion	1 (0.4%)	0	1 (0.2%)
Small Intestinal Obstruction	1 (0.4%)	0	1 (0.2%)
Investigations	26 (9.3%)	21 (7.6%)	47 (8.4%)
Neutrophil Count Decreased	18 (6.5%)	14 (5.0%)	32 (5.7%)
Platelet Count Decreased	1 (0.4%)	2 (0.7%)	3 (0.5%)
Alanine Aminotransferase Increased	0	2 (0.7%)	2 (0.4%)
Aspartate Aminotransferase Increased	0	2 (0.7%)	2 (0.4%)
Weight Decreased	2 (0.7%)	0	2 (0.4%)
White Blood Cell Count Decreased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Blood Bilirubin Increased	0	1 (0.4%)	1 (0.2%)
Blood Pressure Increased	1 (0.4%)	0	1 (0.2%)
Ejection Fraction Decreased	0	1 (0.4%)	1 (0.2%)
Gamma-Glutamyltransferase Increased	1 (0.4%)	0	1 (0.2%)
General Physical Condition Abnormal	1 (0.4%)	0	1 (0.2%)
Platelet Count Increased	1 (0.4%)	0	1 (0.2%)
Blood And Lymphatic System Disorders	18 (6.5%)	18 (6.5%)	36 (6.5%)
Neutropenia	14 (5.0%)	13 (4.7%)	27 (4.8%)
Anaemia	4 (1.4%)	3 (1.1%)	7 (1.3%)
Thrombocytopenia	1 (0.4%)	3 (1.1%)	4 (0.7%)
Disseminated Intravascular Coagulation	1 (0.4%)	0	1 (0.2%)
Eosinophilia	1 (0.4%)	0	1 (0.2%)

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: 09SEP22

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Febrile Neutropenia	0	1 (0.4%)	1 (0.2%)
Leukocytosis	1 (0.4%)	0	1 (0.2%)
Leukopenia	1 (0.4%)	0	1 (0.2%)
Lymphopenia	1 (0.4%)	0	1 (0.2%)
Neutrophilia	1 (0.4%)	0	1 (0.2%)
Thrombocytosis	1 (0.4%)	0	1 (0.2%)
General Disorders And Administration Site Conditions	14 (5.0%)	8 (2.9%)	22 (3.9%)
Fatigue	5 (1.8%)	3 (1.1%)	8 (1.4%)
Asthenia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Chest Discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Malaise	2 (0.7%)	0	2 (0.4%)
Performance Status Decreased	2 (0.7%)	0	2 (0.4%)
Pyrexia	2 (0.7%)	0	2 (0.4%)
Chills	1 (0.4%)	0	1 (0.2%)
Discomfort	0	1 (0.4%)	1 (0.2%)
Gait Disturbance	0	1 (0.4%)	1 (0.2%)
General Physical Health Deterioration	0	1 (0.4%)	1 (0.2%)
Oedema Peripheral	1 (0.4%)	0	1 (0.2%)
Metabolism And Nutrition Disorders	11 (3.9%)	6 (2.2%)	17 (3.1%)
Decreased Appetite	7 (2.5%)	3 (1.1%)	10 (1.8%)
Hypokalaemia	2 (0.7%)	0	2 (0.4%)
Hyponatraemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abnormal Loss Of Weight	0	1 (0.4%)	1 (0.2%)
Adult Failure To Thrive	1 (0.4%)	0	1 (0.2%)
Hyperchloraemia	1 (0.4%)	0	1 (0.2%)
Hyperkalaemia	1 (0.4%)	0	1 (0.2%)

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: 09SEP22

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Hypoalbuminaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	0	1 (0.4%)	1 (0.2%)
Hypoproteinaemia	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	8 (2.9%)	4 (1.4%)	12 (2.2%)
Pneumonia	4 (1.4%)	0	4 (0.7%)
Covid-19 Pneumonia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abscess Soft Tissue	0	1 (0.4%)	1 (0.2%)
Covid-19	0	1 (0.4%)	1 (0.2%)
Device Related Infection	0	1 (0.4%)	1 (0.2%)
Neutropenic Sepsis	1 (0.4%)	0	1 (0.2%)
Oral Candidiasis	1 (0.4%)	0	1 (0.2%)
Pulmonary Sepsis	1 (0.4%)	0	1 (0.2%)
Sepsis	1 (0.4%)	0	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	5 (1.8%)	7 (2.5%)	12 (2.2%)
Malignant Neoplasm Progression	4 (1.4%)	4 (1.4%)	8 (1.4%)
Metastases To Meninges	1 (0.4%)	1 (0.4%)	2 (0.4%)
Malignant Pleural Effusion	0	1 (0.4%)	1 (0.2%)
Tumour Haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	4 (1.4%)	6 (2.2%)	10 (1.8%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.7%)	1 (0.4%)	3 (0.5%)
Erythema	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rash	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dermatitis Exfoliative Generalised	0	1 (0.4%)	1 (0.2%)
Pruritus	0	1 (0.4%)	1 (0.2%)
Urticaria	0	1 (0.4%)	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	3 (1.1%)	5 (1.8%)	8 (1.4%)

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: 09SEP22

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Dyspnoea	0	3 (1.1%)	3 (0.5%)
Interstitial Lung Disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Respiratory Distress Syndrome	0	1 (0.4%)	1 (0.2%)
Acute Respiratory Failure	1 (0.4%)	0	1 (0.2%)
Cough	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	2 (0.7%)	3 (1.1%)	5 (0.9%)
Acute Myocardial Infarction	2 (0.7%)	1 (0.4%)	3 (0.5%)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Cardiac Failure	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	2 (0.7%)	3 (1.1%)	5 (0.9%)
Drug Hypersensitivity	1 (0.4%)	2 (0.7%)	3 (0.5%)
Hypersensitivity	1 (0.4%)	1 (0.4%)	2 (0.4%)
Injury, Poisoning And Procedural Complications	3 (1.1%)	2 (0.7%)	5 (0.9%)
Infusion Related Reaction	2 (0.7%)	2 (0.7%)	4 (0.7%)
Fall	1 (0.4%)	0	1 (0.2%)
Vascular Disorders	3 (1.1%)	2 (0.7%)	5 (0.9%)
Flushing	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypertension	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Hepatobiliary Disorders	1 (0.4%)	3 (1.1%)	4 (0.7%)
Bile Duct Stenosis	0	1 (0.4%)	1 (0.2%)
Hepatic Cytolysis	1 (0.4%)	0	1 (0.2%)
Hepatic Function Abnormal	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	0	1 (0.4%)	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	3 (1.1%)	0	3 (0.5%)
Arthralgia	1 (0.4%)	0	1 (0.2%)

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: 09SEP22

Table 301.1.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Musculoskeletal Chest Pain	1 (0.4%)	0	1 (0.2%)
Pain In Extremity	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	2 (0.7%)	0	2 (0.4%)
Renal Failure	1 (0.4%)	0	1 (0.2%)
Urge Incontinence	1 (0.4%)	0	1 (0.2%)
Congenital, Familial And Genetic Disorders	0	1 (0.4%)	1 (0.2%)
Dihydropyrimidine Dehydrogenase Deficiency	0	1 (0.4%)	1 (0.2%)
Psychiatric Disorders	0	1 (0.4%)	1 (0.2%)
Suicidal Ideation	0	1 (0.4%)	1 (0.2%)

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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Sicherheit

Anhang 4-G4 Unerwünschte Ereignisse von besonderem Interesse

1. Time-to-Event-Analysen

Table 301.1.2001.205.1: Summary and Results of TEAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	95 (34.1%)	104 (37.4%)	
Number of patients censored	184 (65.9%)	174 (62.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	14.5 [10.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.976 [0.738, 1.291]
Log-rank test			
Two-sided stratified log-rank p-value			0.8326

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.205.2: Summary and Results of TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	67 (37.6)	NC [10.8, NC]	177	68 (38.4)	14.0 [8.3, NC]	1.057 [0.754, 1.481]	0.7805	0.3453
>65 years	101	28 (27.7)	NC [NC, NC]	101	36 (35.6)	19.8 [7.0, NC]	0.810 [0.494, 1.328]	0.3954	
Sex									
Male	174	56 (32.2)	NC [13.2, NC]	173	64 (37.0)	17.4 [10.7, NC]	0.902 [0.630, 1.292]	0.5578	0.5906
Female	105	39 (37.1)	NC [8.0, NC]	105	40 (38.1)	13.6 [7.4, NC]	1.071 [0.689, 1.665]	0.7954	
Region									
Asia	87	27 (31.0)	NC [13.1, NC]	88	28 (31.8)	14.5 [7.5, NC]	0.890 [0.522, 1.518]	0.6605	0.7864
Non-Asia	192	68 (35.4)	NC [NC, NC]	190	76 (40.0)	14.0 [8.3, NC]	0.997 [0.718, 1.382]	0.9508	
Number of Organs with Metastatic Sites									
0-2	216	75 (34.7)	NC [13.2, NC]	216	80 (37.0)	14.5 [10.7, NC]	1.014 [0.740, 1.391]	0.9619	0.4838
>=3	63	20 (31.7)	NC [8.3, NC]	62	24 (38.7)	10.9 [6.5, NC]	0.806 [0.445, 1.463]	0.4678	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.206.1: Summary and Results of TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	102 (36.6%)	104 (37.4%)	
Number of patients censored	177 (63.4%)	174 (62.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [13.1, NC]	18.1 [12.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.963 [0.732, 1.268]
Log-rank test			
Two-sided stratified log-rank p-value			0.7989

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.206.2: Summary and Results of TEAEs by Subgroups - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	65 (36.5)	NC [9.3, NC]	177	70 (39.5)	14.6 [8.5, NC]	0.866 [0.617, 1.214]	0.4061	0.4248
>65 years	101	37 (36.6)	NC [12.6, NC]	101	34 (33.7)	NC [12.5, NC]	1.086 [0.681, 1.730]	0.7275	
Sex									
Male	174	53 (30.5)	NC [14.9, NC]	173	59 (34.1)	NC [12.5, NC]	0.834 [0.575, 1.209]	0.3373	0.3443
Female	105	49 (46.7)	9.3 [3.9, NC]	105	45 (42.9)	10.3 [5.3, NC]	1.089 [0.726, 1.633]	0.6707	
Region									
Asia	87	34 (39.1)	NC [9.2, NC]	88	29 (33.0)	NC [8.5, NC]	1.043 [0.635, 1.714]	0.8659	0.6218
Non-Asia	192	68 (35.4)	NC [12.6, NC]	190	75 (39.5)	18.1 [10.3, NC]	0.893 [0.643, 1.240]	0.5036	
Number of Organs with Metastatic Sites									
0-2	216	72 (33.3)	NC [13.3, NC]	216	77 (35.6)	NC [14.6, NC]	0.870 [0.631, 1.200]	0.4030	0.3110
>=3	63	30 (47.6)	8.3 [3.4, NC]	62	27 (43.5)	12.5 [6.2, NC]	1.207 [0.717, 2.033]	0.4794	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.207.1: Summary and Results of TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	60 (21.5%)	69 (24.8%)	
Number of patients censored	219 (78.5%)	209 (75.2%)	
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			0.781 [0.551, 1.108]
Log-rank test			
Two-sided stratified log-rank p-value			0.1650

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.207.2: Summary and Results of TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	37 (20.8)	NC [NC, NC]	177	44 (24.9)	NC [NC, NC]	0.780 [0.503, 1.209]	0.2654	0.8625
>65 years	101	23 (22.8)	NC [17.5, NC]	101	25 (24.8)	NC [17.6, NC]	0.821 [0.465, 1.450]	0.5008	
Sex									
Male	174	33 (19.0)	NC [NC, NC]	173	46 (26.6)	NC [NC, NC]	0.623 [0.397, 0.976]	0.0374	0.0944
Female	105	27 (25.7)	NC [16.6, NC]	105	23 (21.9)	NC [17.6, NC]	1.178 [0.675, 2.057]	0.5625	
Region									
Asia	87	27 (31.0)	NC [14.3, NC]	88	29 (33.0)	NC [17.6, NC]	0.732 [0.431, 1.243]	0.2483	0.8752
Non-Asia	192	33 (17.2)	NC [NC, NC]	190	40 (21.1)	NC [NC, NC]	0.806 [0.508, 1.279]	0.3586	
Number of Organs with Metastatic Sites									
0-2	216	42 (19.4)	NC [NC, NC]	216	55 (25.5)	NC [NC, NC]	0.679 [0.454, 1.017]	0.0592	0.1193
>=3	63	18 (28.6)	16.6 [11.2, NC]	62	14 (22.6)	NC [10.7, NC]	1.280 [0.635, 2.579]	0.4918	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.208.1: Summary and Results of TEAEs - Infusion Related Reaction (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	124 (44.4%)	33 (11.9%)	
Number of patients censored	155 (55.6%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [5.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.962 [3.373, 7.299]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.208.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	71 (39.9)	NC [18.4, NC]	177	26 (14.7)	NC [NC, NC]	3.352 [2.137, 5.259]	<.0001	0.0168
>65 years	101	53 (52.5)	4.7 [1.6, NC]	101	7 (6.9)	NC [NC, NC]	10.451 [4.744, 23.027]	<.0001	
Sex									
Male	174	75 (43.1)	NC [4.9, NC]	173	21 (12.1)	NC [NC, NC]	4.538 [2.794, 7.370]	<.0001	0.6868
Female	105	49 (46.7)	13.5 [2.1, NC]	105	12 (11.4)	NC [NC, NC]	5.294 [2.812, 9.965]	<.0001	
Region									
Asia	87	30 (34.5)	NC [NC, NC]	88	14 (15.9)	NC [NC, NC]	2.527 [1.339, 4.768]	0.0036	0.0158
Non-Asia	192	94 (49.0)	6.4 [2.3, NC]	190	19 (10.0)	NC [NC, NC]	6.716 [4.096, 11.011]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	92 (42.6)	NC [5.6, NC]	216	29 (13.4)	NC [NC, NC]	3.974 [2.616, 6.037]	<.0001	0.0800
>=3	63	32 (50.8)	5.5 [1.4, NC]	62	4 (6.5)	NC [NC, NC]	11.231 [3.961, 31.843]	<.0001	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.209.1: Summary and Results of TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	230 (82.4%)	169 (60.8%)	
Number of patients censored	49 (17.6%)	109 (39.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	2.0 [0.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.177 [1.777, 2.668]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.209.2: Summary and Results of TEAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	146 (82.0)	0.0 [0.0, 0.1]	177	117 (66.1)	1.0 [0.6, 2.2]	1.954 [1.530, 2.497]	<.0001	0.1070
>65 years	101	84 (83.2)	0.1 [0.0, 0.4]	101	52 (51.5)	3.5 [1.5, NC]	2.764 [1.949, 3.921]	<.0001	
Sex									
Male	174	137 (78.7)	0.1 [0.0, 0.4]	173	106 (61.3)	2.0 [0.8, 3.3]	1.890 [1.464, 2.439]	<.0001	0.0975
Female	105	93 (88.6)	0.0 [0.0, 0.1]	105	63 (60.0)	2.1 [0.7, 5.0]	2.914 [2.105, 4.034]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.1]	88	60 (68.2)	1.1 [0.5, 2.4]	2.029 [1.442, 2.857]	<.0001	0.4532
Non-Asia	192	155 (80.7)	0.0 [0.0, 0.1]	190	109 (57.4)	2.4 [0.9, 4.8]	2.301 [1.797, 2.946]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	182 (84.3)	0.0 [0.0, 0.1]	216	132 (61.1)	1.6 [0.9, 3.3]	2.321 [1.851, 2.910]	<.0001	0.4221
>=3	63	48 (76.2)	0.1 [0.0, 0.7]	62	37 (59.7)	2.2 [0.5, NC]	1.841 [1.197, 2.833]	0.0106	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.210.1: Summary and Results of TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	187 (67.0%)	179 (64.4%)	
Number of patients censored	92 (33.0%)	99 (35.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.0 [1.6, 2.2]	2.3 [1.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.106 [0.900, 1.359]
Log-rank test			
Two-sided stratified log-rank p-value			0.3167

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.210.2: Summary and Results of TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	120 (67.4)	2.1 [1.6, 2.2]	177	113 (63.8)	2.3 [1.5, 3.4]	1.149 [0.888, 1.486]	0.2763	0.8113
>65 years	101	67 (66.3)	1.8 [1.1, 3.5]	101	66 (65.3)	2.1 [1.4, 3.3]	1.080 [0.769, 1.518]	0.6300	
Sex									
Male	174	107 (61.5)	2.1 [2.0, 3.5]	173	101 (58.4)	3.1 [2.1, 5.1]	1.162 [0.885, 1.526]	0.2631	0.6727
Female	105	80 (76.2)	1.4 [0.8, 2.0]	105	78 (74.3)	1.2 [0.7, 2.1]	1.062 [0.777, 1.451]	0.6768	
Region									
Asia	87	68 (78.2)	1.3 [0.7, 2.0]	88	59 (67.0)	1.9 [0.7, 2.5]	1.237 [0.873, 1.754]	0.2073	0.4967
Non-Asia	192	119 (62.0)	2.1 [1.9, 2.3]	190	120 (63.2)	2.6 [2.0, 3.5]	1.073 [0.832, 1.383]	0.5729	
Number of Organs with Metastatic Sites									
0-2	216	143 (66.2)	2.0 [1.7, 2.3]	216	147 (68.1)	2.1 [1.4, 2.6]	0.990 [0.787, 1.247]	0.9615	0.0251
>=3	63	44 (69.8)	1.4 [0.7, 2.6]	62	32 (51.6)	4.0 [1.9, NC]	1.748 [1.107, 2.762]	0.0136	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.211.1: Summary and Results of TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	188 (67.4%)	101 (36.3%)	
Number of patients censored	91 (32.6%)	177 (63.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.7 [0.3, 1.4]	NC [16.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.905 [2.271, 3.716]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.211.2: Summary and Results of TEAEs by Subgroups - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	127 (71.3)	0.5 [0.0, 0.9]	177	74 (41.8)	16.6 [7.9, NC]	2.639 [1.978, 3.521]	<.0001	0.4309
>65 years	101	61 (60.4)	1.6 [0.7, 5.9]	101	27 (26.7)	NC [NC, NC]	3.191 [2.025, 5.027]	<.0001	
Sex									
Male	174	111 (63.8)	0.9 [0.5, 2.9]	173	56 (32.4)	NC [16.6, NC]	2.889 [2.092, 3.990]	<.0001	0.6690
Female	105	77 (73.3)	0.2 [0.0, 1.1]	105	45 (42.9)	NC [4.8, NC]	2.672 [1.846, 3.865]	<.0001	
Region									
Asia	87	54 (62.1)	1.2 [0.1, 12.2]	88	28 (31.8)	16.6 [12.0, NC]	2.530 [1.596, 4.011]	<.0001	0.7839
Non-Asia	192	134 (69.8)	0.5 [0.1, 1.2]	190	73 (38.4)	NC [NC, NC]	2.887 [2.167, 3.846]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	148 (68.5)	0.7 [0.1, 1.1]	216	76 (35.2)	NC [16.0, NC]	2.981 [2.258, 3.937]	<.0001	0.2695
>=3	63	40 (63.5)	1.4 [0.2, 5.1]	62	25 (40.3)	NC [3.1, NC]	2.153 [1.304, 3.553]	0.0032	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.212.1: Summary and Results of Non-Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	92 (33.0%)	104 (37.4%)	
Number of patients censored	187 (67.0%)	174 (62.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	14.5 [10.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.931 [0.702, 1.235]
Log-rank test			
Two-sided stratified log-rank p-value			0.6015

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.212.2: Summary and Results of Non-Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	65 (36.5)	NC [13.1, NC]	177	68 (38.4)	14.0 [8.3, NC]	1.012 [0.720, 1.422]	0.9705	0.3463
>65 years	101	27 (26.7)	NC [NC, NC]	101	36 (35.6)	19.8 [7.0, NC]	0.773 [0.469, 1.275]	0.3074	
Sex									
Male	174	53 (30.5)	NC [NC, NC]	173	64 (37.0)	17.4 [10.7, NC]	0.840 [0.583, 1.209]	0.3392	0.4489
Female	105	39 (37.1)	NC [8.0, NC]	105	40 (38.1)	13.6 [7.4, NC]	1.063 [0.684, 1.653]	0.8097	
Region									
Asia	87	27 (31.0)	NC [13.1, NC]	88	28 (31.8)	14.5 [7.5, NC]	0.892 [0.523, 1.521]	0.6653	0.9407
Non-Asia	192	65 (33.9)	NC [NC, NC]	190	76 (40.0)	14.0 [8.3, NC]	0.935 [0.671, 1.302]	0.6701	
Number of Organs with Metastatic Sites									
0-2	216	72 (33.3)	NC [NC, NC]	216	80 (37.0)	14.5 [10.7, NC]	0.959 [0.697, 1.319]	0.7745	0.5904
>=3	63	20 (31.7)	NC [8.3, NC]	62	24 (38.7)	10.9 [6.5, NC]	0.806 [0.445, 1.463]	0.4678	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.213.1: Summary and Results of Non-Severe TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	96 (34.4%)	98 (35.3%)	
Number of patients censored	183 (65.6%)	180 (64.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [13.3, NC]	NC [14.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.960 [0.723, 1.275]
Log-rank test			
Two-sided stratified log-rank p-value			0.7876

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.213.2: Summary and Results of Non-Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

Subgroup	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
	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	178	60 (33.7)	NC [14.9, NC]	177	66 (37.3)	NC [10.3, NC]	0.852 [0.600, 1.209]	0.3723	0.3493
>65 years	101	36 (35.6)	NC [12.6, NC]	101	32 (31.7)	NC [12.5, NC]	1.118 [0.694, 1.800]	0.6455	
Sex									
Male	174	51 (29.3)	NC [14.9, NC]	173	56 (32.4)	NC [12.5, NC]	0.844 [0.577, 1.234]	0.3821	0.4032
Female	105	45 (42.9)	9.8 [4.6, NC]	105	42 (40.0)	18.1 [7.0, NC]	1.079 [0.709, 1.644]	0.7126	
Region									
Asia	87	32 (36.8)	NC [9.3, NC]	88	27 (30.7)	NC [11.8, NC]	1.044 [0.625, 1.745]	0.8669	0.6196
Non-Asia	192	64 (33.3)	NC [13.1, NC]	190	71 (37.4)	18.1 [12.5, NC]	0.893 [0.637, 1.252]	0.5154	
Number of Organs with Metastatic Sites									
0-2	216	68 (31.5)	NC [14.9, NC]	216	74 (34.3)	NC [14.6, NC]	0.862 [0.620, 1.199]	0.3839	0.2663
>=3	63	28 (44.4)	8.3 [4.4, NC]	62	24 (38.7)	12.5 [8.2, NC]	1.249 [0.723, 2.157]	0.4249	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.214.1: Summary and Results of Non-Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	55 (19.7%)	67 (24.1%)	
Number of patients censored	224 (80.3%)	211 (75.9%)	
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			0.735 [0.513, 1.053]
Log-rank test			
Two-sided stratified log-rank p-value			0.0920

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.214.2: Summary and Results of Non-Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	34 (19.1)	NC [NC, NC]	177	43 (24.3)	NC [NC, NC]	0.729 [0.464, 1.145]	0.1678	0.8456
>65 years	101	21 (20.8)	NC [NC, NC]	101	24 (23.8)	NC [17.6, NC]	0.775 [0.430, 1.395]	0.3964	
Sex									
Male	174	30 (17.2)	NC [NC, NC]	173	45 (26.0)	NC [NC, NC]	0.574 [0.360, 0.914]	0.0178	0.0846
Female	105	25 (23.8)	NC [16.6, NC]	105	22 (21.0)	NC [17.6, NC]	1.134 [0.639, 2.012]	0.6676	
Region									
Asia	87	26 (29.9)	NC [14.3, NC]	88	28 (31.8)	NC [17.6, NC]	0.725 [0.423, 1.243]	0.2427	0.8962
Non-Asia	192	29 (15.1)	NC [NC, NC]	190	39 (20.5)	NC [NC, NC]	0.721 [0.446, 1.167]	0.1797	
Number of Organs with Metastatic Sites									
0-2	216	38 (17.6)	NC [NC, NC]	216	54 (25.0)	NC [NC, NC]	0.621 [0.409, 0.942]	0.0239	0.0777
>=3	63	17 (27.0)	NC [11.2, NC]	62	13 (21.0)	NC [10.7, NC]	1.301 [0.630, 2.685]	0.4789	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.215.1: Summary and Results of Non-Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	115 (41.2%)	32 (11.5%)	
Number of patients censored	164 (58.8%)	246 (88.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [13.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.640 [3.130, 6.879]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.215.2: Summary and Results of Non-Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	64 (36.0)	NC [18.4, NC]	177	26 (14.7)	NC [NC, NC]	2.946 [1.866, 4.652]	<.0001	0.0062
>65 years	101	51 (50.5)	6.4 [1.6, NC]	101	6 (5.9)	NC [NC, NC]	11.558 [4.952, 26.975]	<.0001	
Sex									
Male	174	69 (39.7)	NC [18.4, NC]	173	20 (11.6)	NC [NC, NC]	4.271 [2.594, 7.033]	<.0001	0.7220
Female	105	46 (43.8)	13.5 [2.3, NC]	105	12 (11.4)	NC [NC, NC]	4.912 [2.599, 9.284]	<.0001	
Region									
Asia	87	30 (34.5)	NC [NC, NC]	88	13 (14.8)	NC [NC, NC]	2.722 [1.419, 5.221]	0.0019	0.0581
Non-Asia	192	85 (44.3)	13.5 [5.3, NC]	190	19 (10.0)	NC [NC, NC]	5.896 [3.581, 9.709]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	85 (39.4)	NC [18.4, NC]	216	28 (13.0)	NC [NC, NC]	3.722 [2.427, 5.710]	<.0001	0.0876
>=3	63	30 (47.6)	7.4 [1.6, NC]	62	4 (6.5)	NC [NC, NC]	10.374 [3.644, 29.533]	<.0001	

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.
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Table 301.1.2001.216.1: Summary and Results of Non-Severe TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	219 (78.5%)	167 (60.1%)	
Number of patients censored	60 (21.5%)	111 (39.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.2]	2.1 [1.0, 3.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.976 [1.609, 2.426]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.216.2: Summary and Results of Non-Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	137 (77.0)	0.1 [0.0, 0.2]	177	116 (65.5)	1.1 [0.7, 2.4]	1.693 [1.321, 2.171]	0.0002	0.0417
>65 years	101	82 (81.2)	0.1 [0.0, 0.5]	101	51 (50.5)	5.0 [1.6, NC]	2.673 [1.878, 3.805]	<.0001	
Sex									
Male	174	134 (77.0)	0.2 [0.1, 0.5]	173	104 (60.1)	2.1 [1.0, 3.5]	1.811 [1.400, 2.342]	<.0001	0.3290
Female	105	85 (81.0)	0.0 [0.0, 0.1]	105	63 (60.0)	2.1 [0.7, 5.0]	2.337 [1.681, 3.248]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.2]	88	59 (67.0)	1.5 [0.6, 2.5]	2.048 [1.453, 2.889]	<.0001	0.9671
Non-Asia	192	144 (75.0)	0.1 [0.0, 0.5]	190	108 (56.8)	2.5 [1.0, 7.4]	1.974 [1.536, 2.537]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	174 (80.6)	0.1 [0.0, 0.2]	216	130 (60.2)	2.1 [1.0, 3.5]	2.095 [1.666, 2.633]	<.0001	0.3830
>=3	63	45 (71.4)	0.2 [0.0, 0.7]	62	37 (59.7)	2.2 [0.6, NC]	1.640 [1.060, 2.538]	0.0429	

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.
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Table 301.1.2001.217.1: Summary and Results of Non-Severe TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	132 (47.3%)	136 (48.9%)	
Number of patients censored	147 (52.7%)	142 (51.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.2 [4.4, NC]	5.7 [3.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.942 [0.741, 1.199]
Log-rank test			
Two-sided stratified log-rank p-value			0.6301

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.217.2: Summary and Results of Non-Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	86 (48.3)	4.9 [3.7, NC]	177	90 (50.8)	5.5 [3.3, NC]	0.927 [0.690, 1.246]	0.6170	0.7631
>65 years	101	46 (45.5)	7.8 [4.4, NC]	101	46 (45.5)	6.6 [3.6, NC]	0.999 [0.664, 1.504]	0.9943	
Sex									
Male	174	81 (46.6)	6.2 [4.1, NC]	173	77 (44.5)	NC [5.1, NC]	1.075 [0.787, 1.469]	0.6463	0.2308
Female	105	51 (48.6)	5.7 [2.7, NC]	105	59 (56.2)	3.5 [2.3, 5.8]	0.793 [0.545, 1.154]	0.2300	
Region									
Asia	87	51 (58.6)	4.6 [2.3, 7.4]	88	48 (54.5)	4.6 [2.1, 9.7]	0.989 [0.666, 1.469]	0.9610	0.7560
Non-Asia	192	81 (42.2)	8.4 [4.4, NC]	190	88 (46.3)	6.3 [4.0, NC]	0.924 [0.683, 1.250]	0.6083	
Number of Organs with Metastatic Sites									
0-2	216	100 (46.3)	6.7 [4.4, NC]	216	111 (51.4)	5.1 [3.2, 9.7]	0.847 [0.646, 1.110]	0.2302	0.0756
>=3	63	32 (50.8)	4.6 [2.5, NC]	62	25 (40.3)	NC [4.0, NC]	1.479 [0.875, 2.500]	0.1397	

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.
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Table 301.1.2001.218.1: Summary and Results of Non-Severe TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	175 (62.7%)	97 (34.9%)	
Number of patients censored	104 (37.3%)	181 (65.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.2 [0.7, 2.4]	NC [16.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.678 [2.081, 3.445]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.218.2: Summary and Results of Non-Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	116 (65.2)	0.9 [0.5, 2.7]	177	71 (40.1)	16.6 [9.7, NC]	2.377 [1.767, 3.198]	<.0001	0.2794
>65 years	101	59 (58.4)	2.0 [0.7, 12.2]	101	26 (25.7)	NC [NC, NC]	3.173 [1.997, 5.040]	<.0001	
Sex									
Male	174	105 (60.3)	1.6 [0.7, 3.5]	173	55 (31.8)	NC [16.6, NC]	2.727 [1.965, 3.785]	<.0001	0.6290
Female	105	70 (66.7)	0.9 [0.1, 2.5]	105	42 (40.0)	NC [5.5, NC]	2.421 [1.650, 3.554]	<.0001	
Region									
Asia	87	52 (59.8)	1.4 [0.4, 12.2]	88	28 (31.8)	16.6 [12.0, NC]	2.444 [1.538, 3.885]	0.0002	0.8858
Non-Asia	192	123 (64.1)	1.1 [0.7, 2.5]	190	69 (36.3)	NC [NC, NC]	2.655 [1.974, 3.572]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	137 (63.4)	1.1 [0.7, 2.4]	216	74 (34.3)	NC [16.0, NC]	2.713 [2.042, 3.605]	<.0001	0.4583
>=3	63	38 (60.3)	1.6 [0.6, 12.0]	62	23 (37.1)	NC [4.7, NC]	2.187 [1.301, 3.675]	0.0032	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.219.1: Summary and Results of Severe TEAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	6 (2.2%)	
Number of patients censored	263 (94.3%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.892 [1.130, 7.402]
Log-rank test			
Two-sided stratified log-rank p-value			0.0205

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.219.2: Summary and Results of Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [NC, NC]	177	6 (3.4)	NC [NC, NC]	2.218 [0.843, 5.836]	0.0978	0.9891
>65 years	101	3 (3.0)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	2.8E7 [0.000, NC]	0.0927	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	4 (2.3)	NC [NC, NC]	2.220 [0.683, 7.218]	0.1734	0.6416
Female	105	7 (6.7)	NC [NC, NC]	105	2 (1.9)	NC [NC, NC]	3.577 [0.743, 17.224]	0.0895	
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	0.000 [0.000, NC]	0.3173	0.9893
Non-Asia	192	16 (8.3)	NC [NC, NC]	190	5 (2.6)	NC [NC, NC]	3.449 [1.263, 9.417]	0.0101	
Number of Organs with Metastatic Sites									
0-2	216	13 (6.0)	NC [NC, NC]	216	3 (1.4)	NC [NC, NC]	4.341 [1.237, 15.239]	0.0124	0.1641
>=3	63	3 (4.8)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	1.127 [0.227, 5.590]	0.8839	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.220.1: Summary and Results of Severe TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	26 (9.4%)	
Number of patients censored	254 (91.0%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.953 [0.549, 1.653]
Log-rank test			
Two-sided stratified log-rank p-value			0.8641

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.220.2: Summary and Results of Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	19 (10.7)	NC [28.3, NC]	177	19 (10.7)	NC [NC, NC]	0.996 [0.527, 1.882]	0.9890	0.7303
>65 years	101	6 (5.9)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	0.855 [0.287, 2.545]	0.7777	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	15 (8.7)	NC [NC, NC]	0.661 [0.297, 1.473]	0.3079	0.1989
Female	105	15 (14.3)	NC [28.3, NC]	105	11 (10.5)	NC [NC, NC]	1.358 [0.623, 2.960]	0.4399	
Region									
Asia	87	9 (10.3)	NC [28.3, NC]	88	6 (6.8)	NC [NC, NC]	1.254 [0.443, 3.556]	0.6691	0.4503
Non-Asia	192	16 (8.3)	NC [NC, NC]	190	20 (10.5)	NC [NC, NC]	0.834 [0.432, 1.610]	0.5887	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	20 (9.3)	NC [NC, NC]	0.712 [0.363, 1.395]	0.3200	0.1626
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.762 [0.640, 4.849]	0.2665	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.221.1: Summary and Results of Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	3 (1.1%)	
Number of patients censored	273 (97.8%)	275 (98.9%)	
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			1.996 [0.498, 7.997]
Log-rank test			
Two-sided stratified log-rank p-value			0.3197

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.221.2: Summary and Results of Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	3 (1.7)		177	2 (1.1)				
>65 years	101	3 (3.0)		101	1 (1.0)				
Sex									
Male	174	4 (2.3)		173	1 (0.6)				
Female	105	2 (1.9)		105	2 (1.9)				
Region									
Asia	87	1 (1.1)		88	1 (1.1)				
Non-Asia	192	5 (2.6)		190	2 (1.1)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	2 (0.9)				
>=3	63	2 (3.2)		62	1 (1.6)				

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.
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Table 301.1.2001.222.1: Summary and Results of Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	2 (0.7%)	
Number of patients censored	259 (92.8%)	276 (99.3%)	
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			10.673 [2.494, 45.677]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.222.2: Summary and Results of Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	14 (7.9)	NC [NC, NC]	177	0 (0.0)	NC [NC, NC]	3.13E7 [0.000, NC]	0.0001	0.9907
>65 years	101	6 (5.9)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	3.097 [0.625, 15.345]	0.1453	
Sex									
Male	174	12 (6.9)	NC [NC, NC]	173	2 (1.2)	NC [NC, NC]	6.287 [1.407, 28.088]	0.0058	0.9893
Female	105	8 (7.6)	NC [NC, NC]	105	0 (0.0)	NC [NC, NC]	3.1E7 [0.000, NC]	0.0038	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	2.032 [0.184, 22.403]	0.5545	0.1598
Non-Asia	192	18 (9.4)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	19.192 [2.562, 143.79]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	16 (7.4)	NC [NC, NC]	216	1 (0.5)	NC [NC, NC]	16.918 [2.245, 127.51]	0.0002	0.3485
>=3	63	4 (6.3)	NC [NC, NC]	62	1 (1.6)	NC [NC, NC]	4.116 [0.460, 36.839]	0.1701	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.223.1: Summary and Results of Severe TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	18 (6.5%)	
Number of patients censored	234 (83.9%)	260 (93.5%)	
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			2.662 [1.539, 4.606]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.223.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	29 (16.3)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	2.233 [1.180, 4.226]	0.0121	0.3353
>65 years	101	16 (15.8)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.138 [1.381, 12.398]	0.0060	
Sex									
Male	174	23 (13.2)	NC [NC, NC]	173	10 (5.8)	NC [NC, NC]	2.422 [1.153, 5.089]	0.0166	0.7141
Female	105	22 (21.0)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	2.961 [1.317, 6.657]	0.0061	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	6 (6.8)	NC [NC, NC]	1.434 [0.506, 4.059]	0.5030	0.2087
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	3.304 [1.718, 6.351]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	34 (15.7)	NC [NC, NC]	216	11 (5.1)	NC [NC, NC]	3.277 [1.660, 6.472]	0.0003	0.2395
>=3	63	11 (17.5)	NC [NC, NC]	62	7 (11.3)	NC [NC, NC]	1.660 [0.643, 4.285]	0.2920	

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.
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Table 301.1.2001.224.1: Summary and Results of Severe TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	147 (52.7%)	131 (47.1%)	
Number of patients censored	132 (47.3%)	147 (52.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.9 [2.8, 8.5]	5.9 [3.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.179 [0.931, 1.493]
Log-rank test			
Two-sided stratified log-rank p-value			0.1615

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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.
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Table 301.1.2001.224.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	93 (52.2)	4.1 [2.3, 21.4]	177	82 (46.3)	6.8 [3.7, NC]	1.241 [0.922, 1.671]	0.1461	0.7456
>65 years	101	54 (53.5)	3.6 [2.3, NC]	101	49 (48.5)	4.8 [2.8, NC]	1.150 [0.781, 1.694]	0.4659	
Sex									
Male	174	75 (43.1)	NC [4.1, NC]	173	66 (38.2)	NC [NC, NC]	1.229 [0.883, 1.711]	0.2118	0.9377
Female	105	72 (68.6)	2.1 [1.6, 3.4]	105	65 (61.9)	2.6 [2.1, 4.2]	1.195 [0.854, 1.672]	0.2901	
Region									
Asia	87	57 (65.5)	2.5 [1.7, 4.1]	88	47 (53.4)	4.2 [2.1, NC]	1.281 [0.870, 1.885]	0.1946	0.7082
Non-Asia	192	90 (46.9)	6.3 [3.4, NC]	190	84 (44.2)	NC [3.9, NC]	1.159 [0.861, 1.561]	0.3214	
Number of Organs with Metastatic Sites									
0-2	216	113 (52.3)	4.1 [2.8, 8.5]	216	110 (50.9)	4.7 [3.4, NC]	1.067 [0.820, 1.388]	0.6073	0.0460
>=3	63	34 (54.0)	3.4 [1.4, NC]	62	21 (33.9)	NC [6.8, NC]	1.881 [1.091, 3.245]	0.0199	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.225.1: Summary and Results of Severe TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	16 (5.8%)	
Number of patients censored	234 (83.9%)	262 (94.2%)	
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			3.020 [1.704, 5.352]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.225.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	30 (16.9)	NC [NC, NC]	177	13 (7.3)	NC [NC, NC]	2.452 [1.278, 4.703]	0.0061	0.2910
>65 years	101	15 (14.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	5.289 [1.531, 18.271]	0.0032	
Sex									
Male	174	21 (12.1)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	2.381 [1.090, 5.205]	0.0264	0.4647
Female	105	24 (22.9)	NC [NC, NC]	105	7 (6.7)	NC [NC, NC]	3.783 [1.630, 8.780]	0.0009	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	4 (4.5)	NC [NC, NC]	2.121 [0.648, 6.945]	0.2093	0.5907
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	3.289 [1.711, 6.323]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	35 (16.2)	NC [NC, NC]	216	10 (4.6)	NC [NC, NC]	3.713 [1.838, 7.501]	<.0001	0.2224
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.757 [0.638, 4.837]	0.2728	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.226.1: Summary and Results of TESAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	10 (3.6%)	
Number of patients censored	274 (98.2%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.512 [0.175, 1.502]
Log-rank test			
Two-sided stratified log-rank p-value			0.2144

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.226.2: Summary and Results of TESAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	3 (1.7)	NC [NC, NC]	177	8 (4.5)	NC [NC, NC]	0.370 [0.098, 1.394]	0.1258	0.4409
>65 years	101	2 (2.0)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	0.942 [0.133, 6.698]	0.9526	
Sex									
Male	174	3 (1.7)		173	5 (2.9)				
Female	105	2 (1.9)		105	5 (4.8)				
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	0.000 [0.000, NC]	0.1585	0.9904
Non-Asia	192	5 (2.6)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	0.640 [0.209, 1.957]	0.4299	
Number of Organs with Metastatic Sites									
0-2	216	3 (1.4)	NC [NC, NC]	216	7 (3.2)	NC [NC, NC]	0.412 [0.106, 1.595]	0.1847	0.6892
>=3	63	2 (3.2)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.699 [0.117, 4.193]	0.6941	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.227.1: Summary and Results of TESAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	4 (1.4%)	
Number of patients censored	274 (98.2%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.293 [0.347, 4.817]
Log-rank test			
Two-sided stratified log-rank p-value			0.7011

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.227.2: Summary and Results of TESAEs by Subgroups - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	4 (2.2)		177	2 (1.1)				
>65 years	101	1 (1.0)		101	2 (2.0)				
Sex									
Male	174	3 (1.7)		173	4 (2.3)				
Female	105	2 (1.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)		88	0 (0.0)				
Non-Asia	192	4 (2.1)		190	4 (2.1)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)		216	3 (1.4)				
>=3	63	3 (4.8)		62	1 (1.6)				

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.228.1: Summary and Results of TESAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	1 (0.4%)	
Number of patients censored	275 (98.6%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.994 [0.446, 35.746]
Log-rank test			
Two-sided stratified log-rank p-value			0.1803

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.228.2: Summary and Results of TESAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	3 (3.0)		101	1 (1.0)				
Sex									
Male	174	4 (2.3)		173	1 (0.6)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	1 (1.1)				
Non-Asia	192	4 (2.1)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	1 (0.5)		216	1 (0.5)				
>=3	63	3 (4.8)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.229.1: Summary and Results of TESAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	0 (0.0%)	
Number of patients censored	271 (97.1%)	278 (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			0.0041

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.229.2: Summary and Results of TESAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	6 (3.4)		177	0 (0.0)				
>65 years	101	2 (2.0)		101	0 (0.0)				
Sex									
Male	174	6 (3.4)		173	0 (0.0)				
Female	105	2 (1.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)		88	0 (0.0)				
Non-Asia	192	7 (3.6)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	0 (0.0)				
>=3	63	4 (6.3)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.230.1: Summary and Results of TESAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	19 (6.8%)	11 (4.0%)	
Number of patients censored	260 (93.2%)	267 (96.0%)	
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			1.768 [0.840, 3.724]
Log-rank test			
Two-sided stratified log-rank p-value			0.1293

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.230.2: Summary and Results of TESAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	1.922 [0.767, 4.818]	0.1569	0.7623
>65 years	101	6 (5.9)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	1.426 [0.400, 5.090]	0.5835	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	5 (2.9)	NC [NC, NC]	1.834 [0.614, 5.473]	0.2698	0.9165
Female	105	10 (9.5)	NC [NC, NC]	105	6 (5.7)	NC [NC, NC]	1.657 [0.600, 4.573]	0.3273	
Region									
Asia	87	4 (4.6)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	1.147 [0.251, 5.254]	0.8594	0.6181
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	1.972 [0.836, 4.652]	0.1148	
Number of Organs with Metastatic Sites									
0-2	216	12 (5.6)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	1.993 [0.746, 5.324]	0.1614	0.6478
>=3	63	7 (11.1)	NC [NC, NC]	62	5 (8.1)	NC [NC, NC]	1.421 [0.451, 4.478]	0.5482	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.231.1: Summary and Results of TESAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	8 (2.9%)	
Number of patients censored	263 (94.3%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.047 [0.876, 4.787]
Log-rank test			
Two-sided stratified log-rank p-value			0.0912

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.231.2: Summary and Results of TESAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	11 (6.2)	NC [NC, NC]	177	6 (3.4)	NC [NC, NC]	1.891 [0.699, 5.114]	0.2014	0.7735
>65 years	101	5 (5.0)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	2.512 [0.487, 12.948]	0.2544	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	4 (2.3)	NC [NC, NC]	2.583 [0.810, 8.236]	0.0959	0.5639
Female	105	6 (5.7)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	1.531 [0.432, 5.424]	0.5065	
Region									
Asia	87	3 (3.4)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	1.413 [0.236, 8.476]	0.7039	0.6823
Non-Asia	192	13 (6.8)	NC [NC, NC]	190	6 (3.2)	NC [NC, NC]	2.261 [0.859, 5.949]	0.0893	
Number of Organs with Metastatic Sites									
0-2	216	9 (4.2)	NC [NC, NC]	216	8 (3.7)	NC [NC, NC]	1.140 [0.440, 2.954]	0.7878	0.9903
>=3	63	7 (11.1)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.06E7 [0.000, NC]	0.0072	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.232.1: Summary and Results of TESAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	23 (8.2%)	14 (5.0%)	
Number of patients censored	256 (91.8%)	264 (95.0%)	
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			1.754 [0.902, 3.409]
Log-rank test			
Two-sided stratified log-rank p-value			0.0954

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.232.2: Summary and Results of TESAEs by Subgroups - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	16 (9.0)	NC [NC, NC]	177	11 (6.2)	NC [NC, NC]	1.502 [0.697, 3.237]	0.3008	0.5614
>65 years	101	7 (6.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	2.379 [0.615, 9.200]	0.1956	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	7 (4.0)	NC [NC, NC]	1.293 [0.482, 3.474]	0.6106	0.4860
Female	105	14 (13.3)	NC [NC, NC]	105	7 (6.7)	NC [NC, NC]	2.115 [0.854, 5.241]	0.0999	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	0.336 [0.035, 3.232]	0.3215	0.1229
Non-Asia	192	22 (11.5)	NC [NC, NC]	190	11 (5.8)	NC [NC, NC]	2.116 [1.026, 4.365]	0.0387	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	9 (4.2)	NC [NC, NC]	1.717 [0.751, 3.923]	0.1972	0.9427
>=3	63	8 (12.7)	NC [NC, NC]	62	5 (8.1)	NC [NC, NC]	1.626 [0.532, 4.972]	0.3921	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.233.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	2 (0.7%)	1 (0.4%)	
Number of patients censored	277 (99.3%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.197 [0.199, 24.233]
Log-rank test			
Two-sided stratified log-rank p-value			0.5095

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.233.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	1 (1.0)		101	1 (1.0)				
Sex									
Male	174	2 (1.1)		173	1 (0.6)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	2 (1.0)		190	1 (0.5)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)		216	1 (0.5)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.234.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	3 (1.1%)	
Number of patients censored	275 (98.6%)	275 (98.9%)	
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			1.339 [0.298, 6.008]
Log-rank test			
Two-sided stratified log-rank p-value			0.7025

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.234.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)		177	2 (1.1)				
>65 years	101	2 (2.0)		101	1 (1.0)				
Sex									
Male	174	3 (1.7)		173	3 (1.7)				
Female	105	1 (1.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	4 (2.1)		190	3 (1.6)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	1 (0.5)				
>=3	63	0 (0.0)		62	2 (3.2)				

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.235.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	8 (2.9%)	
Number of patients censored	274 (98.2%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.565 [0.184, 1.733]
Log-rank test			
Two-sided stratified log-rank p-value			0.3116

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.235.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)		177	5 (2.8)				
>65 years	101	3 (3.0)		101	3 (3.0)				
Sex									
Male	174	3 (1.7)		173	6 (3.5)				
Female	105	2 (1.9)		105	2 (1.9)				
Region									
Asia	87	2 (2.3)		88	7 (8.0)				
Non-Asia	192	3 (1.6)		190	1 (0.5)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	0.673 [0.190, 2.385]	0.5363	0.8629
>=3	63	1 (1.6)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.549 [0.050, 6.059]	0.6195	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.236.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	11 (4.0%)	
Number of patients censored	262 (93.9%)	267 (96.0%)	
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			1.571 [0.735, 3.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.2414

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.236.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [NC, NC]	177	8 (4.5)	NC [NC, NC]	1.673 [0.694, 4.038]	0.2483	0.8074
>65 years	101	4 (4.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	1.353 [0.303, 6.048]	0.6909	
Sex									
Male	174	8 (4.6)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	1.012 [0.380, 2.698]	0.9809	0.1784
Female	105	9 (8.6)	NC [NC, NC]	105	3 (2.9)	NC [NC, NC]	3.147 [0.852, 11.626]	0.0698	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	0.378 [0.073, 1.951]	0.2272	0.0455
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	6 (3.2)	NC [NC, NC]	2.624 [1.018, 6.764]	0.0382	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	7 (3.2)	NC [NC, NC]	2.209 [0.901, 5.418]	0.0757	0.1337
>=3	63	2 (3.2)	NC [NC, NC]	62	4 (6.5)	NC [NC, NC]	0.524 [0.096, 2.863]	0.4482	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.237.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	3 (1.1%)	
Number of patients censored	261 (93.5%)	275 (98.9%)	
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			5.957 [1.751, 20.261]
Log-rank test			
Two-sided stratified log-rank p-value			0.0012

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.237.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	11 (6.2)	NC [NC, NC]	177	2 (1.1)	NC [NC, NC]	5.646 [1.252, 25.471]	0.0109	0.8707
>65 years	101	7 (6.9)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	6.569 [0.805, 53.617]	0.0429	
Sex									
Male	174	8 (4.6)	NC [NC, NC]	173	1 (0.6)	NC [NC, NC]	8.177 [1.023, 65.386]	0.0180	0.7115
Female	105	10 (9.5)	NC [NC, NC]	105	2 (1.9)	NC [NC, NC]	4.838 [1.055, 22.176]	0.0250	
Region									
Asia	87	3 (3.4)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	1.150 [0.185, 7.135]	0.8808	0.0724
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	15.802 [2.088, 119.60]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	14 (6.5)	NC [NC, NC]	216	3 (1.4)	NC [NC, NC]	4.552 [1.305, 15.874]	0.0091	0.9916
>=3	63	4 (6.3)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	2.96E7 [0.000, NC]	0.0454	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.238.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	33 (11.8%)	28 (10.1%)	
Number of patients censored	246 (88.2%)	250 (89.9%)	
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			1.165 [0.703, 1.930]
Log-rank test			
Two-sided stratified log-rank p-value			0.5511

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.238.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	17 (9.6)	NC [NC, NC]	177	16 (9.0)	NC [NC, NC]	1.057 [0.534, 2.093]	0.8723	0.6445
>65 years	101	16 (15.8)	NC [NC, NC]	101	12 (11.9)	NC [NC, NC]	1.368 [0.647, 2.893]	0.4111	
Sex									
Male	174	20 (11.5)	NC [NC, NC]	173	15 (8.7)	NC [NC, NC]	1.364 [0.698, 2.666]	0.3611	0.5400
Female	105	13 (12.4)	NC [NC, NC]	105	13 (12.4)	NC [NC, NC]	0.968 [0.448, 2.089]	0.9345	
Region									
Asia	87	13 (14.9)	NC [NC, NC]	88	11 (12.5)	NC [NC, NC]	1.147 [0.513, 2.566]	0.7371	0.8994
Non-Asia	192	20 (10.4)	NC [NC, NC]	190	17 (8.9)	NC [NC, NC]	1.219 [0.638, 2.327]	0.5471	
Number of Organs with Metastatic Sites									
0-2	216	24 (11.1)	NC [NC, NC]	216	26 (12.0)	NC [NC, NC]	0.919 [0.528, 1.601]	0.7655	0.0495
>=3	63	9 (14.3)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	4.778 [1.031, 22.138]	0.0271	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.239.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	1 (0.4%)	
Number of patients censored	259 (92.8%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			20.963 [2.813, 156.24]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.239.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	12 (6.7)	NC [NC, NC]	177	1 (0.6)	NC [NC, NC]	12.299 [1.599, 94.588]	0.0020	0.9905
>65 years	101	8 (7.9)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	3.03E7 [0.000, NC]	0.0042	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	1 (0.6)	NC [NC, NC]	9.150 [1.159, 72.225]	0.0106	0.9911
Female	105	11 (10.5)	NC [NC, NC]	105	0 (0.0)	NC [NC, NC]	3.1E7 [0.000, NC]	0.0007	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.54E7 [0.000, NC]	0.1947	0.9931
Non-Asia	192	18 (9.4)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	18.867 [2.518, 141.35]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	14 (6.5)	NC [NC, NC]	216	1 (0.5)	NC [NC, NC]	14.446 [1.900, 109.84]	0.0006	0.9889
>=3	63	6 (9.5)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	2.98E7 [0.000, NC]	0.0140	

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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.261.1: Summary and Results of TEAEs leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.261.2: Summary and Results of TEAEs leading to Death by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.262.1: Summary and Results of TEAEs leading to Death - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.262.2: Summary and Results of TEAEs leading to Death by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.263.1: Summary and Results of TEAEs leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.263.2: Summary and Results of TEAEs leading to Death by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.264.1: Summary and Results of TEAEs leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.264.2: Summary and Results of TEAEs leading to Death by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.265.1: Summary and Results of TEAEs leading to Death - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.265.2: Summary and Results of TEAEs leading to Death by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.266.1: Summary and Results of TEAEs leading to Death - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	278 (99.6%)	278 (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			0.3362

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.266.2: Summary and Results of TEAEs leading to Death by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	1 (0.6)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	1 (0.5)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	1 (1.6)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2001.267.1: Summary and Results of TEAEs leading to Death - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 09SEP22

Table 301.1.2001.267.2: Summary and Results of TEAEs leading to Death by Subgroups - Vomiting (AESI) - Safety Analysis Set

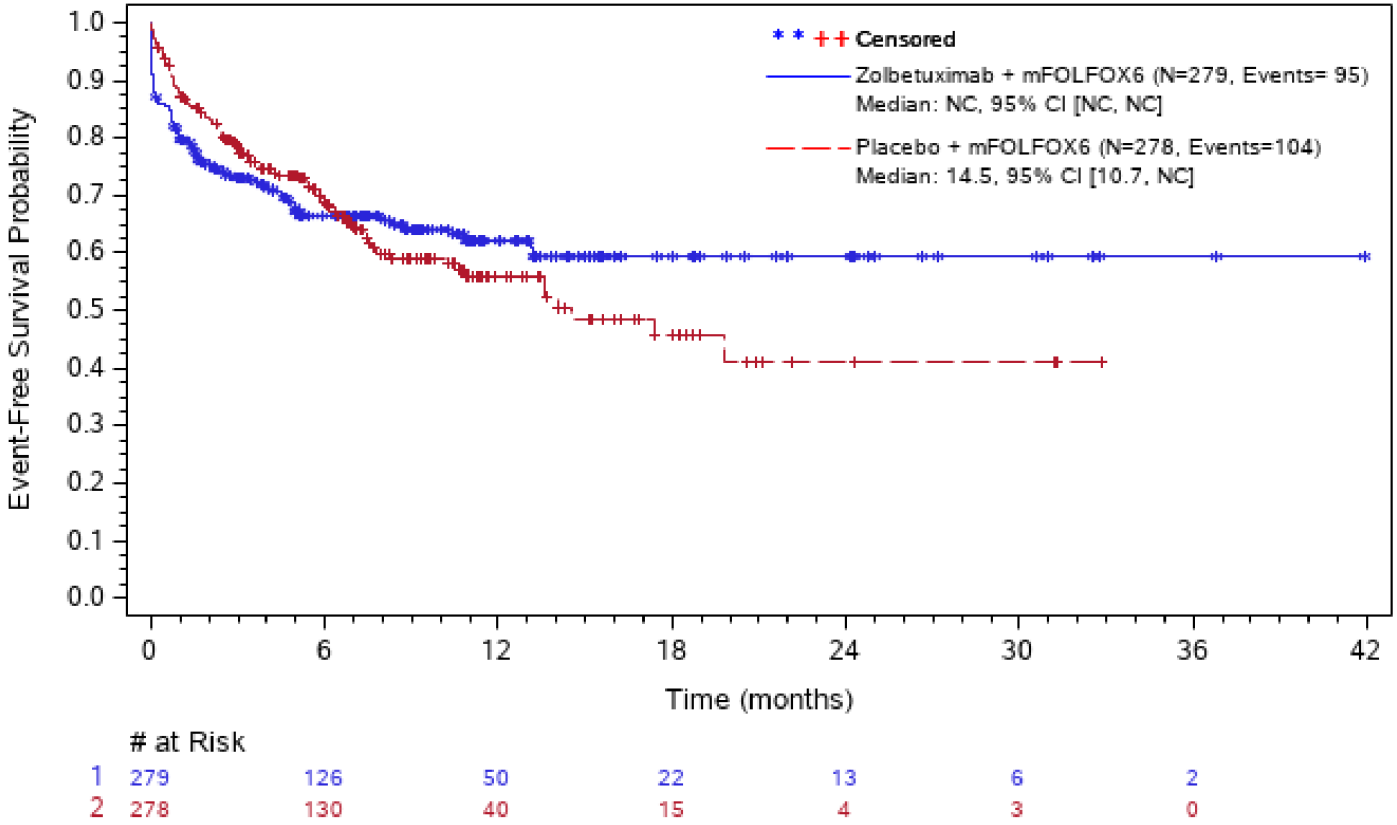
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Age Group 1									
<=65 years	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse von besonderem Interesse

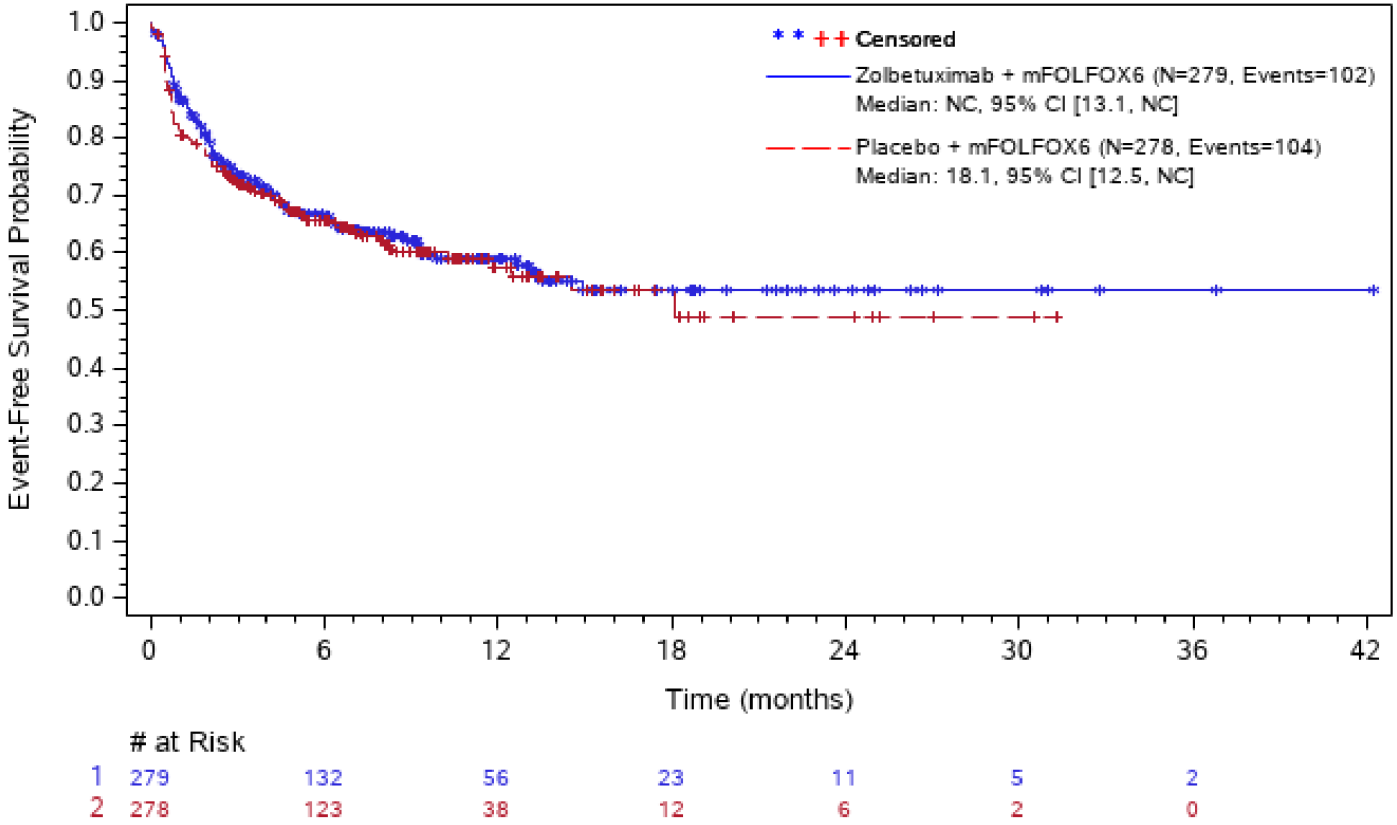
2. Kaplan-Meier-Plots

Figure 301.1.2001.205: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (AESI) - Safety Analysis Set



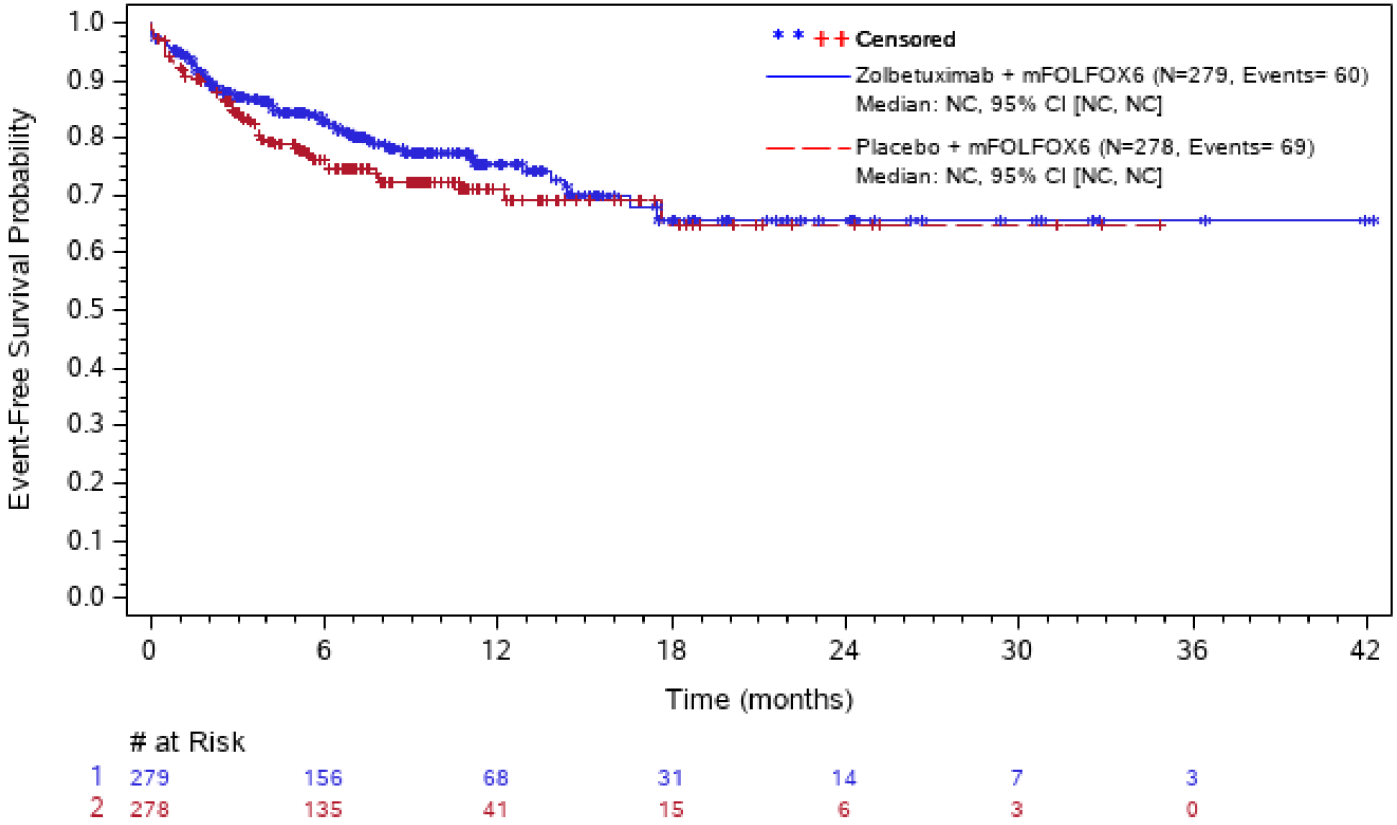
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.206: Kaplan-Meier Plot of Time to first TEAE - Anemia (AESI) - Safety Analysis Set



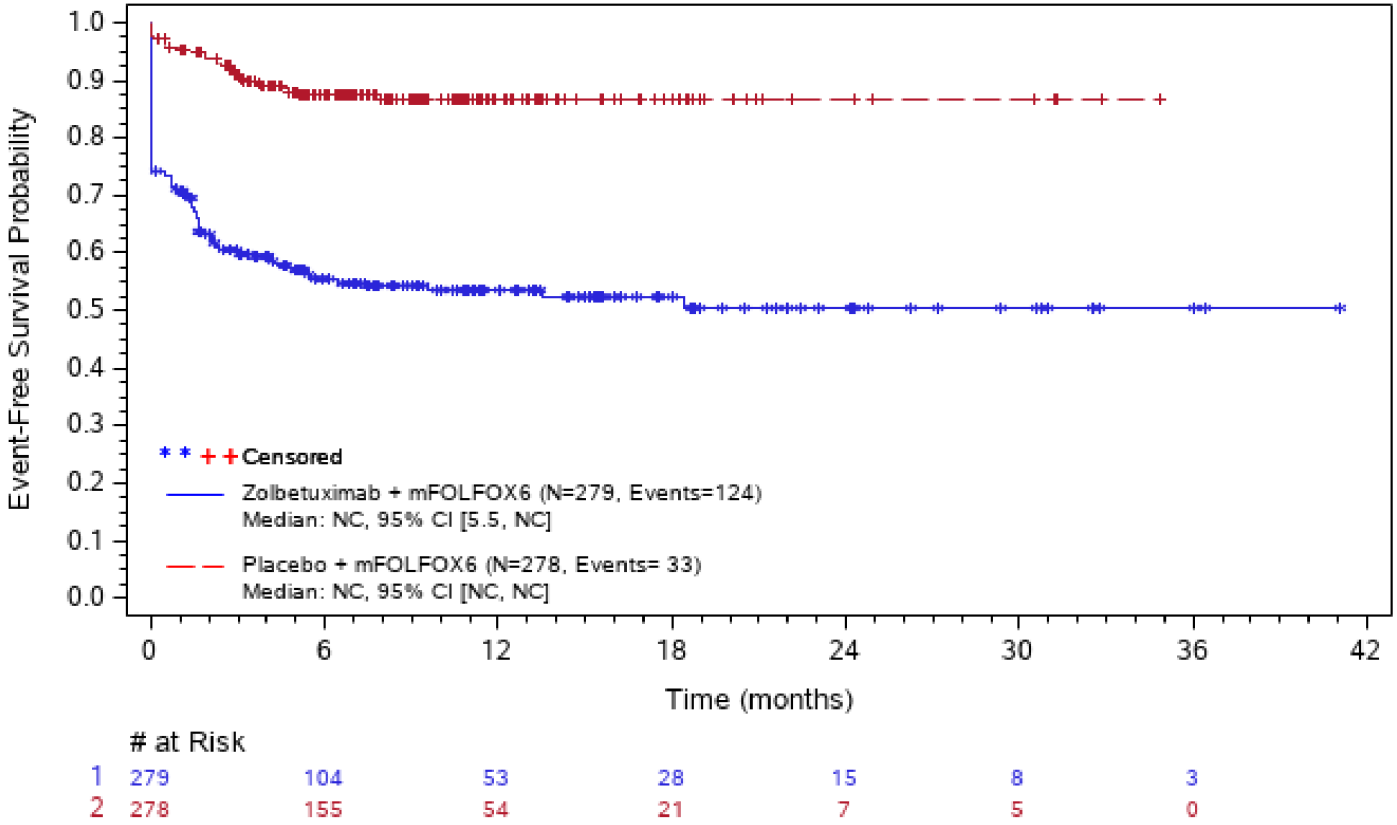
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.207: Kaplan-Meier Plot of Time to first TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



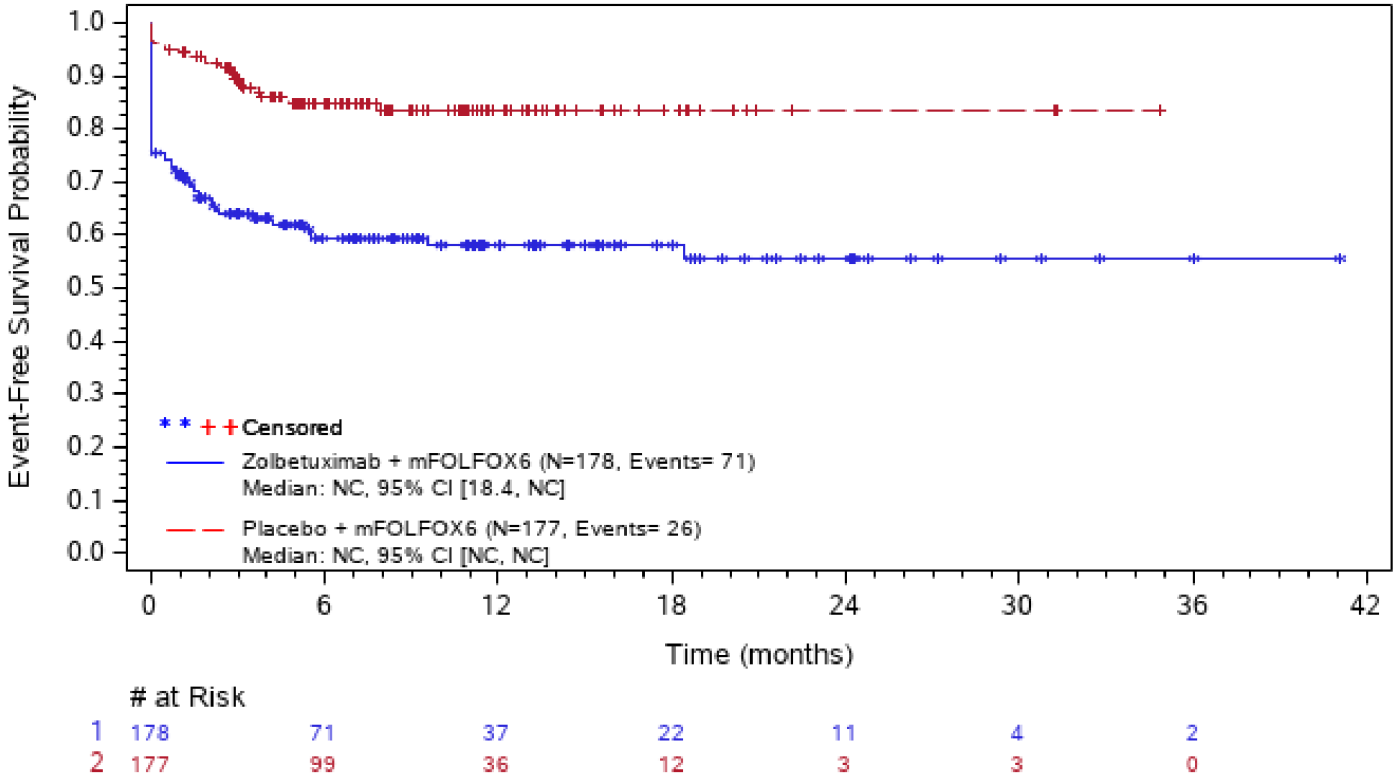
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.208: Kaplan-Meier Plot of Time to first 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: 09SEP22

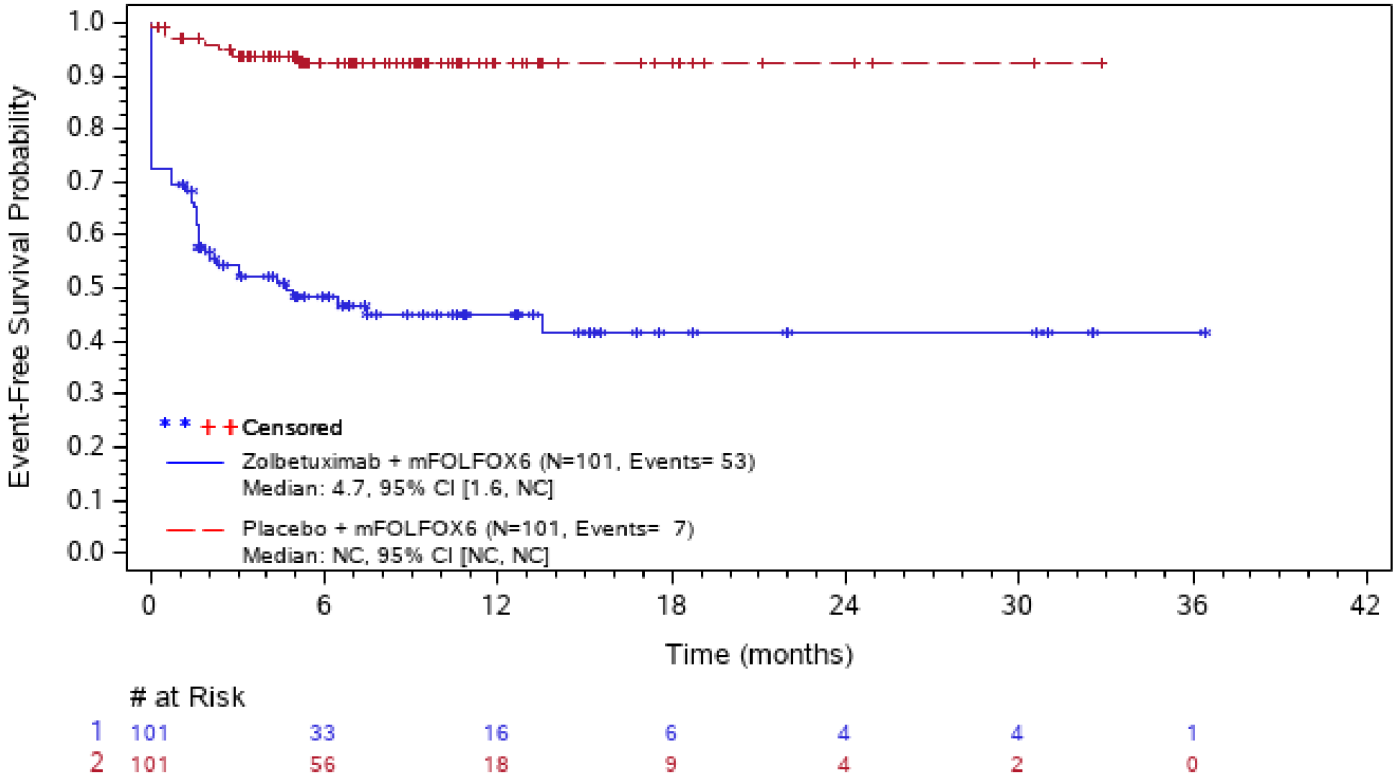
Figure 301.1.2001.208.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set
Age Group 1: <=65 years



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: 09SEP22

Figure 301.1.2001.208.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set

Age Group 1: >65 years

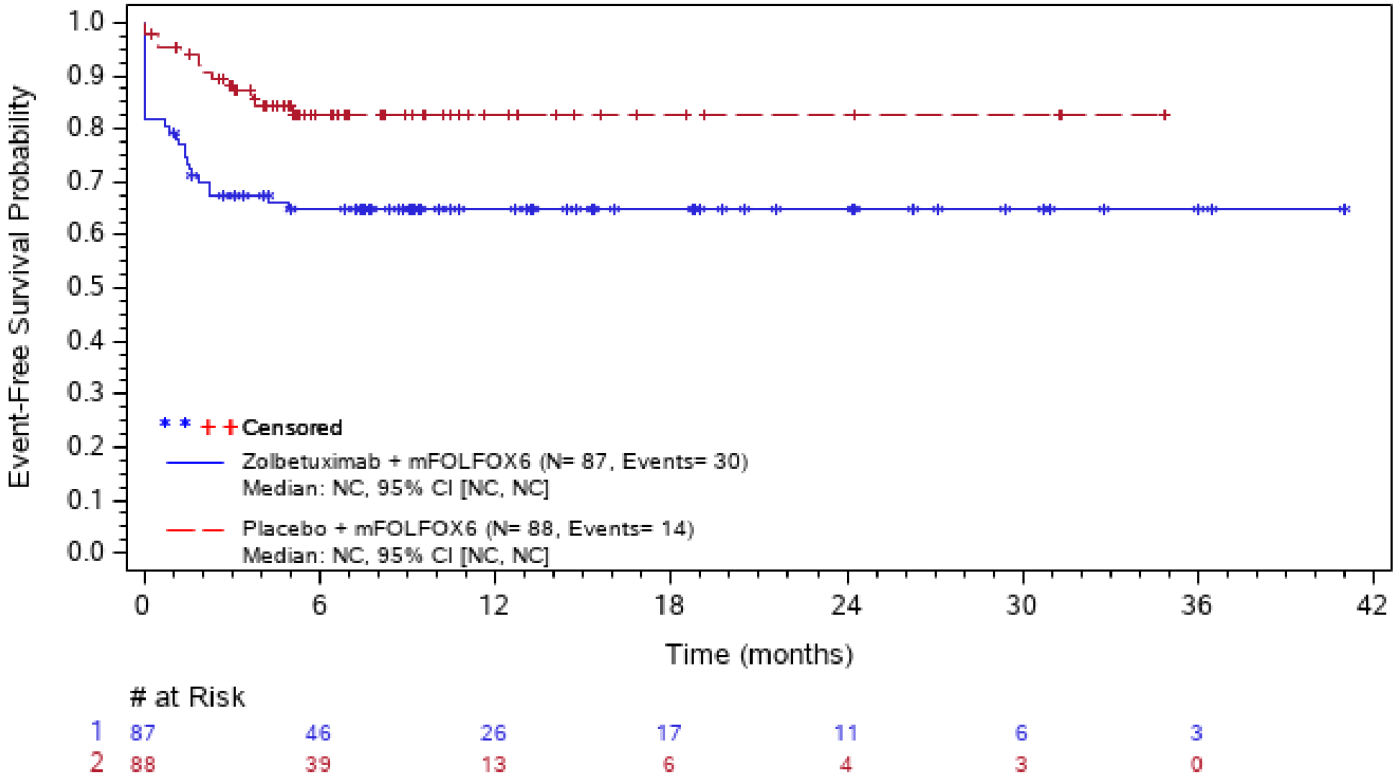


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.208.3: Kaplan-Meier Plot of Time to first TEAE by Region - Infusion Related Reaction (AESI) - Safety Analysis Set

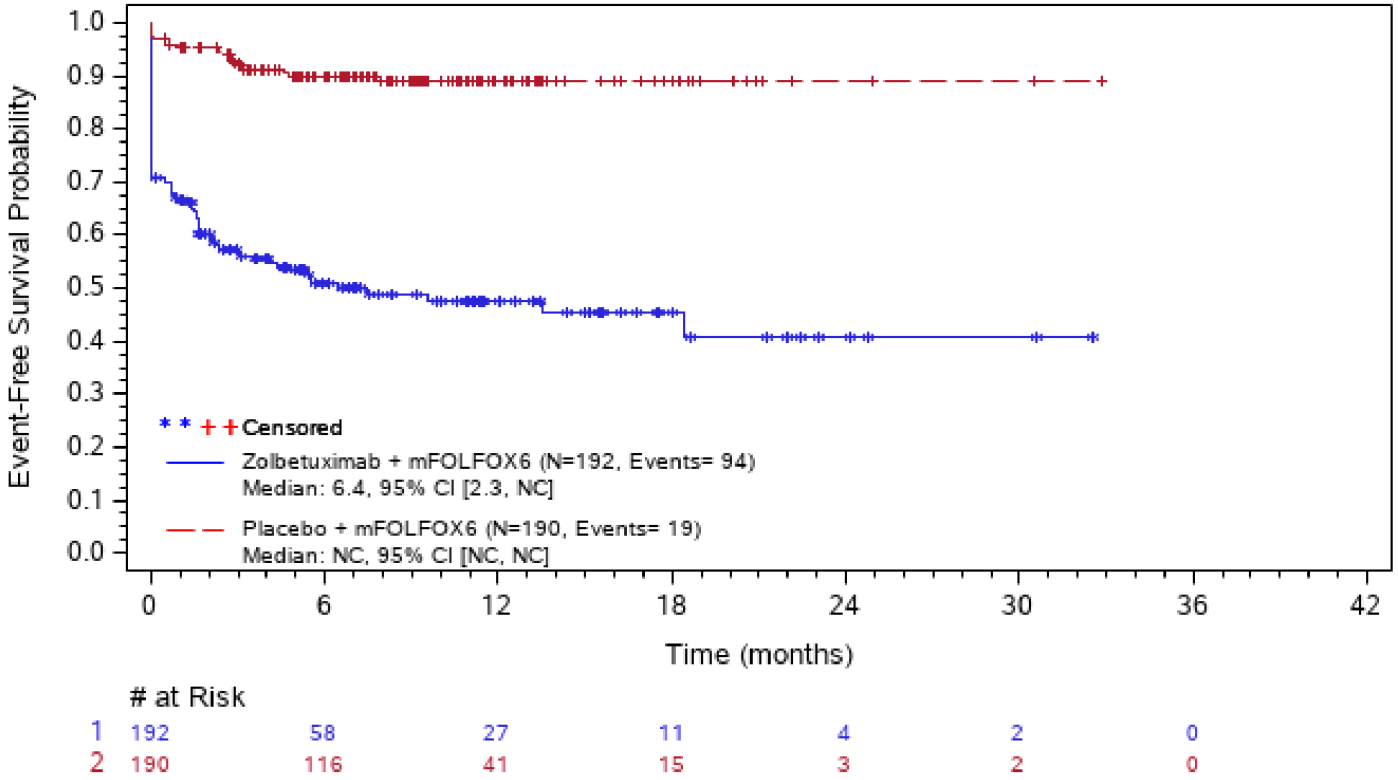
Region: Asia



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.

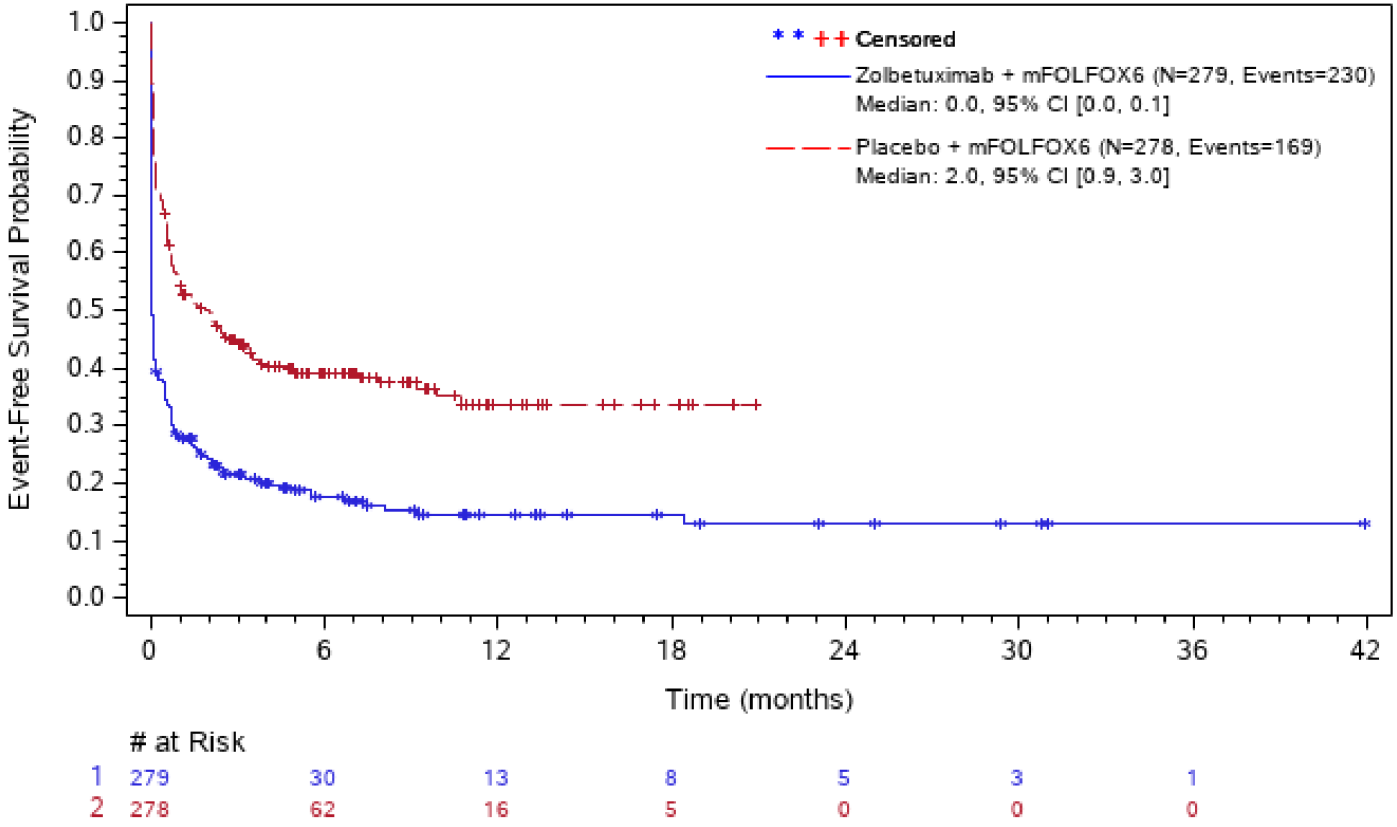
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.208.3: Kaplan-Meier Plot of Time to first TEAE by Region - Infusion Related Reaction (AESI) - Safety Analysis Set
Region: Non-Asia



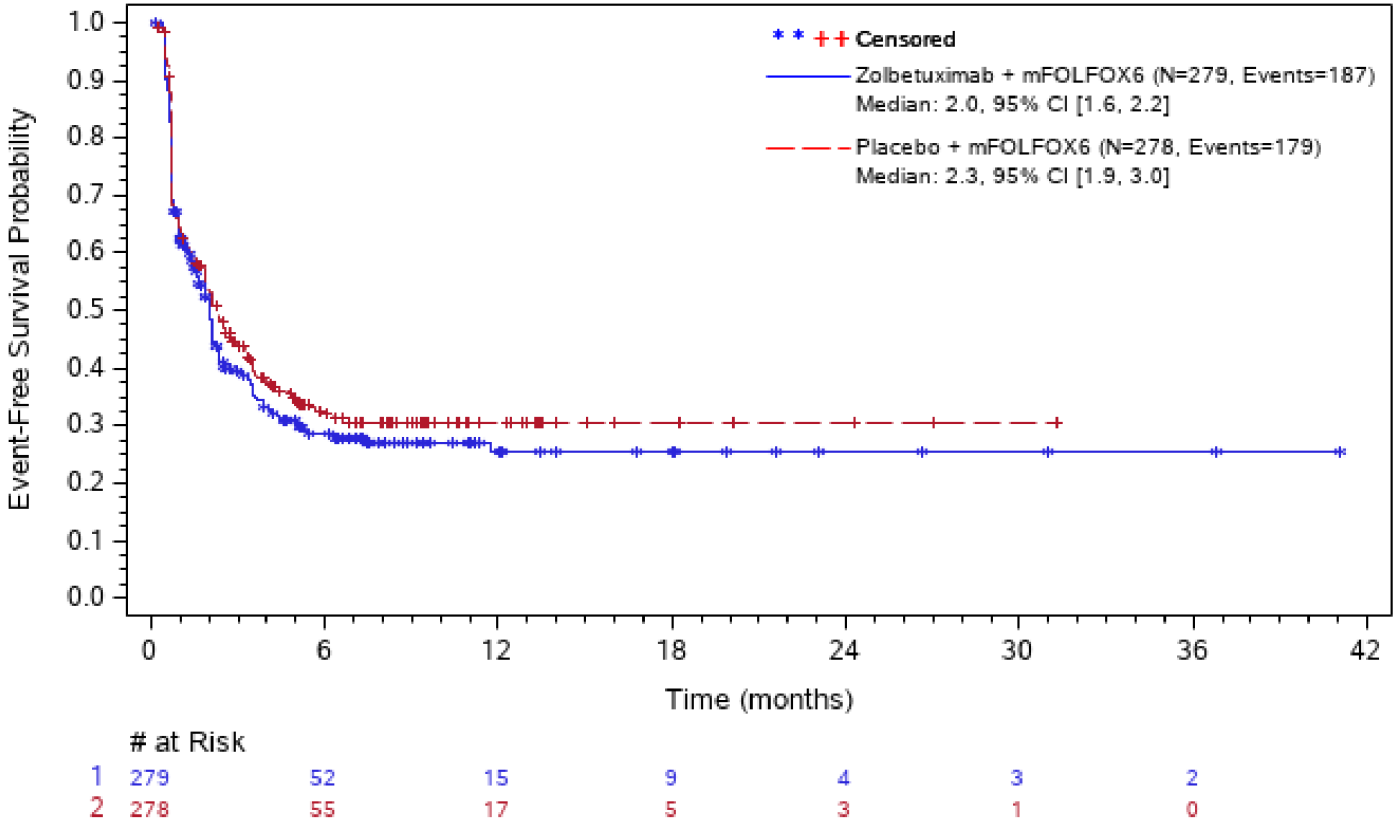
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.209: Kaplan-Meier Plot of Time to first TEAE - Nausea (AESI) - Safety Analysis Set



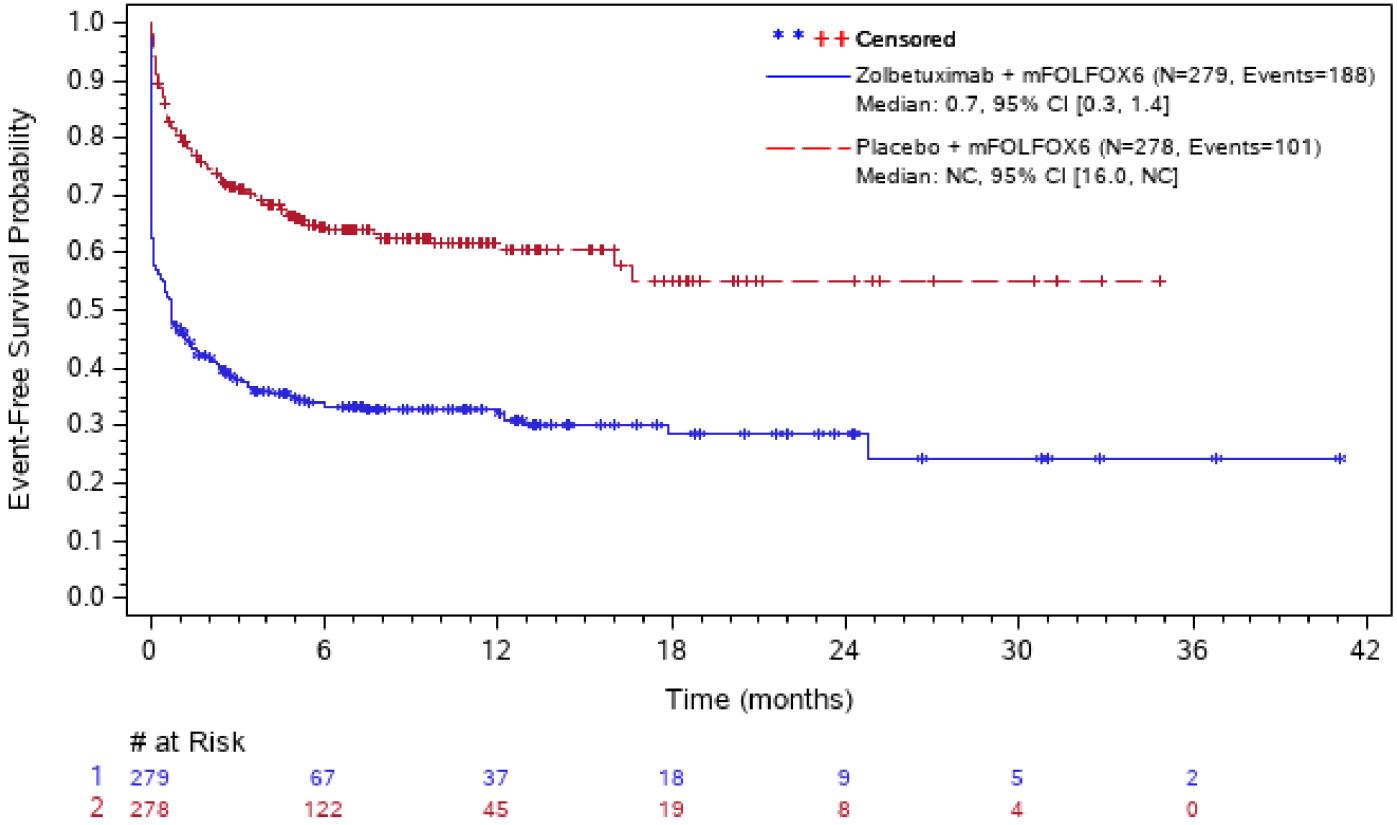
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.210: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (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: 09SEP22

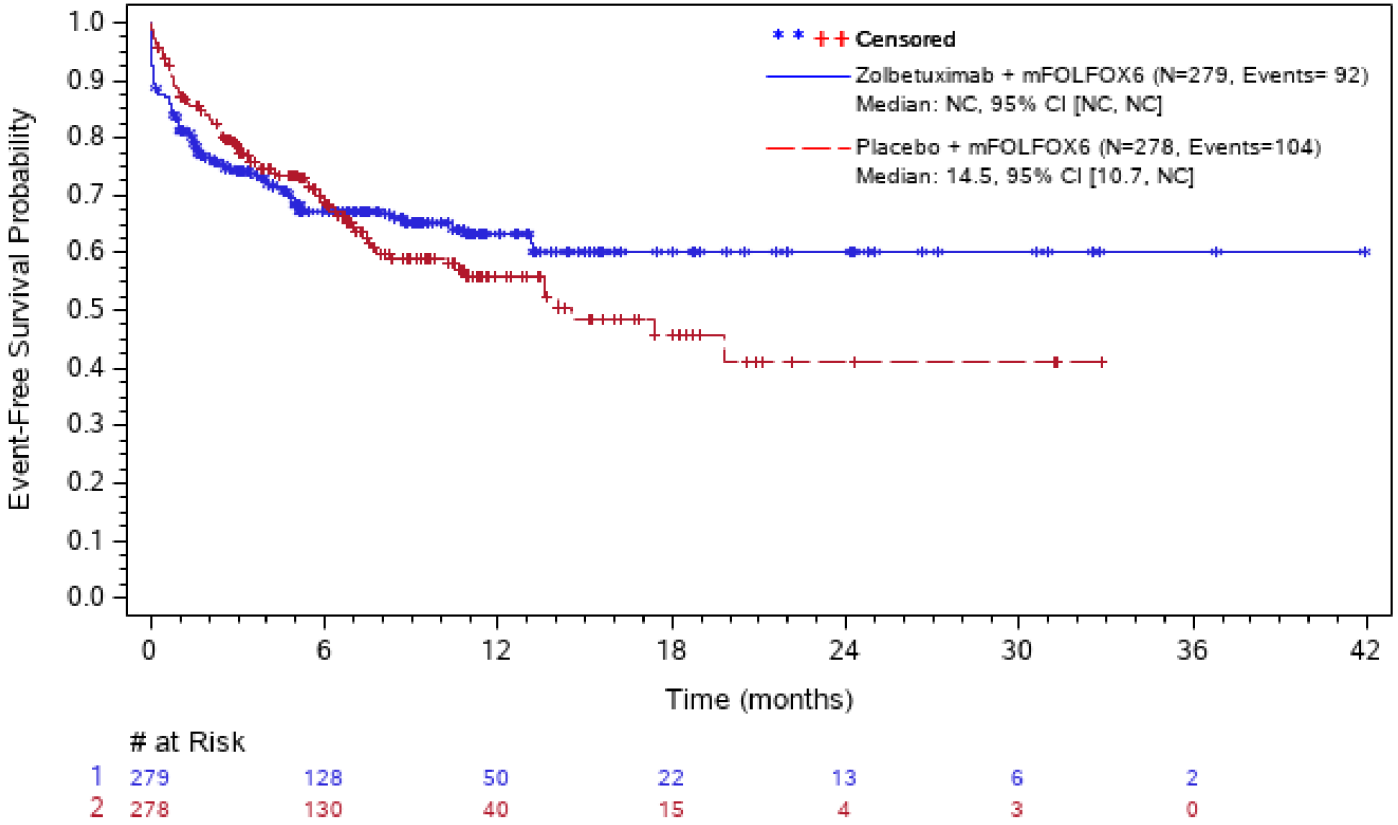
Figure 301.1.2001.211: Kaplan-Meier Plot of Time to first TEAE - Vomiting (AESI) - Safety Analysis Set



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.

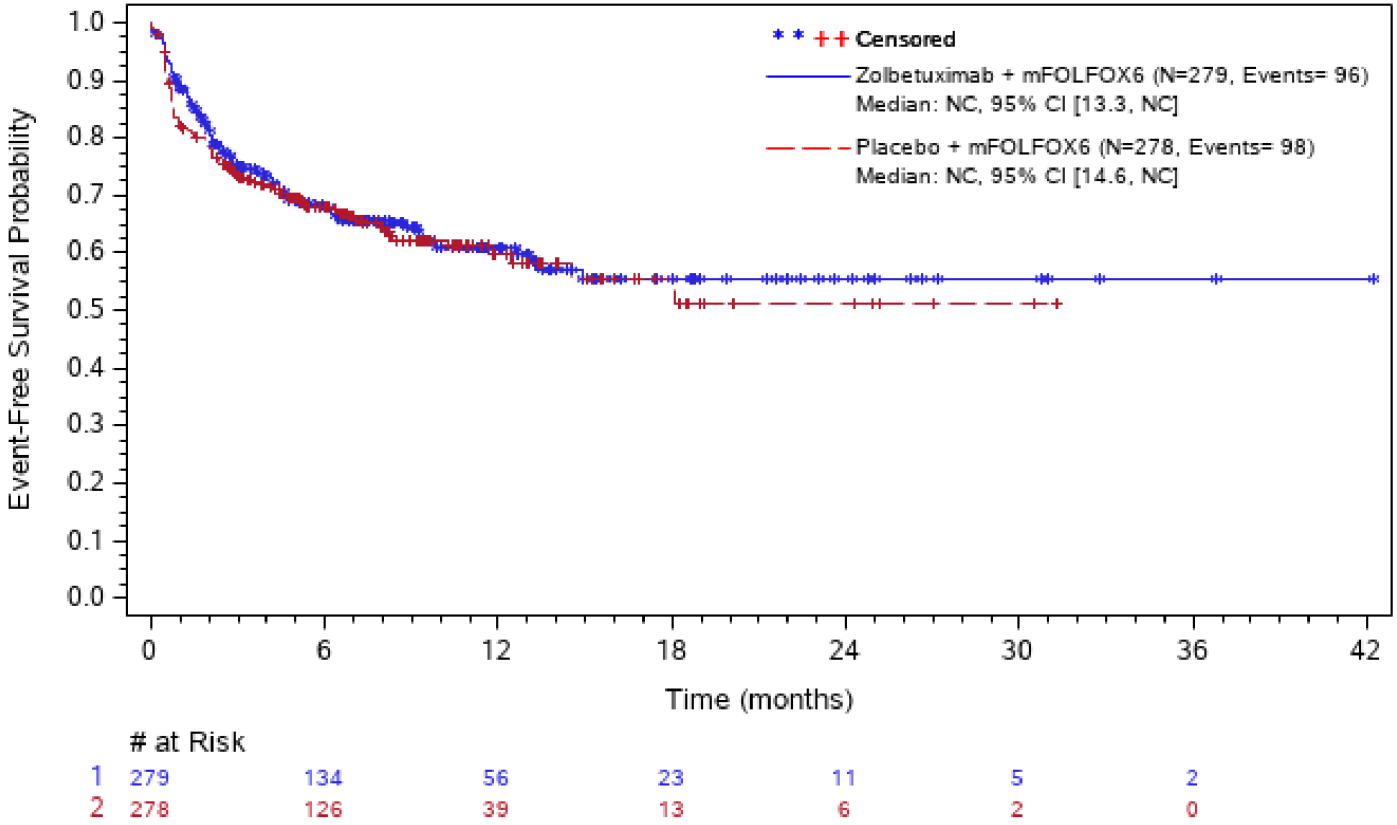
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.212: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Abdominal Pain (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: 09SEP22

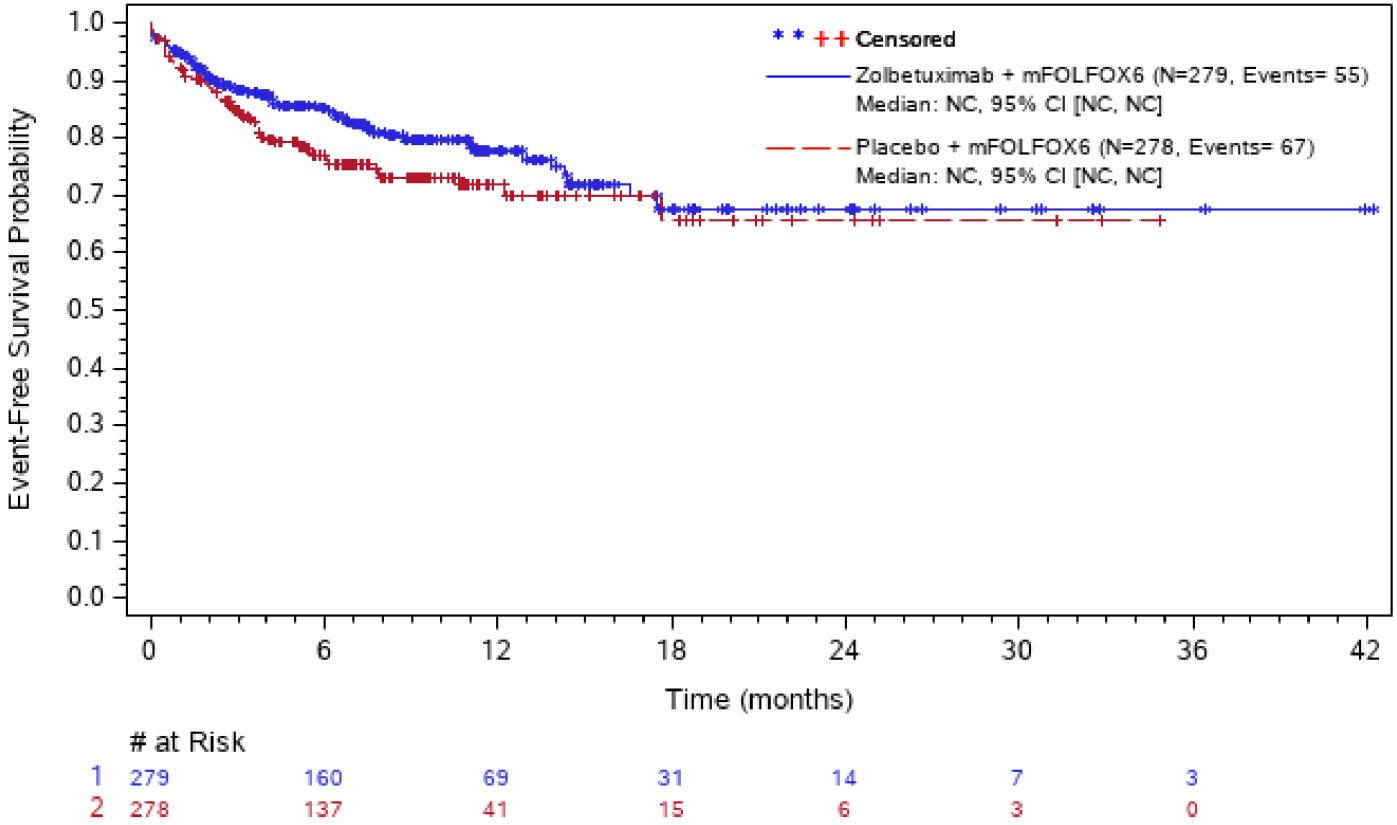
Figure 301.1.2001.213: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Anemia (AESI) - Safety Analysis Set



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.

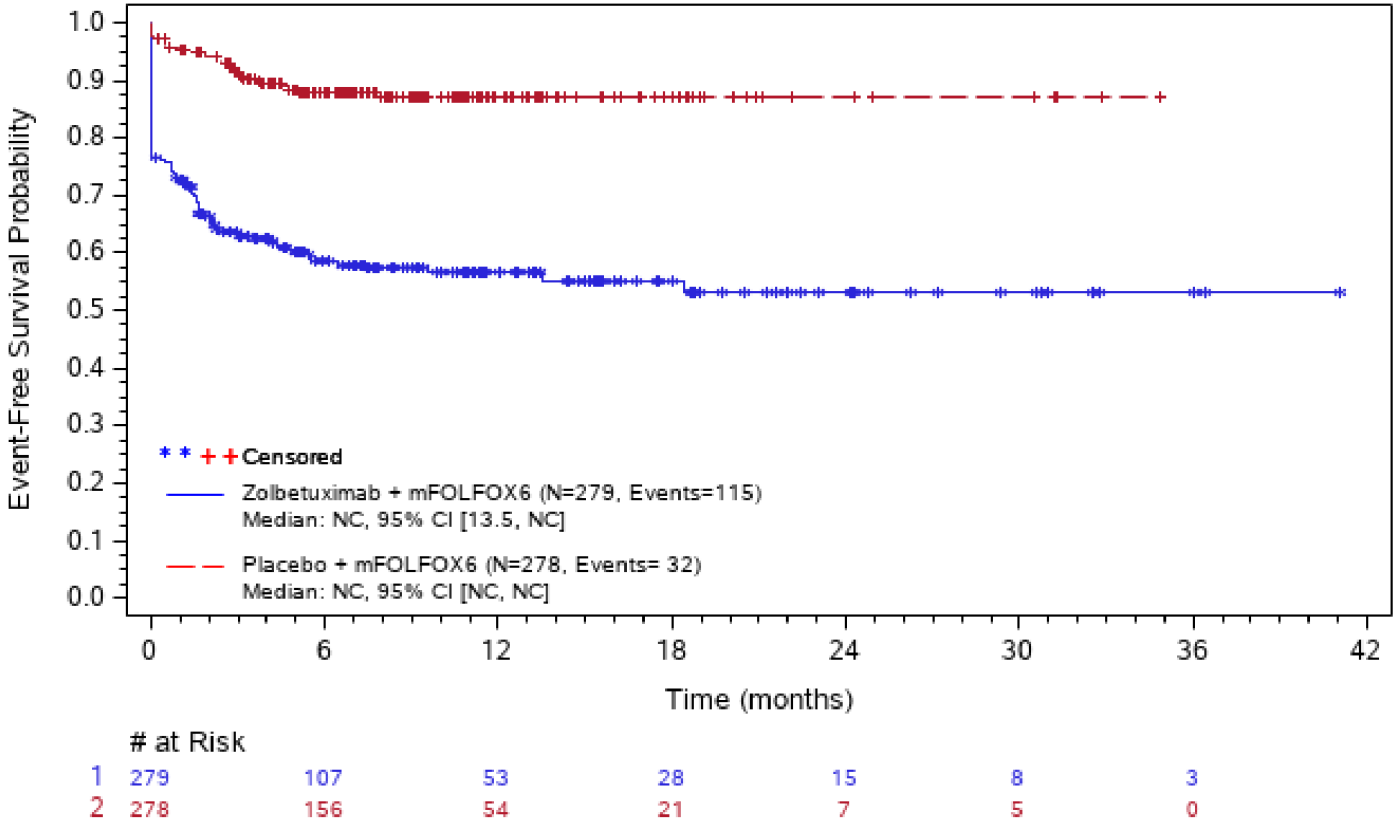
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.214: 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: 09SEP22

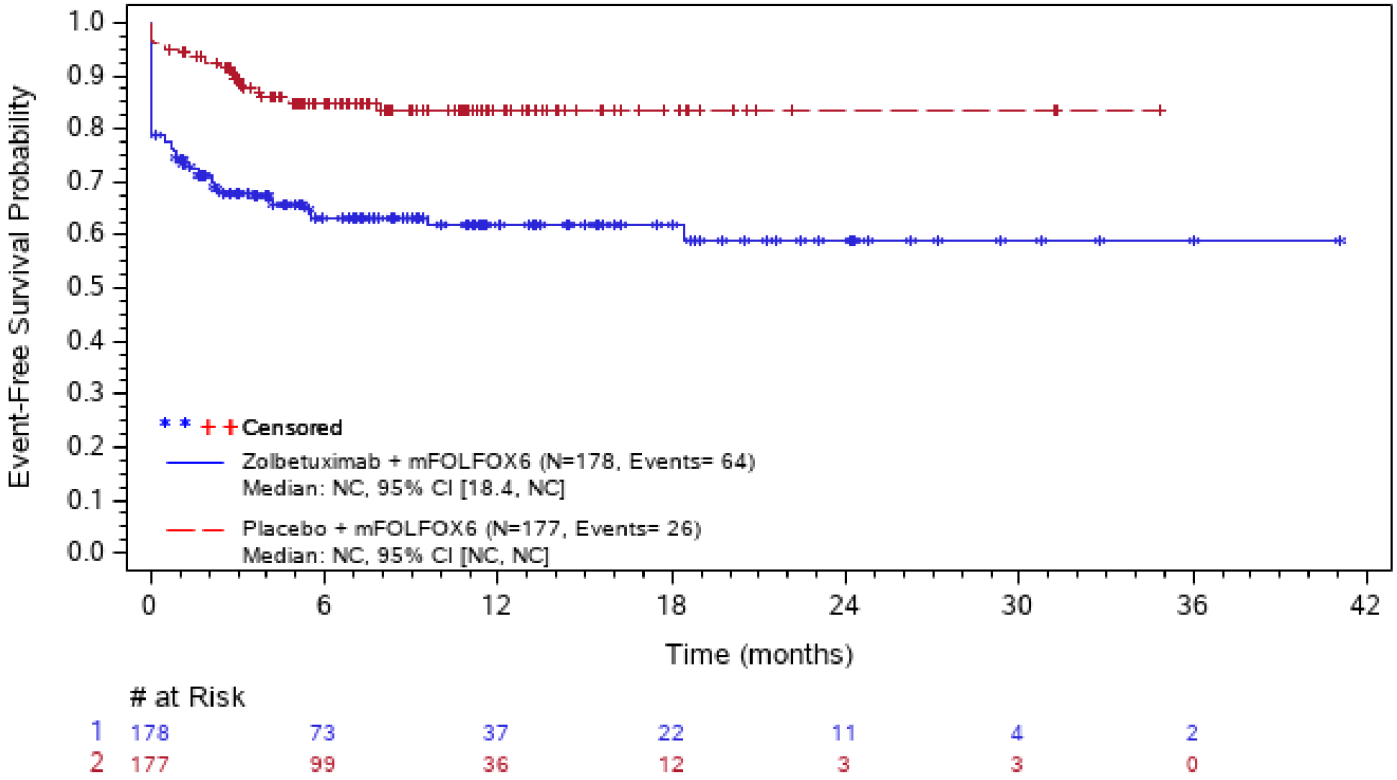
Figure 301.1.2001.215: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



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: 09SEP22

Figure 301.1.2001.215.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set

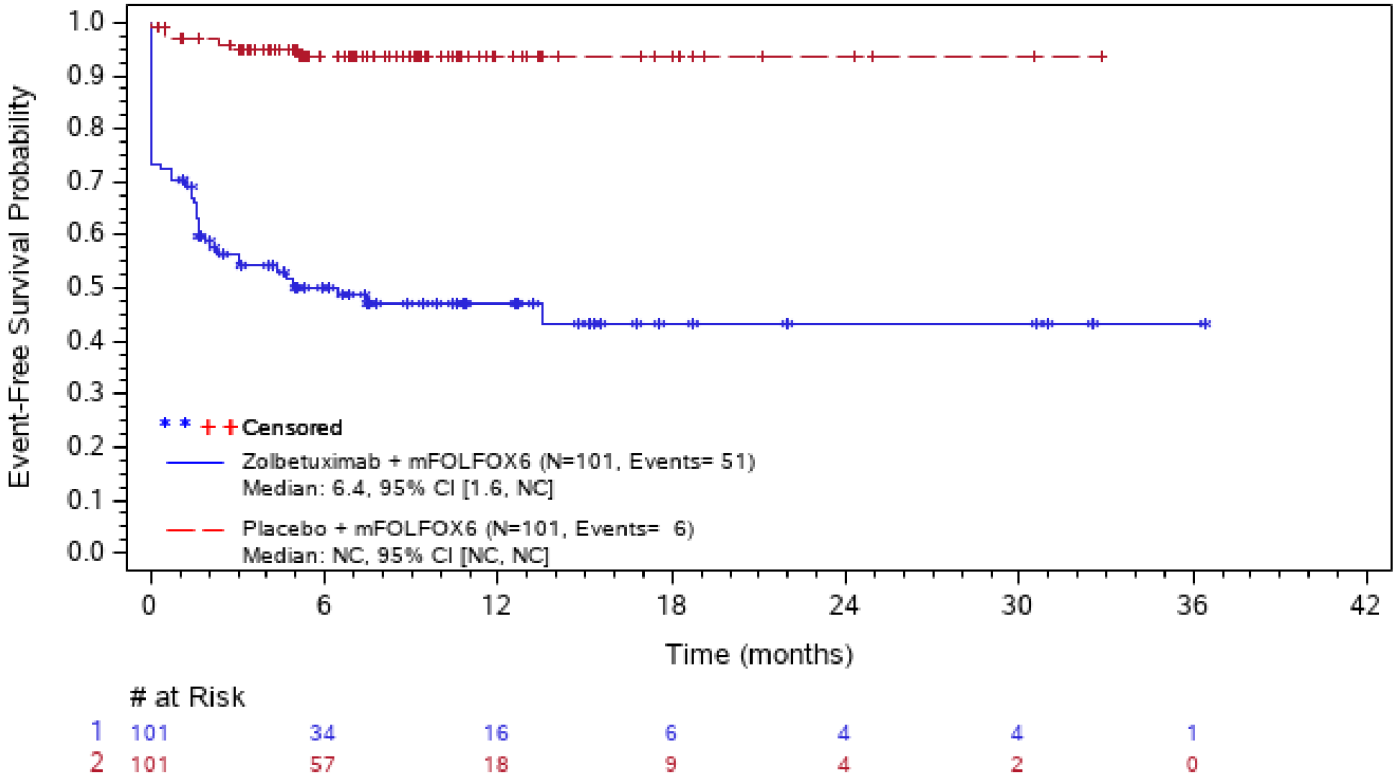
Age Group 1: <=65 years



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.

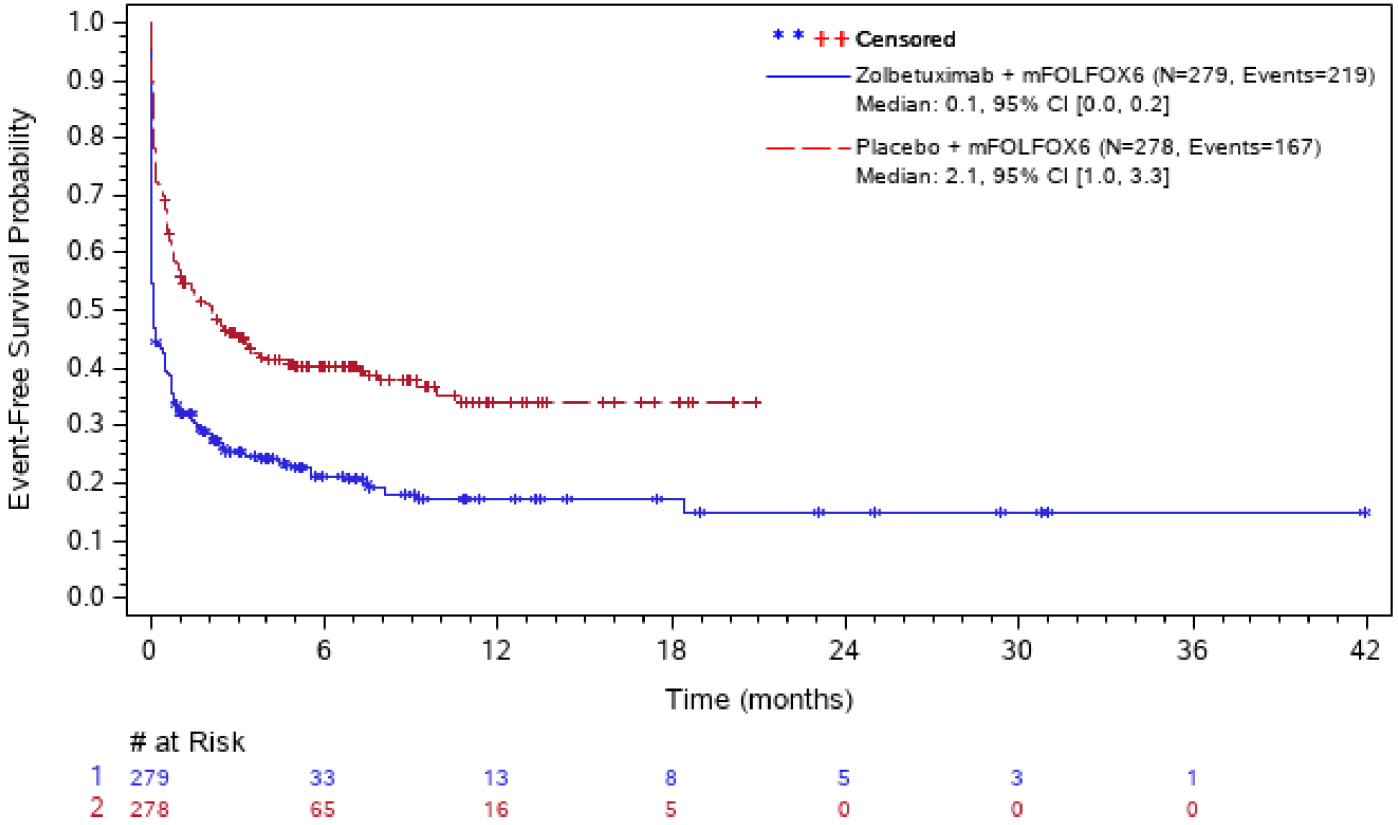
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.215.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Infusion Related Reaction (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: 09SEP22

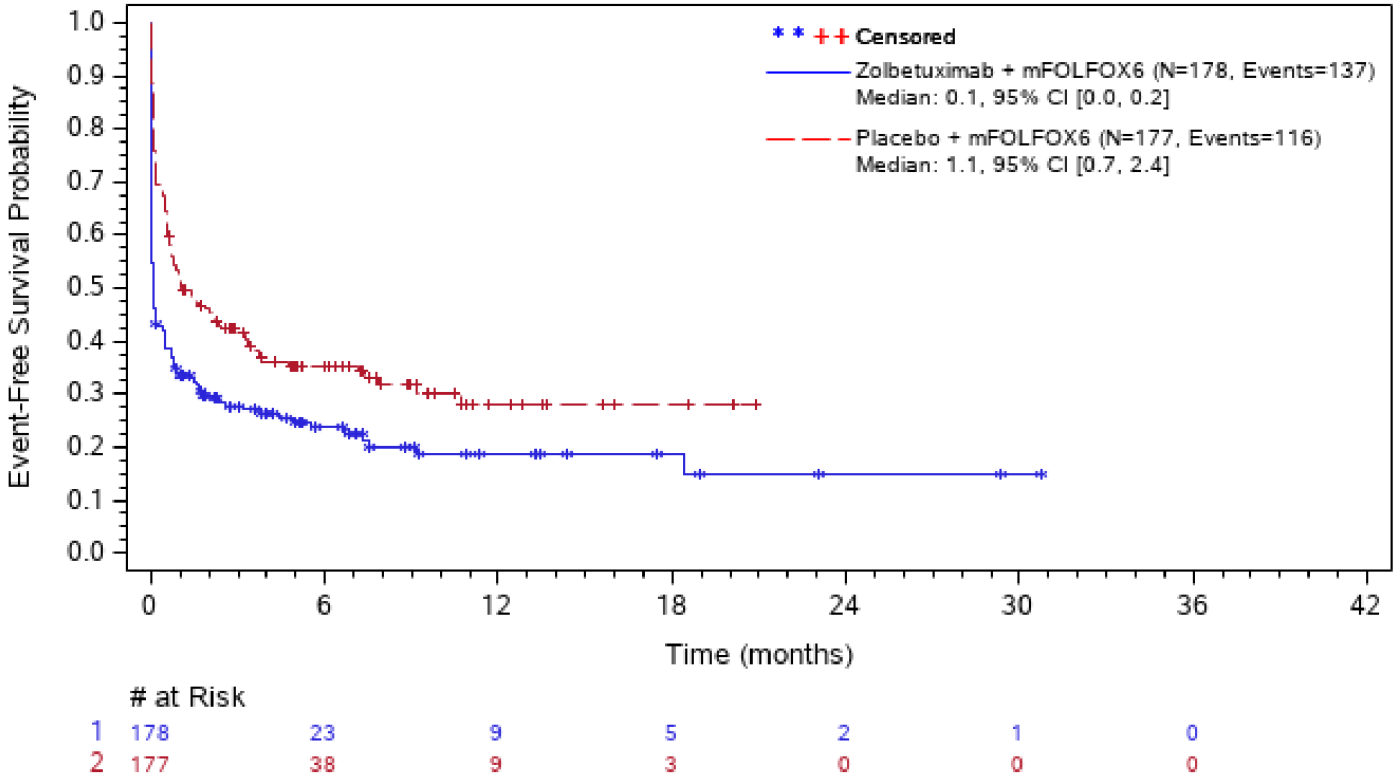
Figure 301.1.2001.216: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Nausea (AESI) - Safety Analysis Set



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: 09SEP22

Figure 301.1.2001.216.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set

Age Group 1: <=65 years

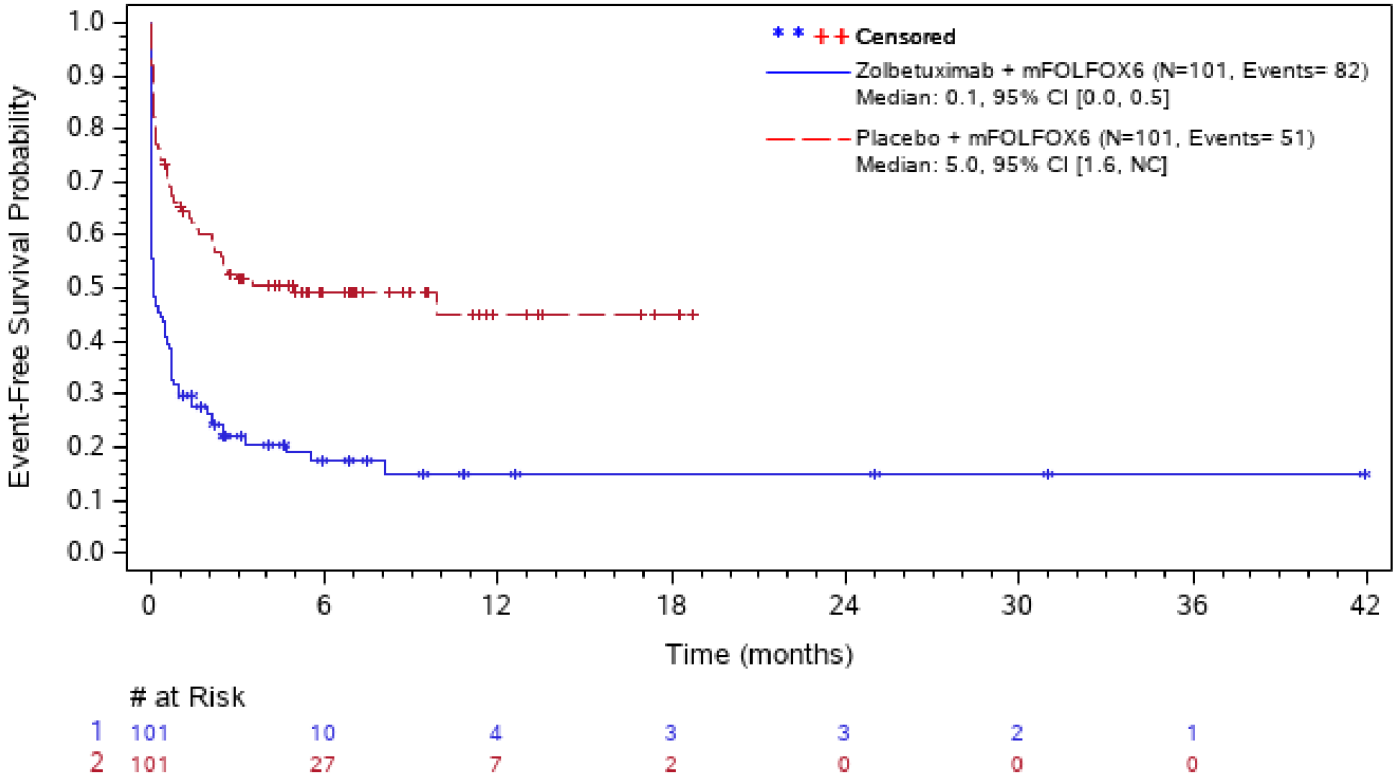


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.216.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set

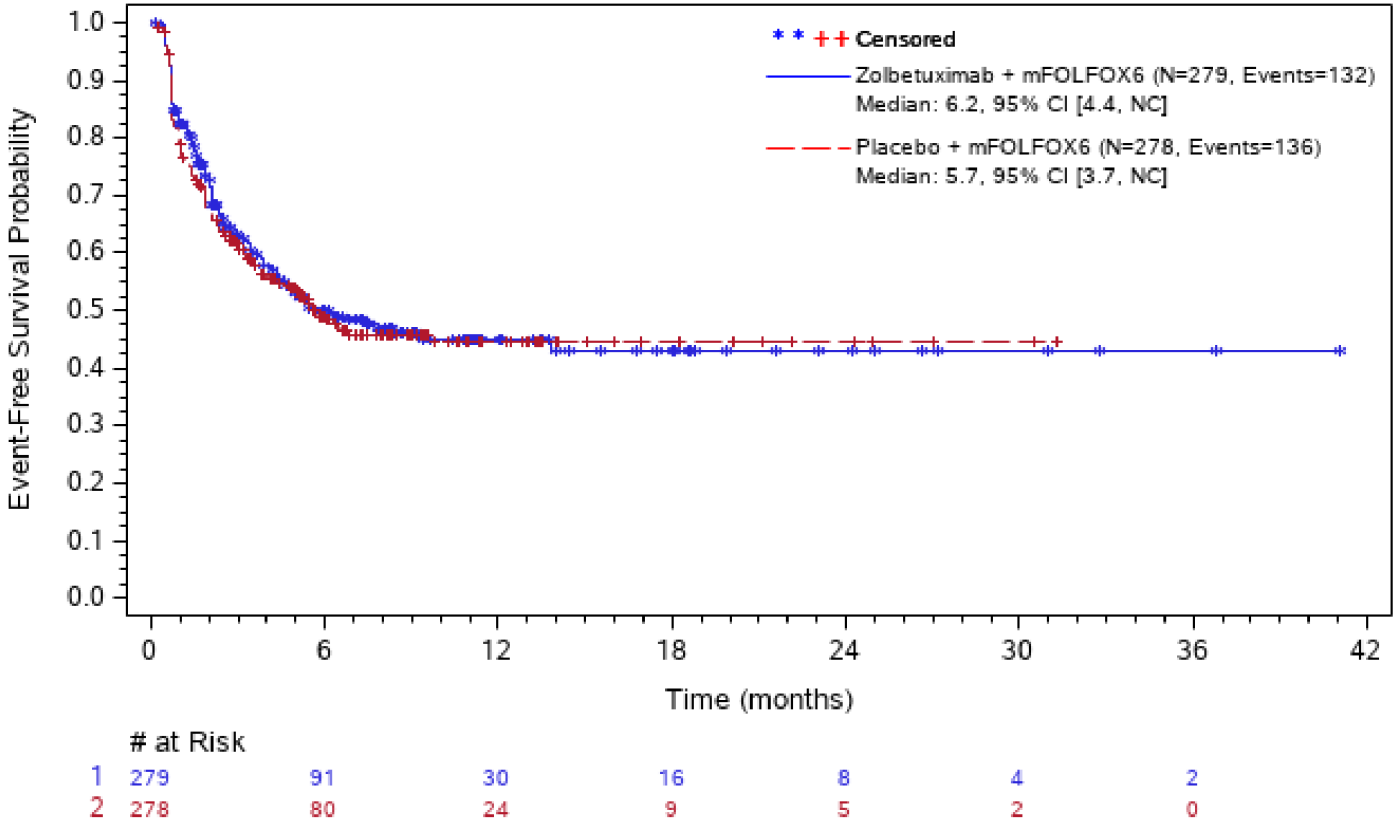
Age Group 1: >65 years



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: 09SEP22

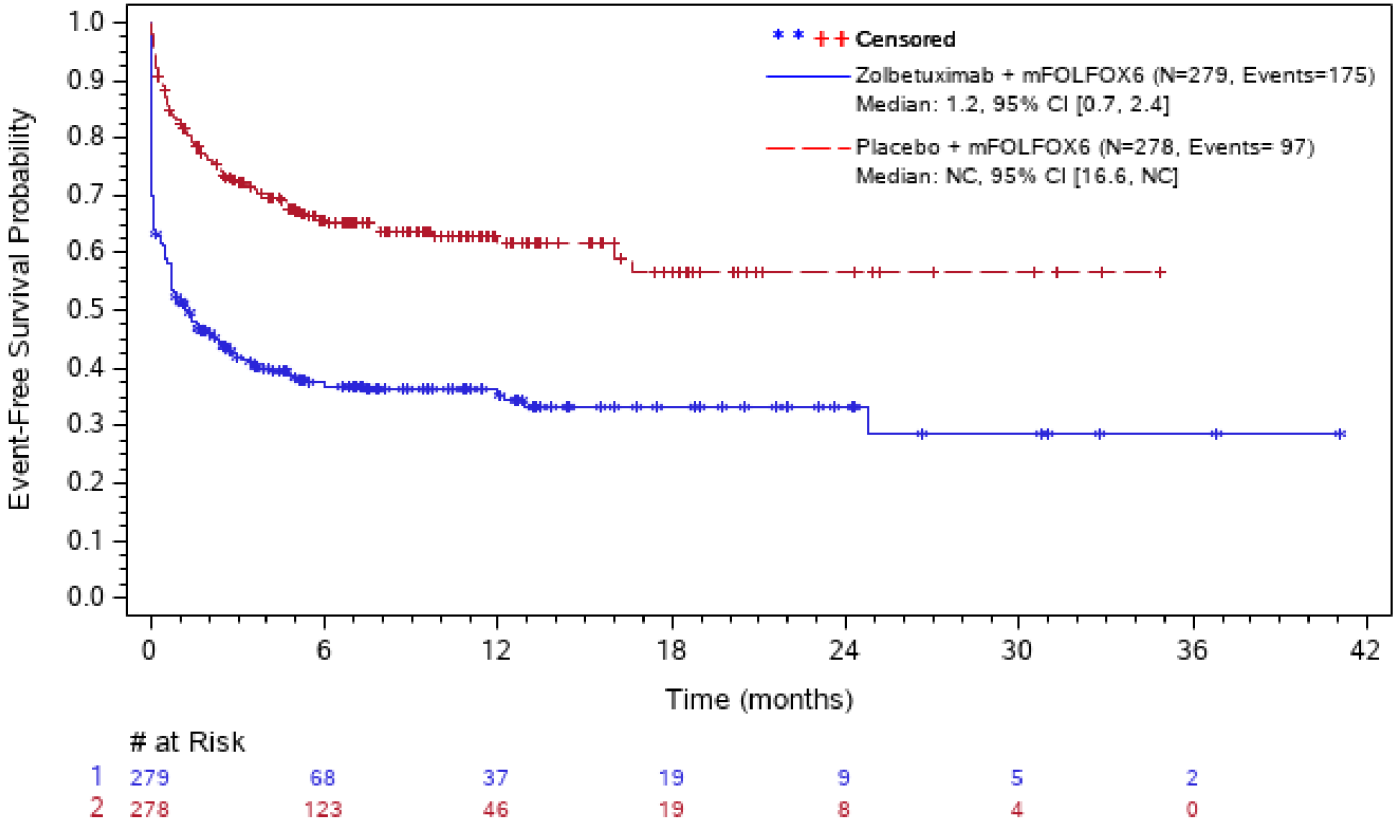
Figure 301.1.2001.217: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Neutropenia (AESI) - Safety Analysis Set



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.

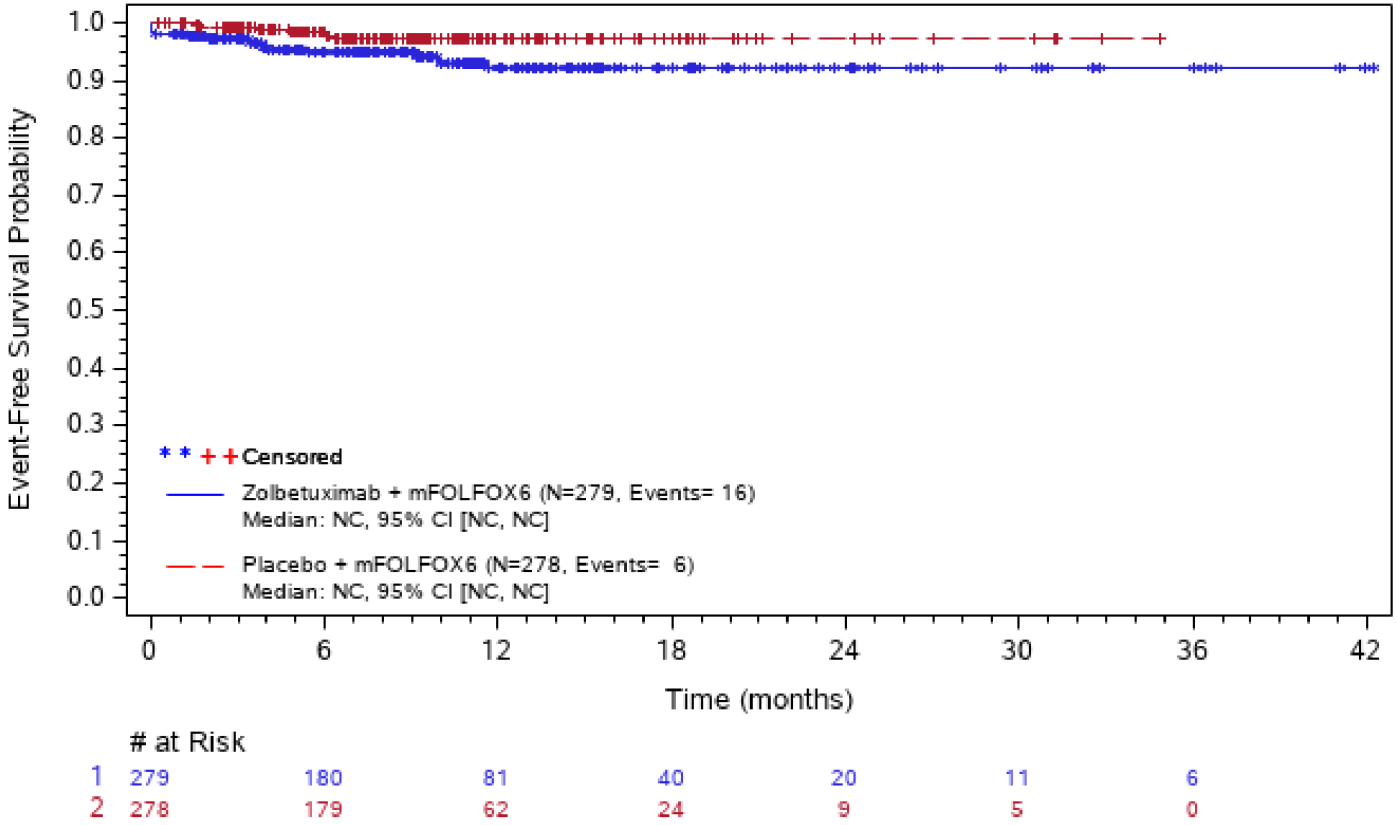
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.218: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Vomiting (AESI) - Safety Analysis Set



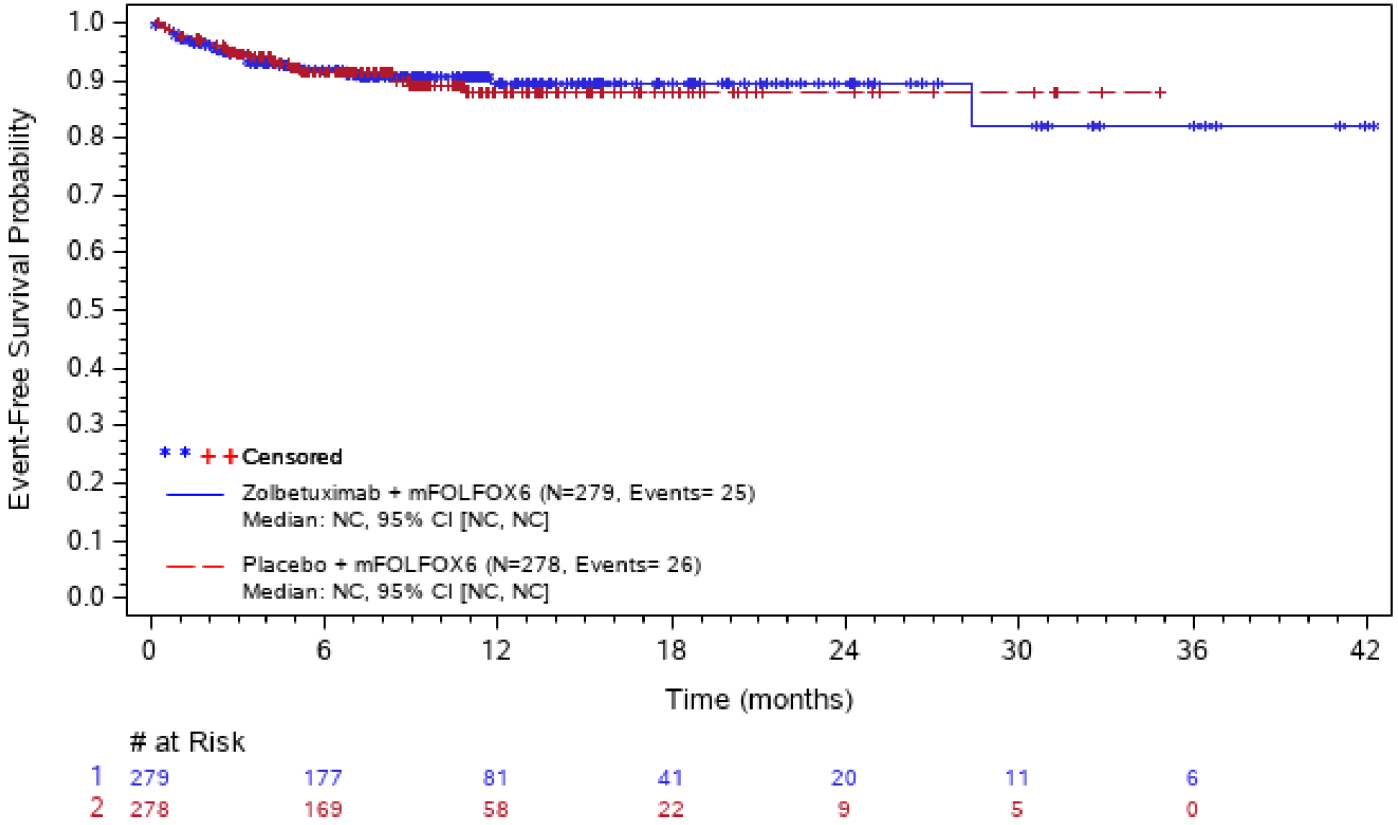
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.219: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set



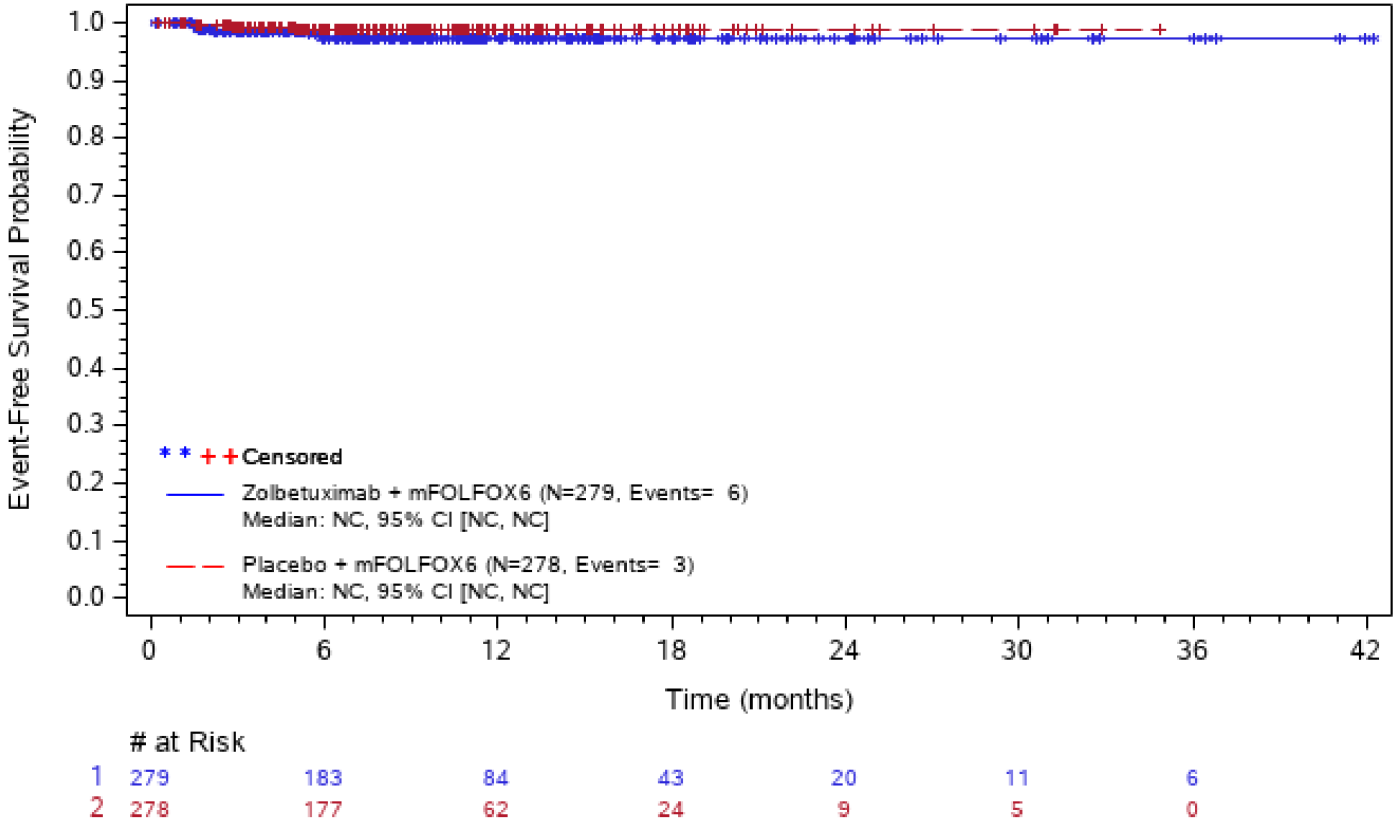
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.220: Kaplan-Meier Plot of Time to first Severe TEAE - Anemia (AESI) - Safety Analysis Set



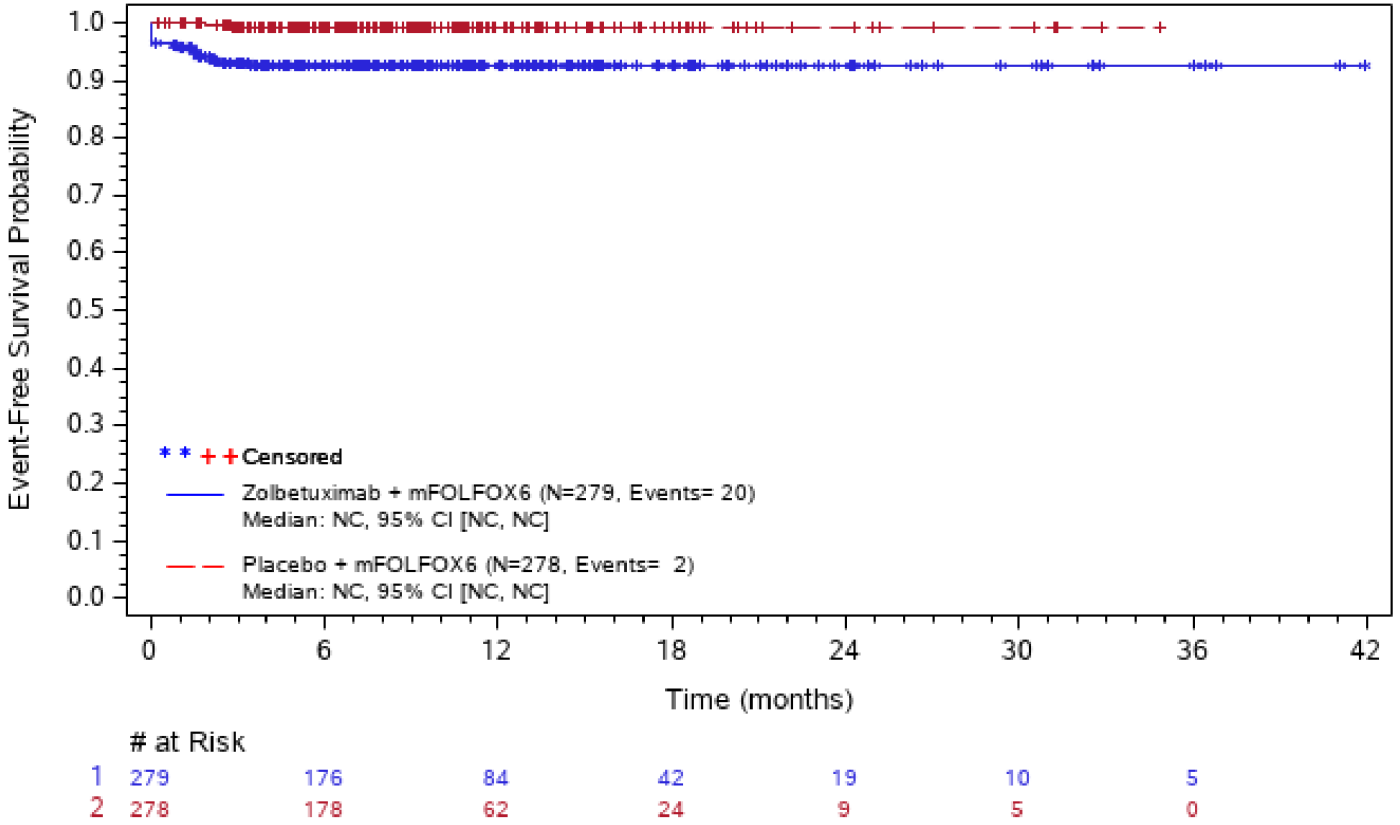
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.221: Kaplan-Meier Plot of Time to first Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



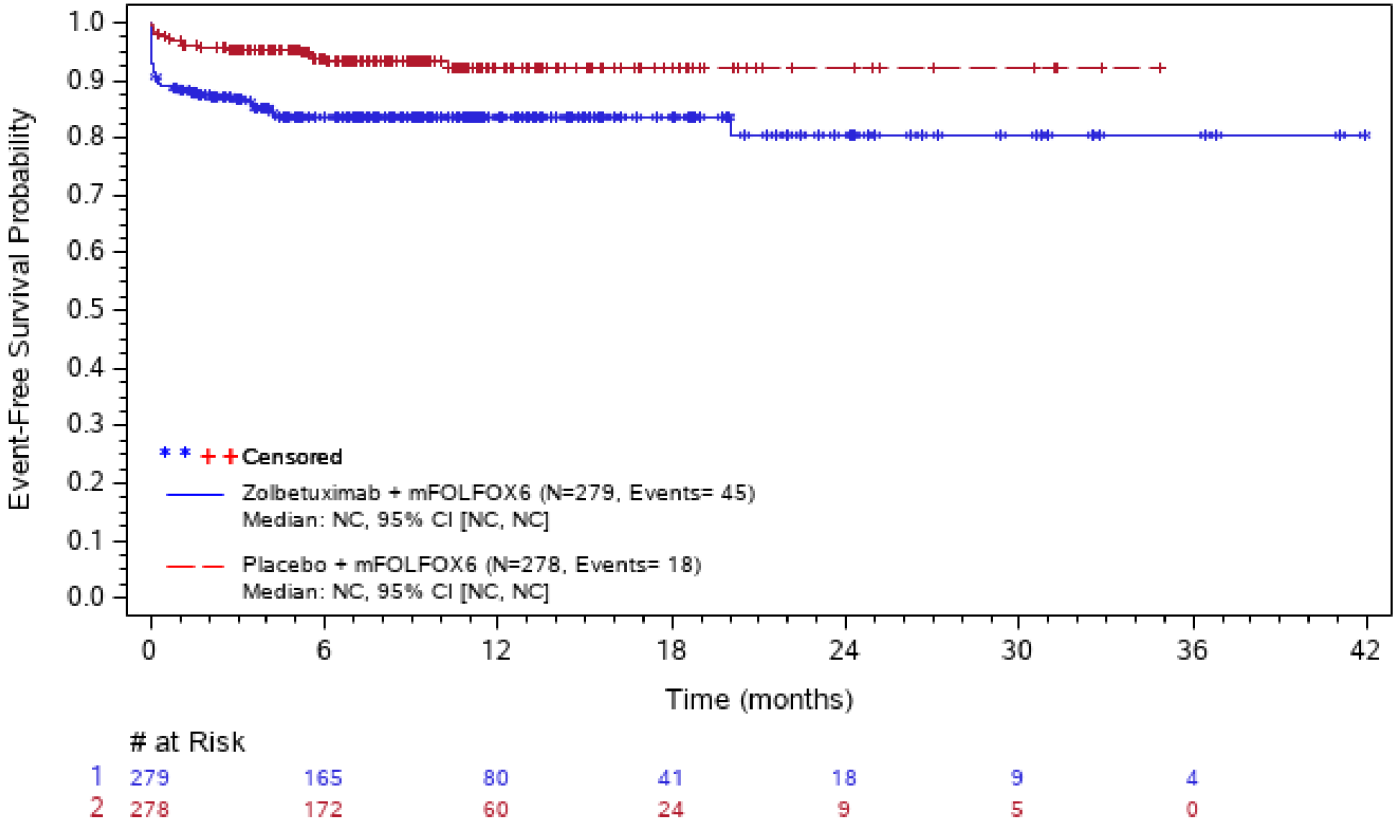
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.222: Kaplan-Meier Plot of Time to first Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



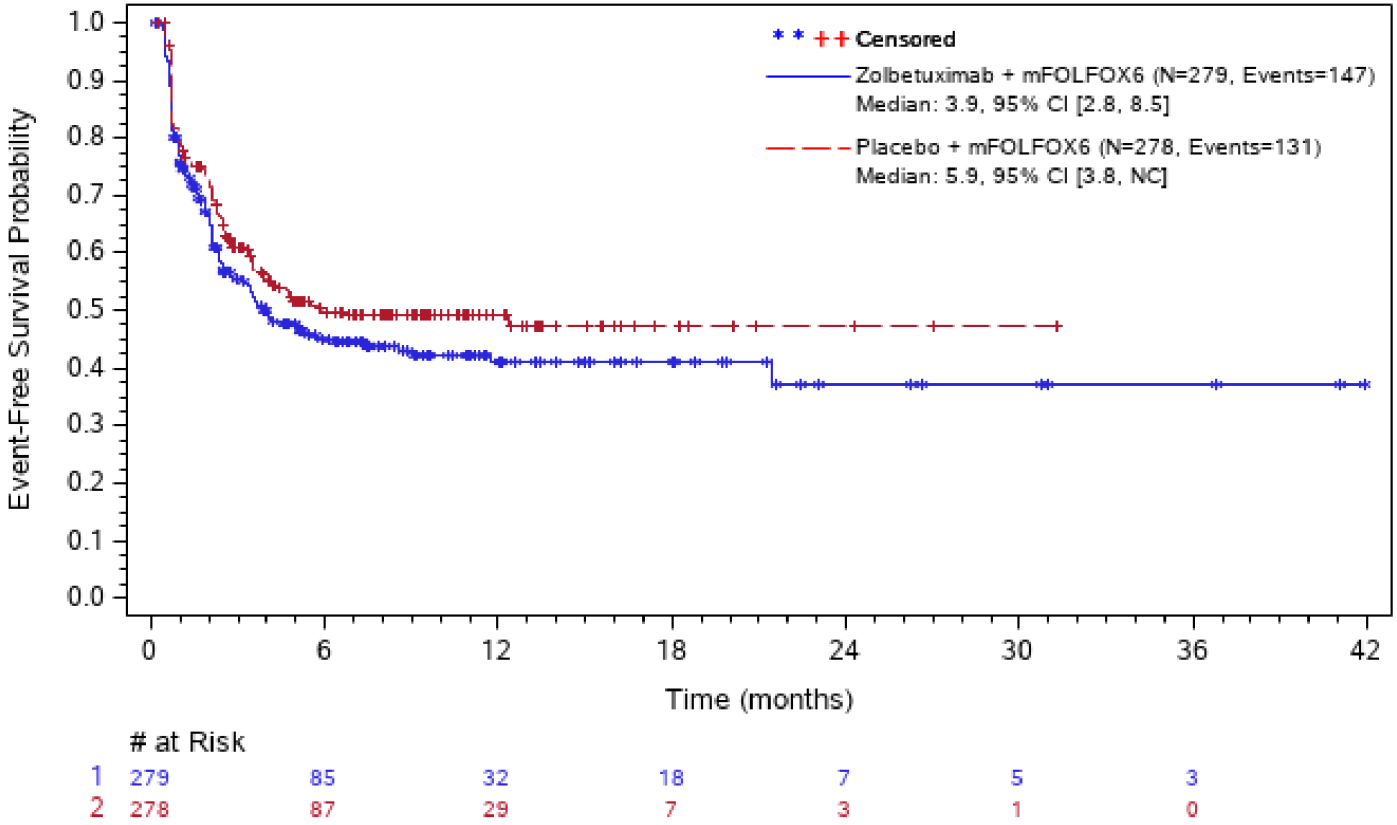
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.223: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (AESI) - Safety Analysis Set



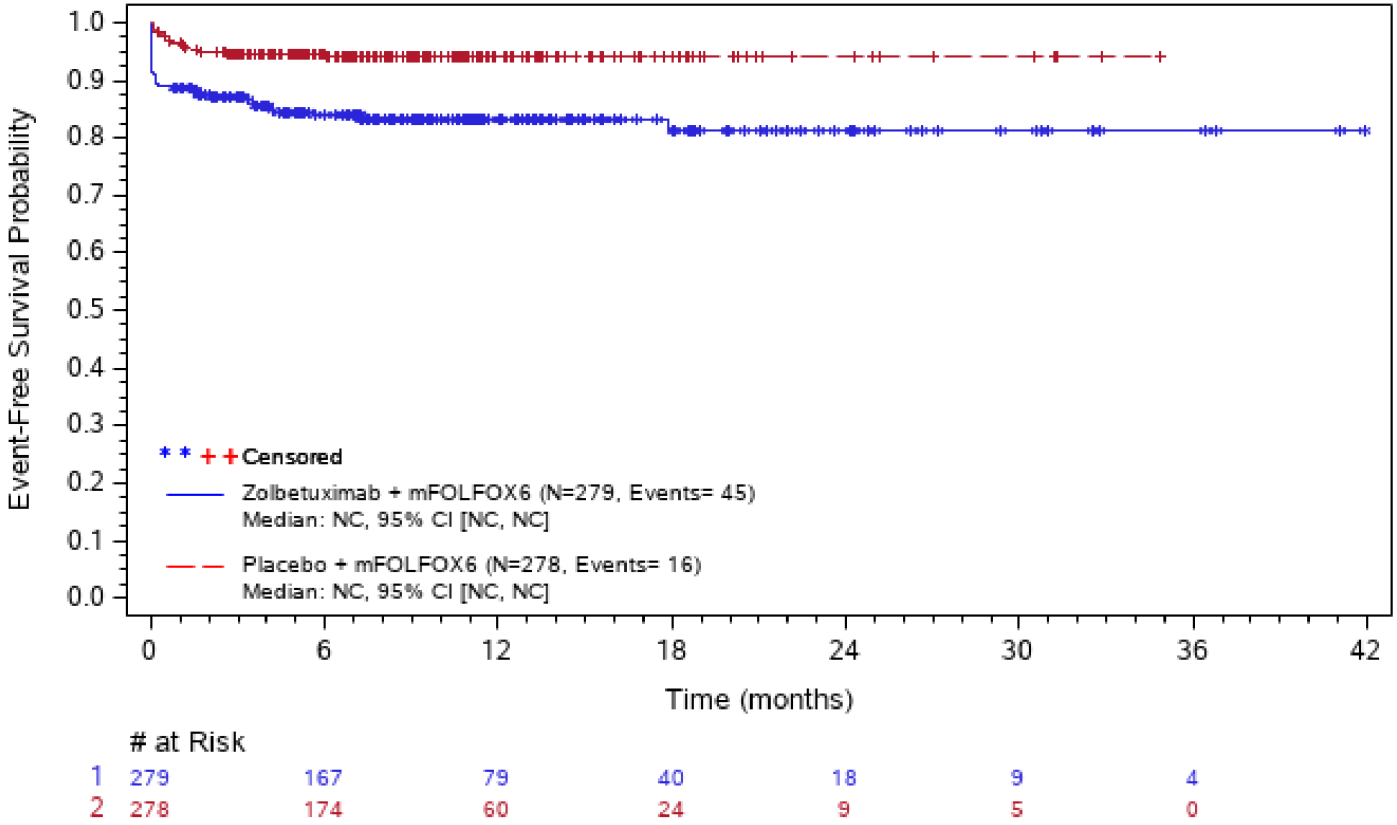
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.224: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (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: 09SEP22

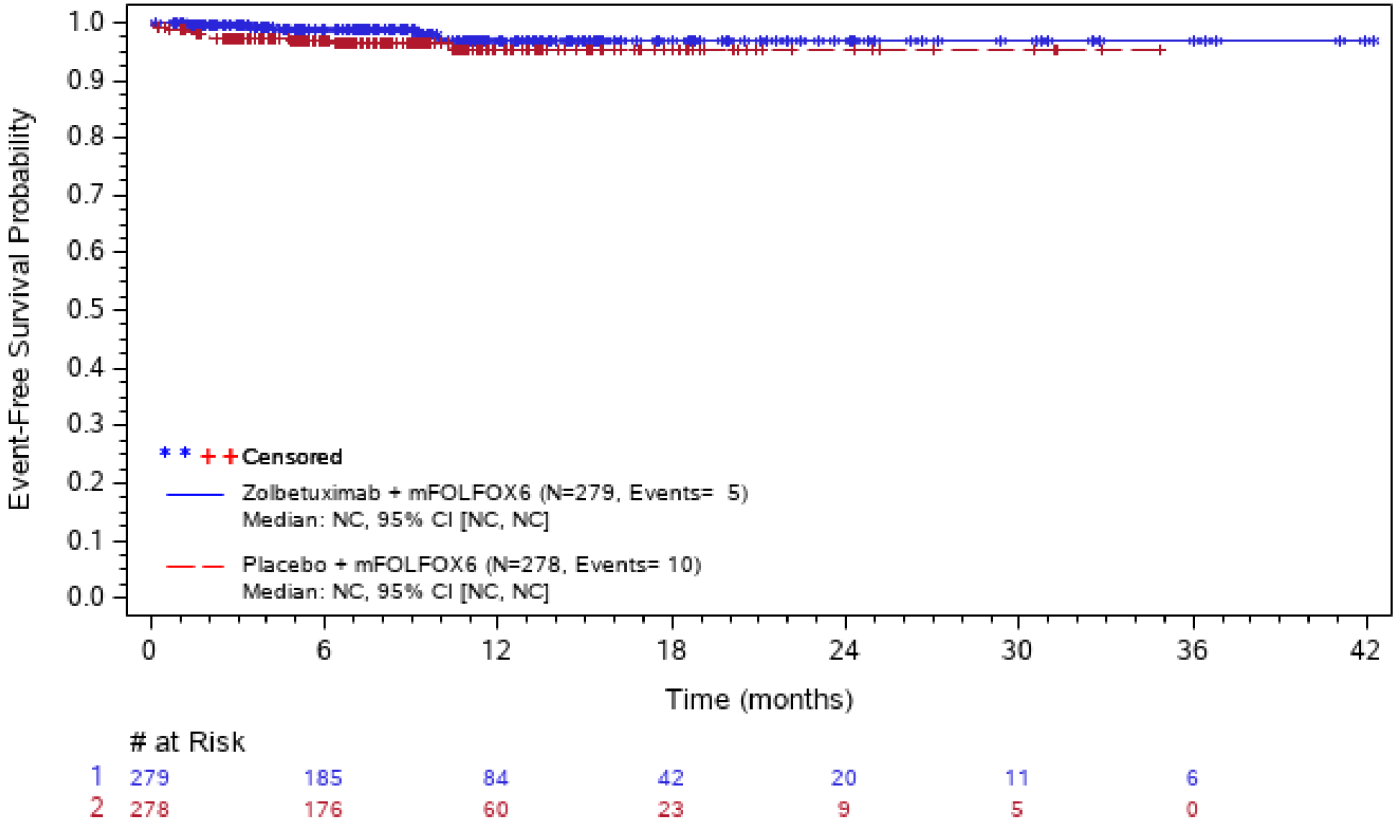
Figure 301.1.2001.225: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (AESI) - Safety Analysis Set



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: 09SEP22

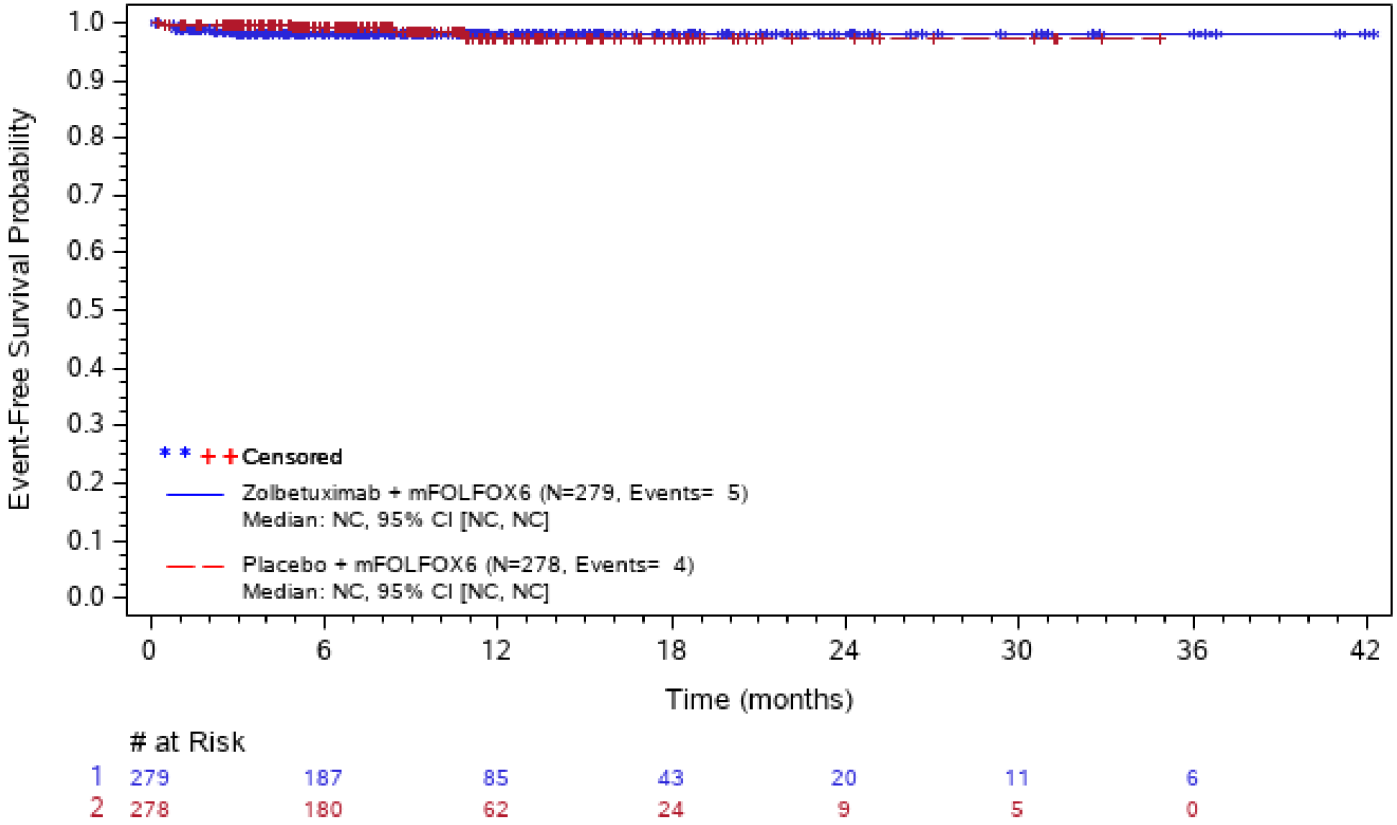
Figure 301.1.2001.226: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (AESI) - Safety Analysis Set



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.

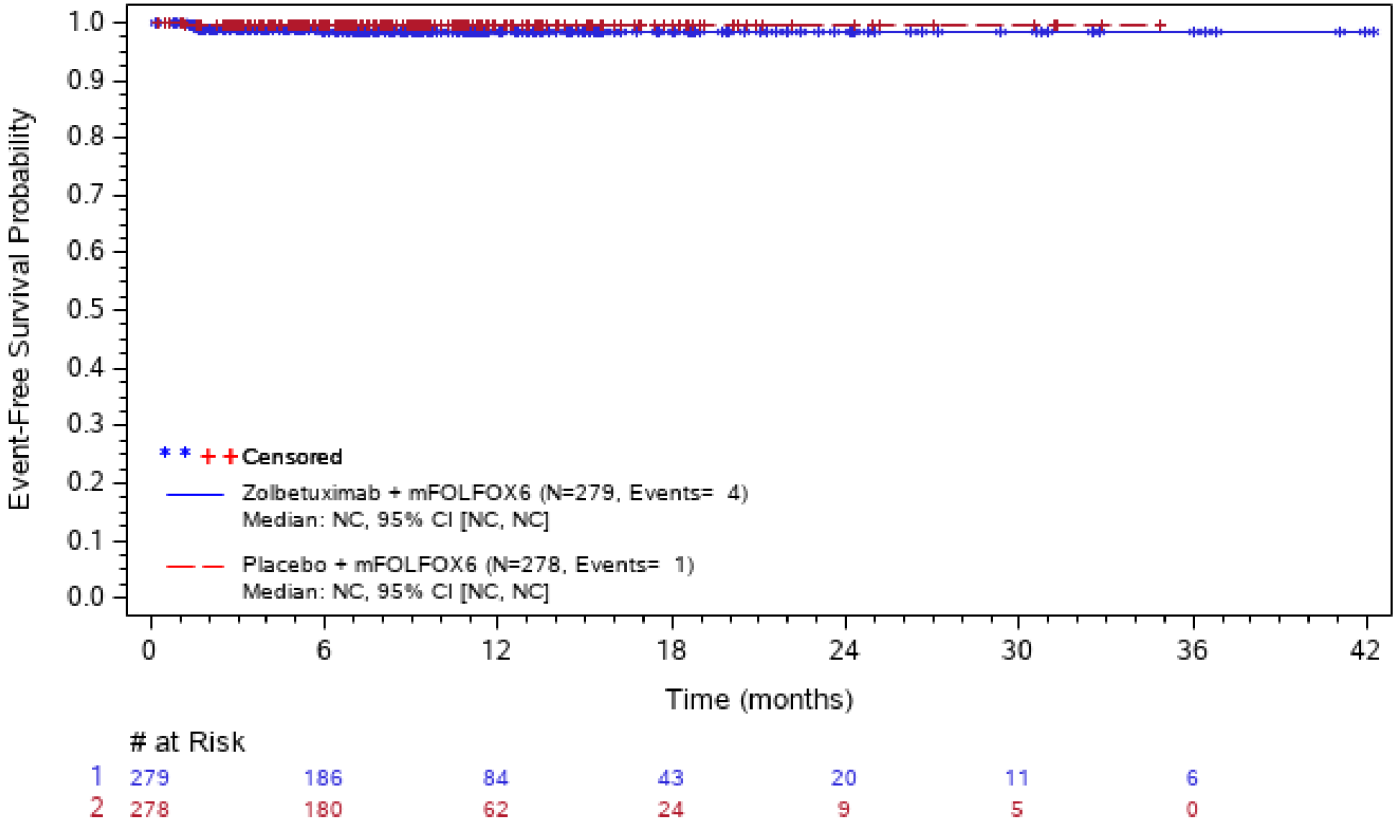
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.227: Kaplan-Meier Plot of Time to first TESAE - Anemia (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: 09SEP22

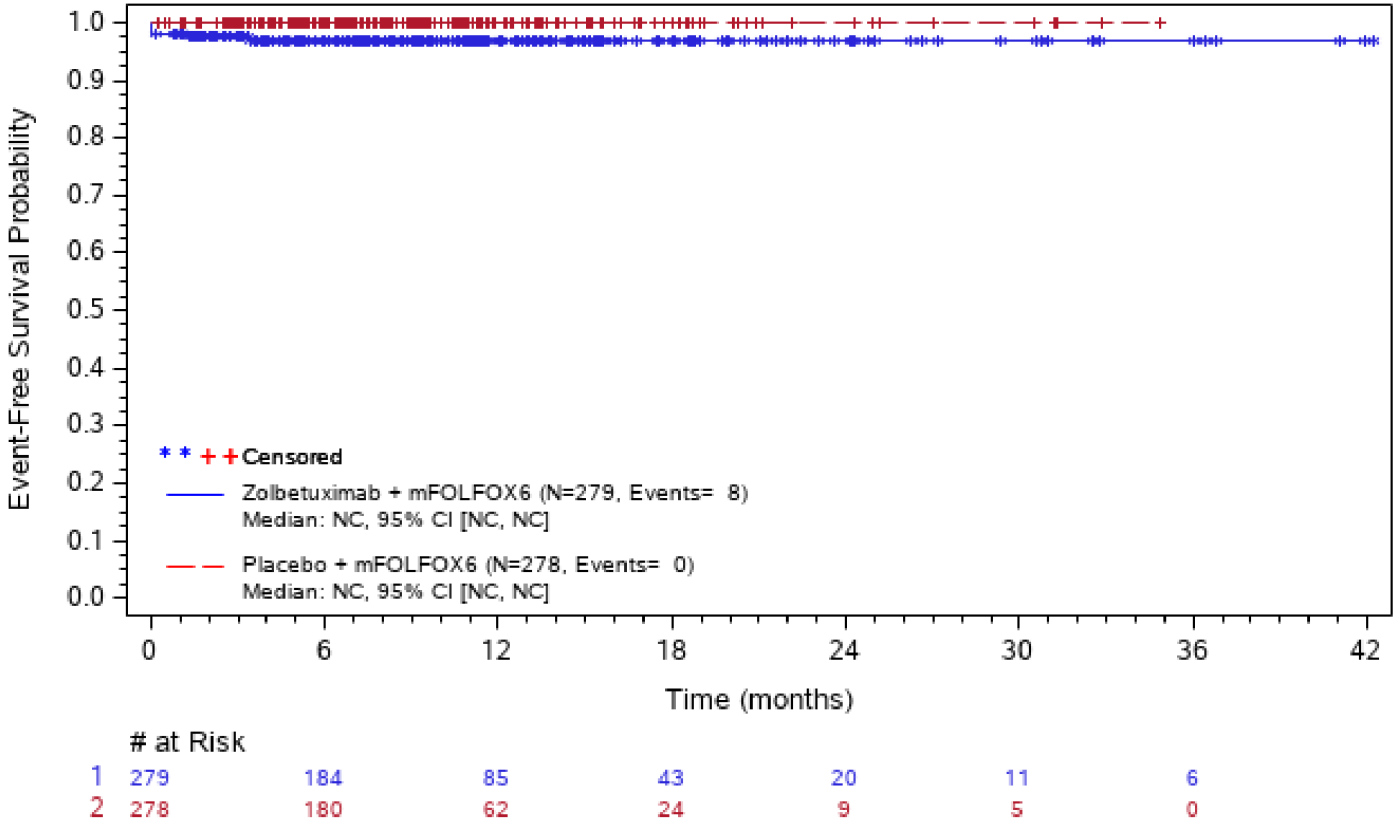
Figure 301.1.2001.228: Kaplan-Meier Plot of Time to first TESAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



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.

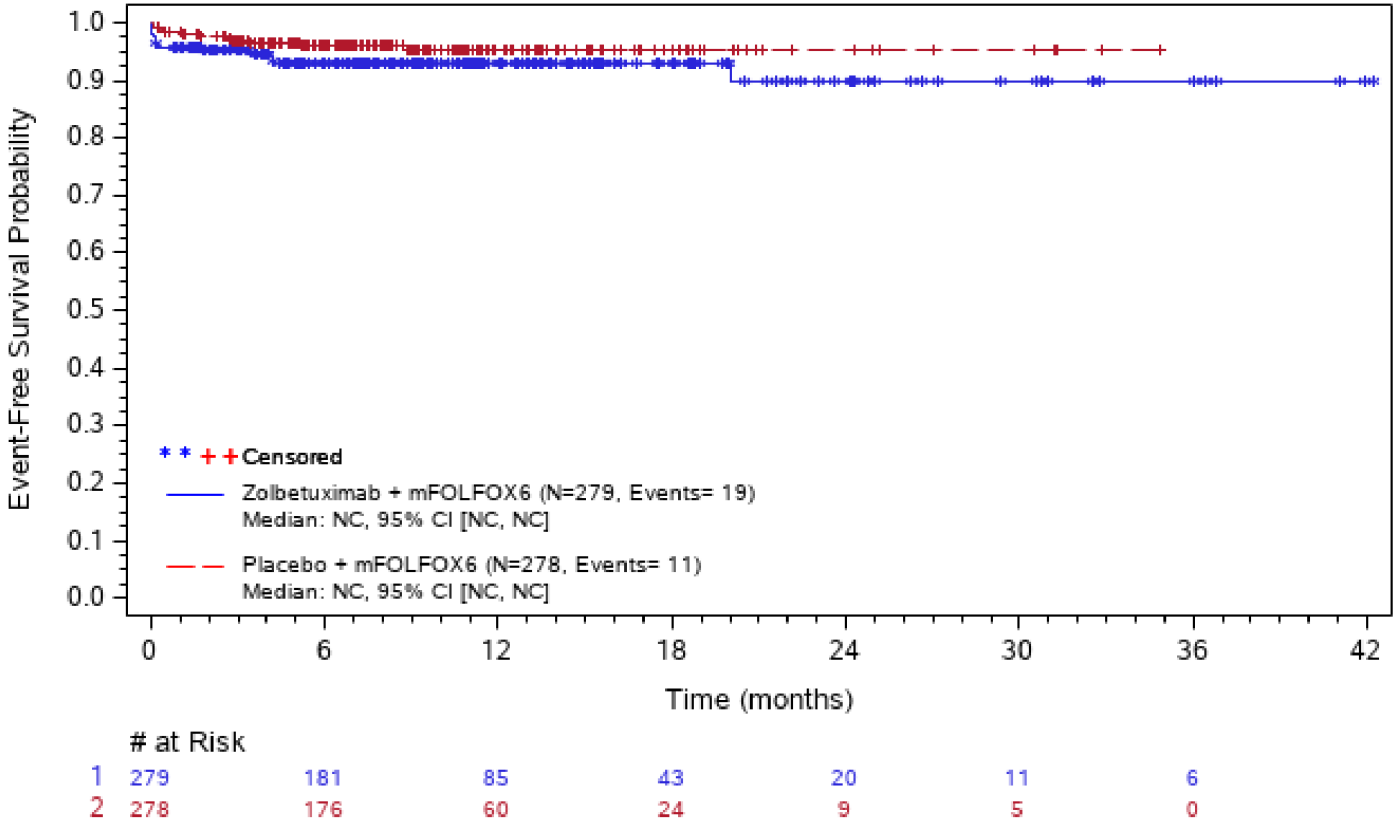
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.229: 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: 09SEP22

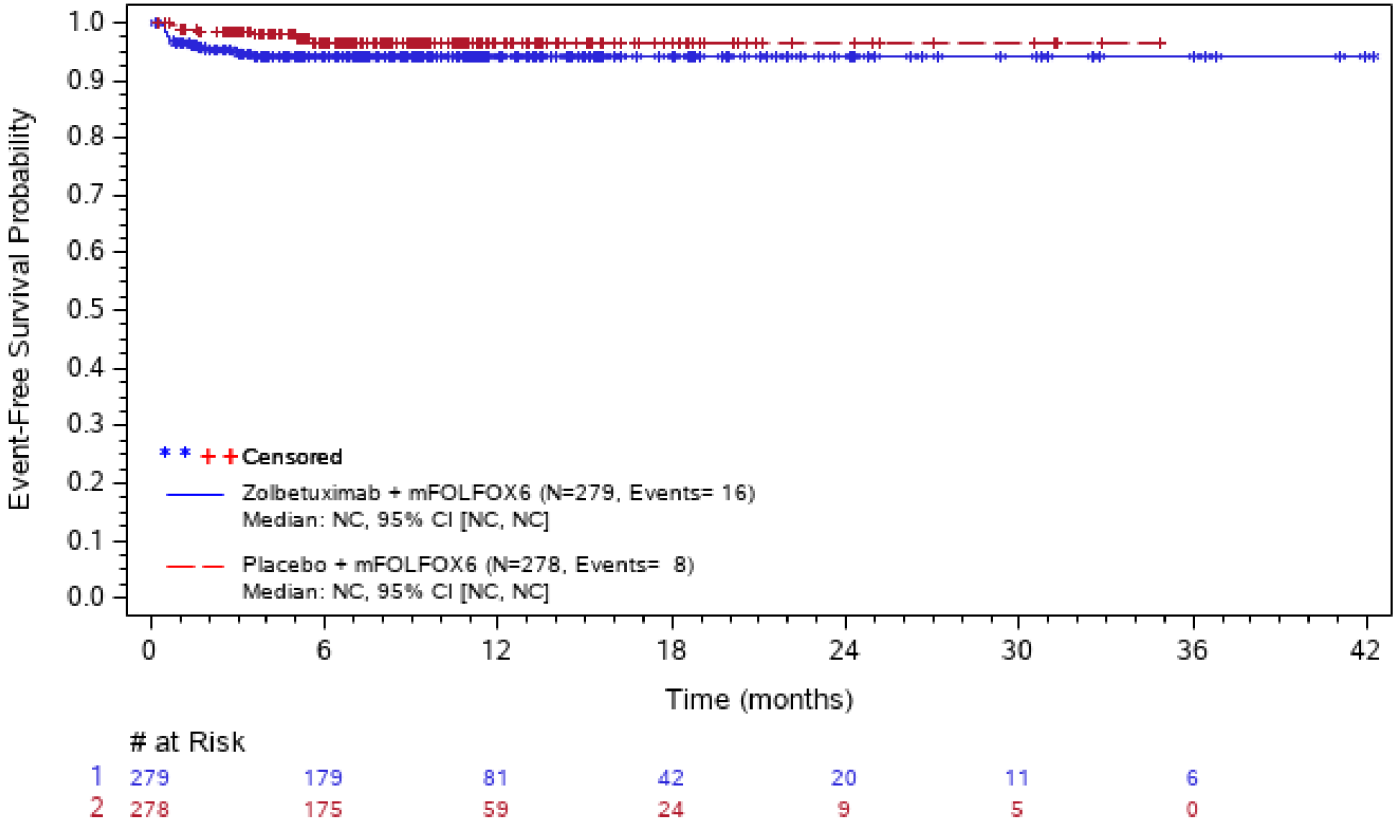
Figure 301.1.2001.230: Kaplan-Meier Plot of Time to first TESAE - Nausea (AESI) - Safety Analysis Set



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.

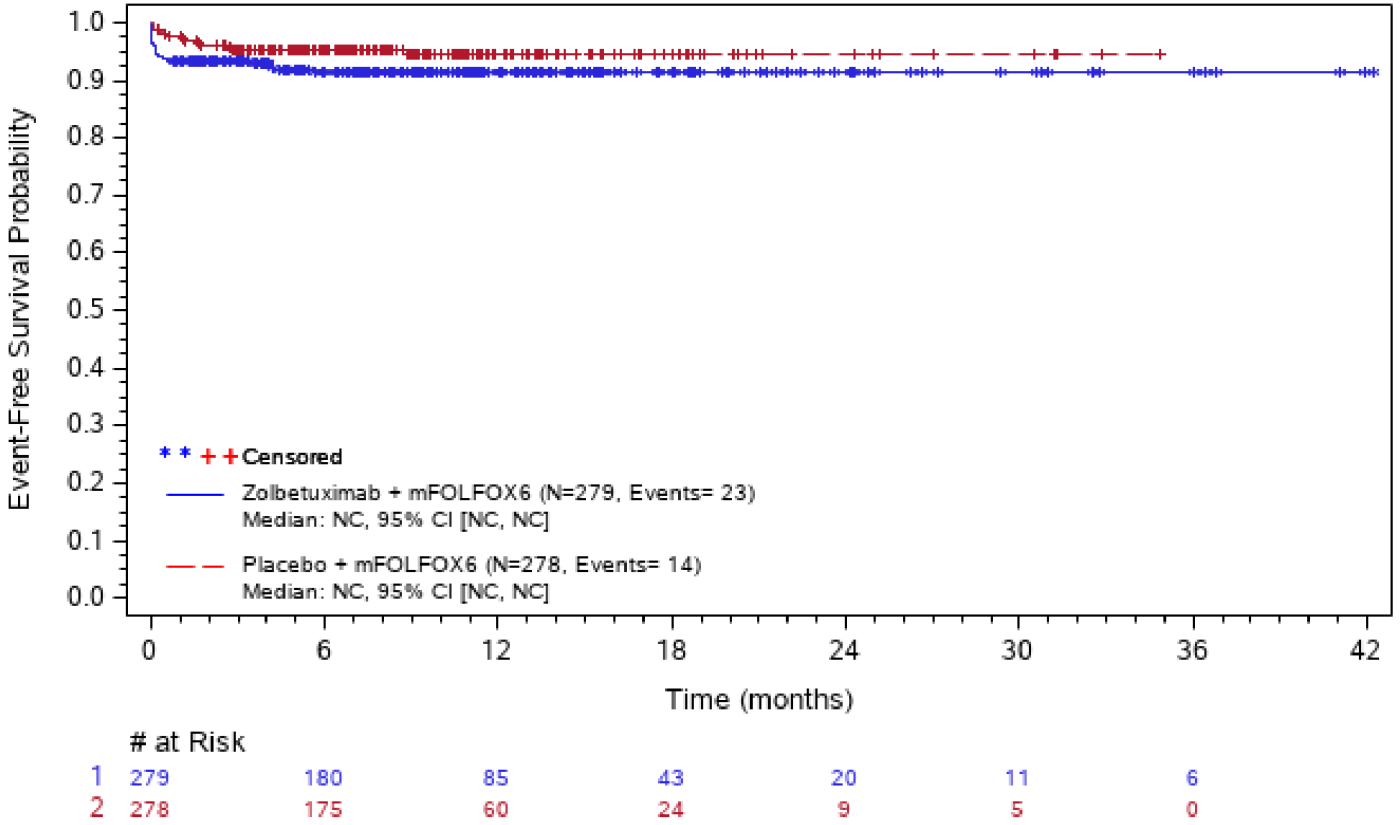
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.231: Kaplan-Meier Plot of Time to first TESAE - Neutropenia (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: 09SEP22

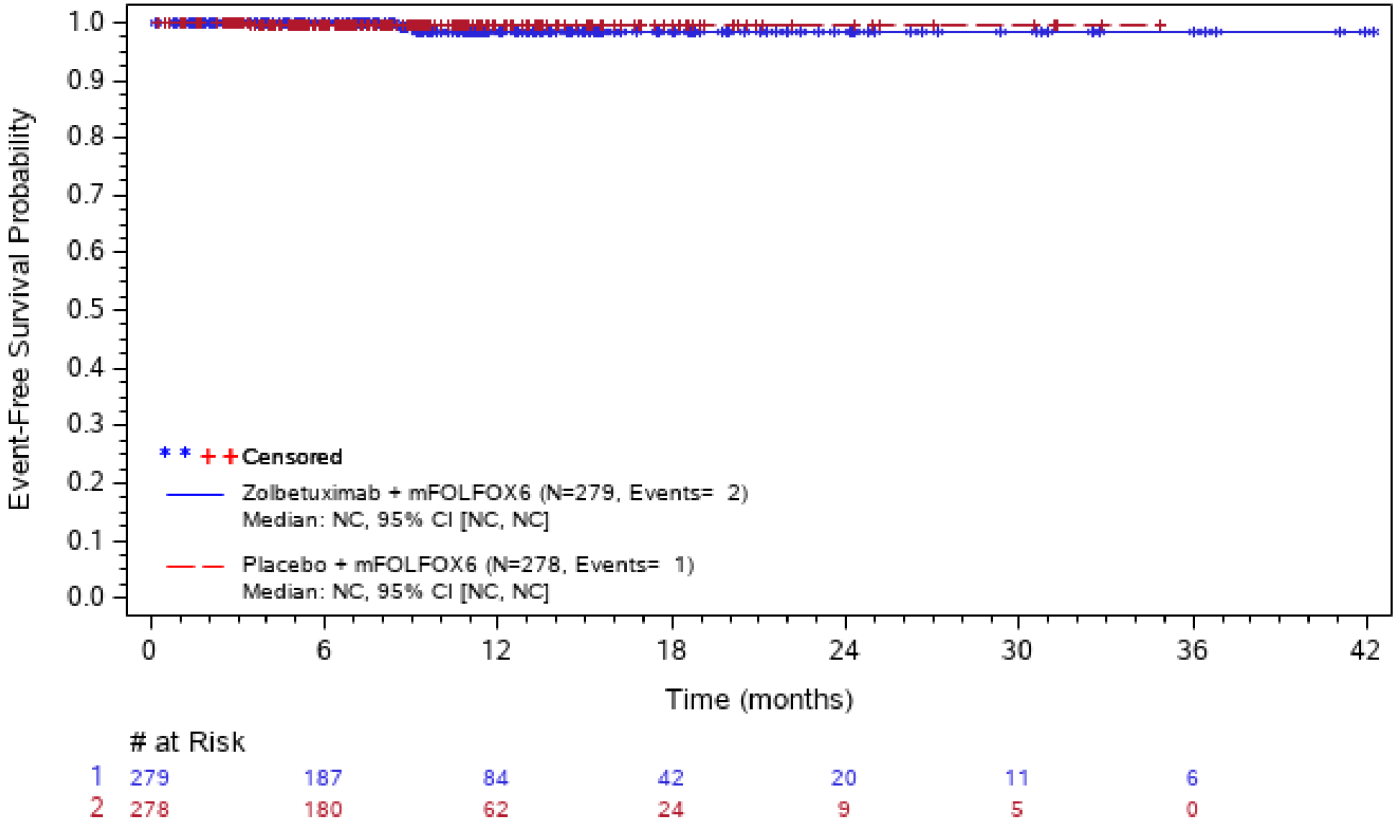
Figure 301.1.2001.232: Kaplan-Meier Plot of Time to first TESAE - Vomiting (AESI) - Safety Analysis Set



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: 09SEP22

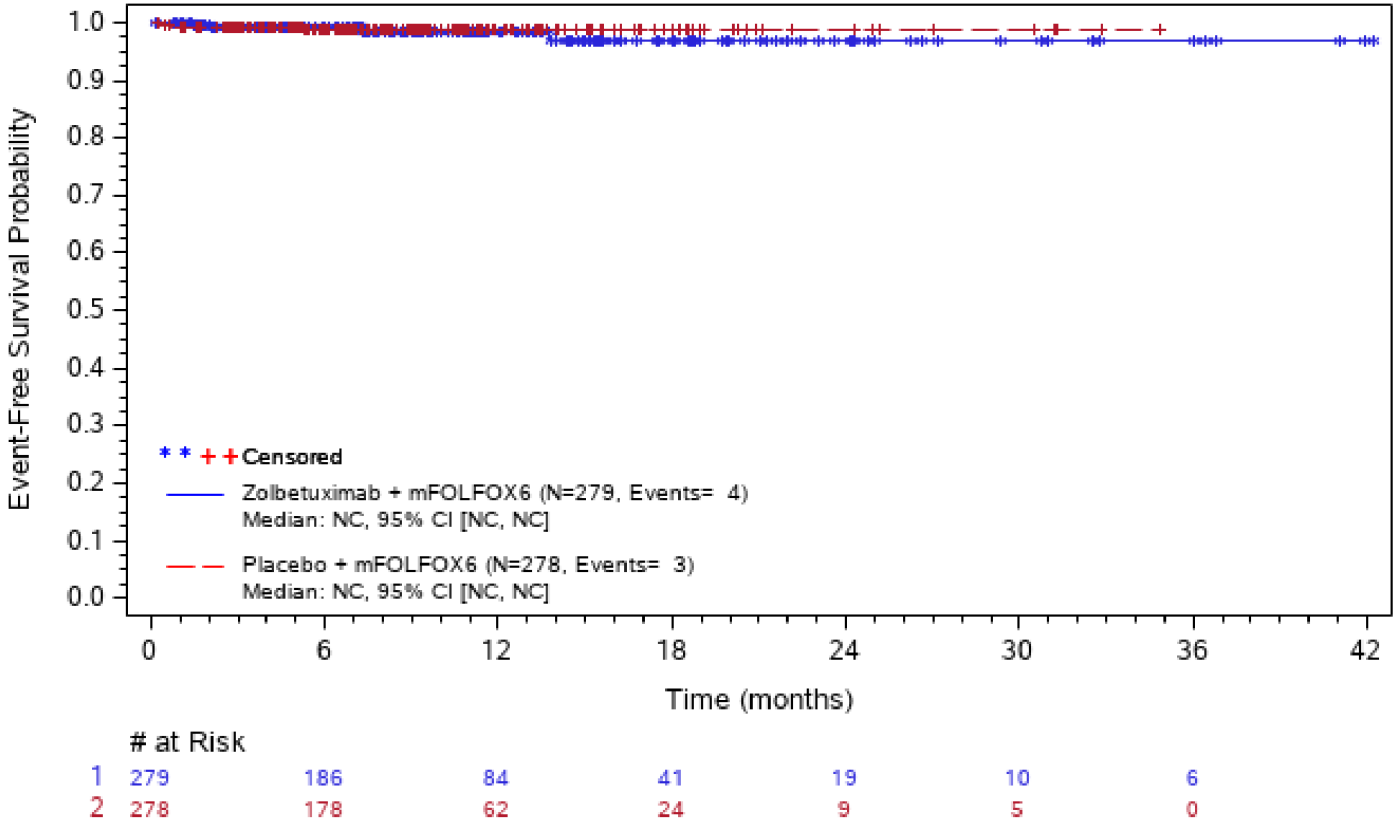
Figure 301.1.2001.233: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set



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.

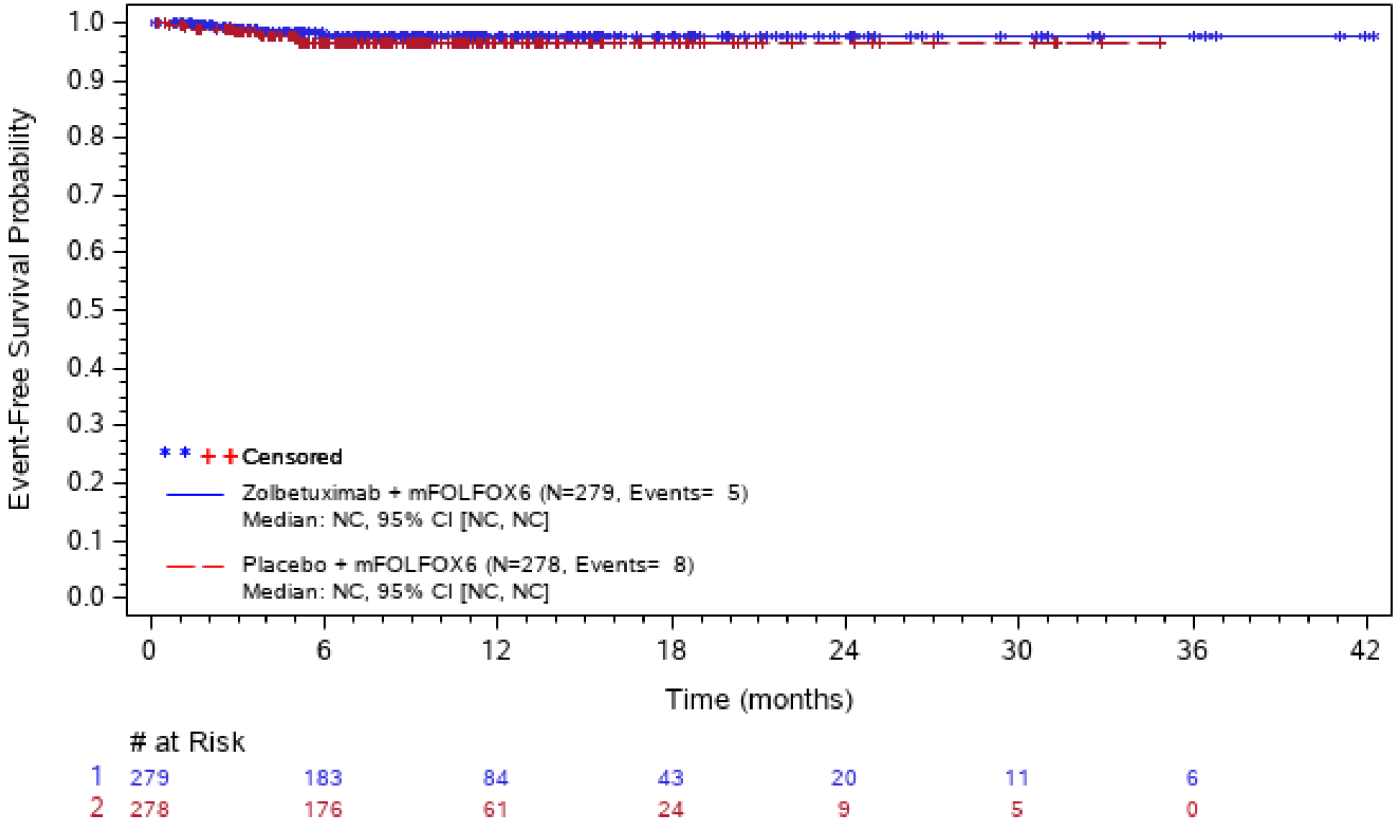
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.234: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set



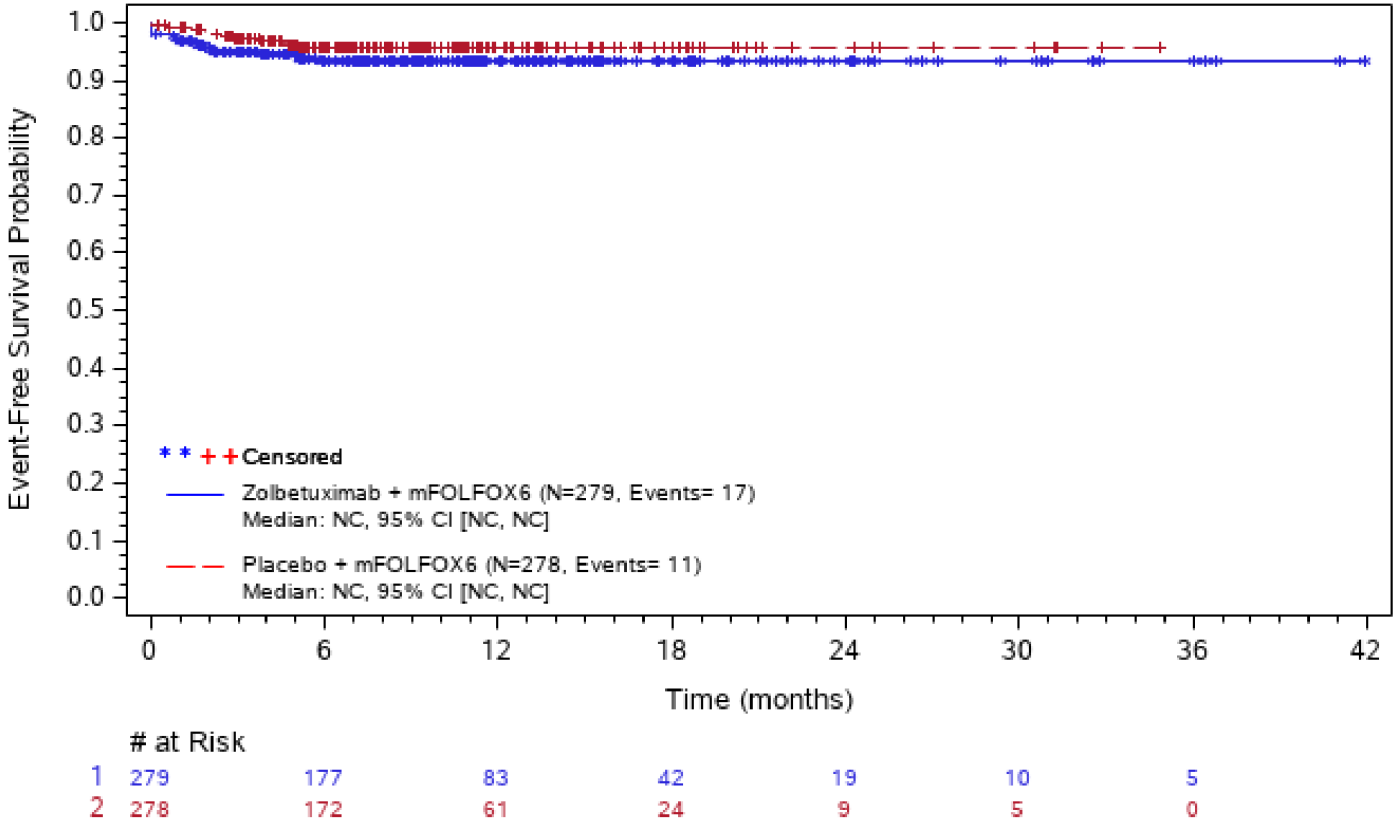
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.235: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set



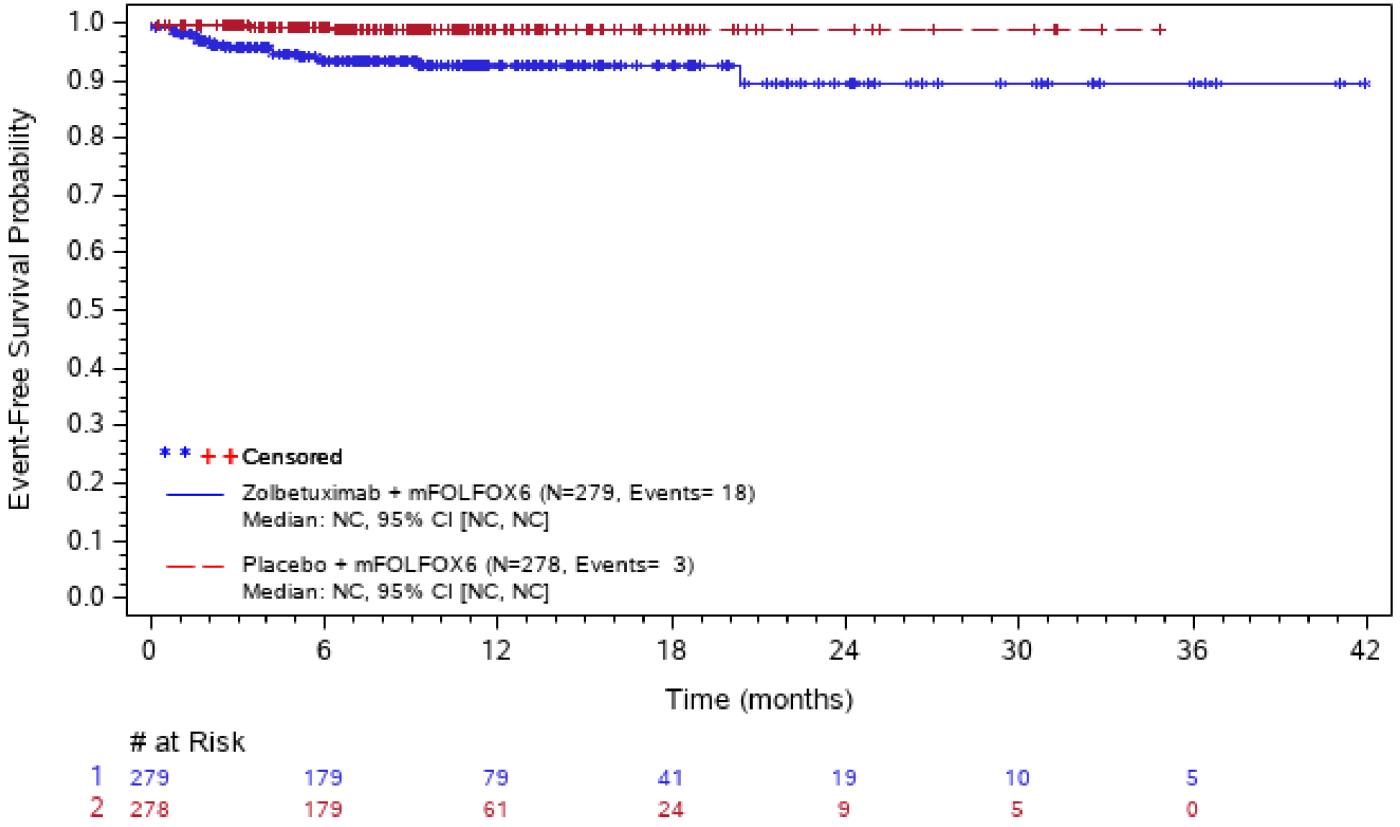
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.236: 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: 09SEP22

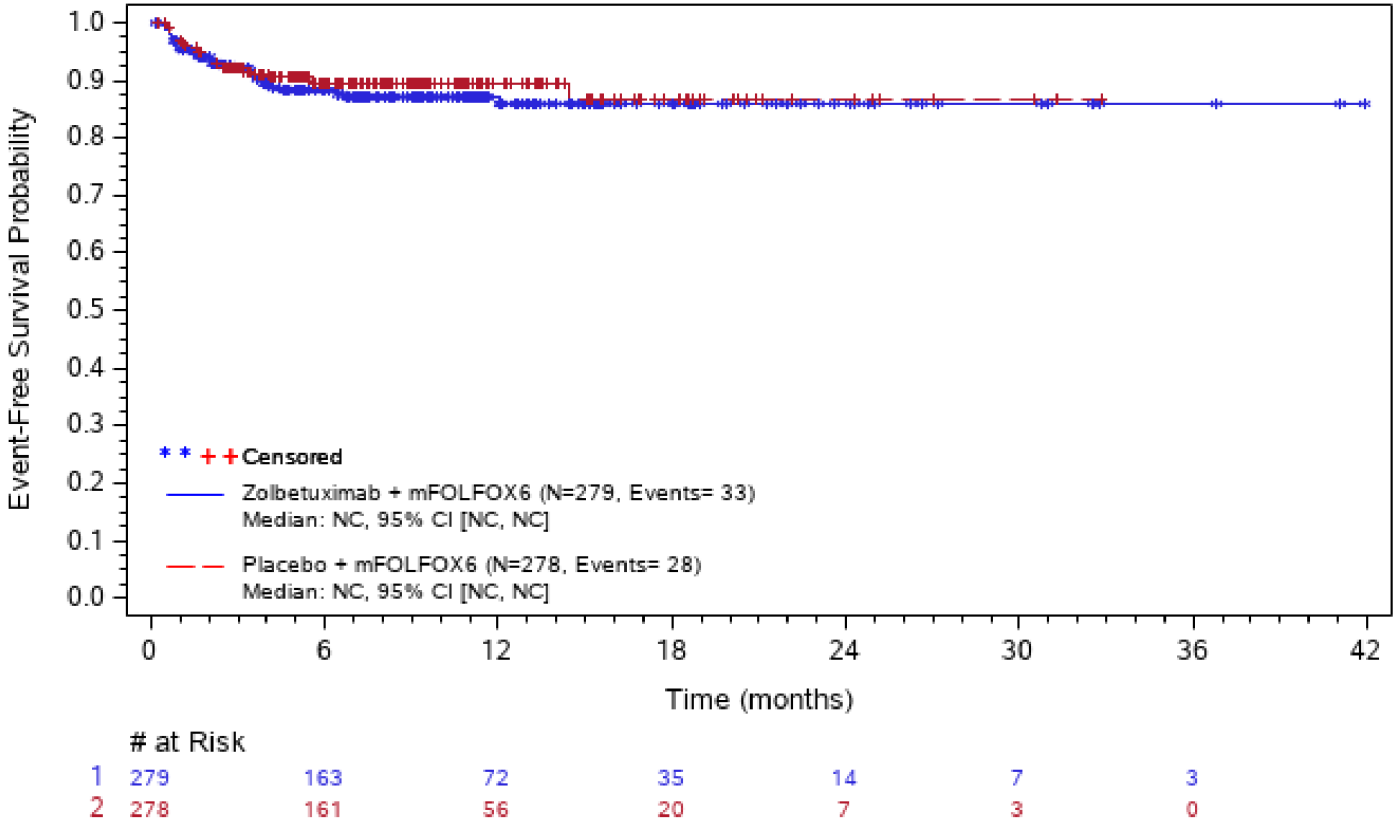
Figure 301.1.2001.237: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set



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.

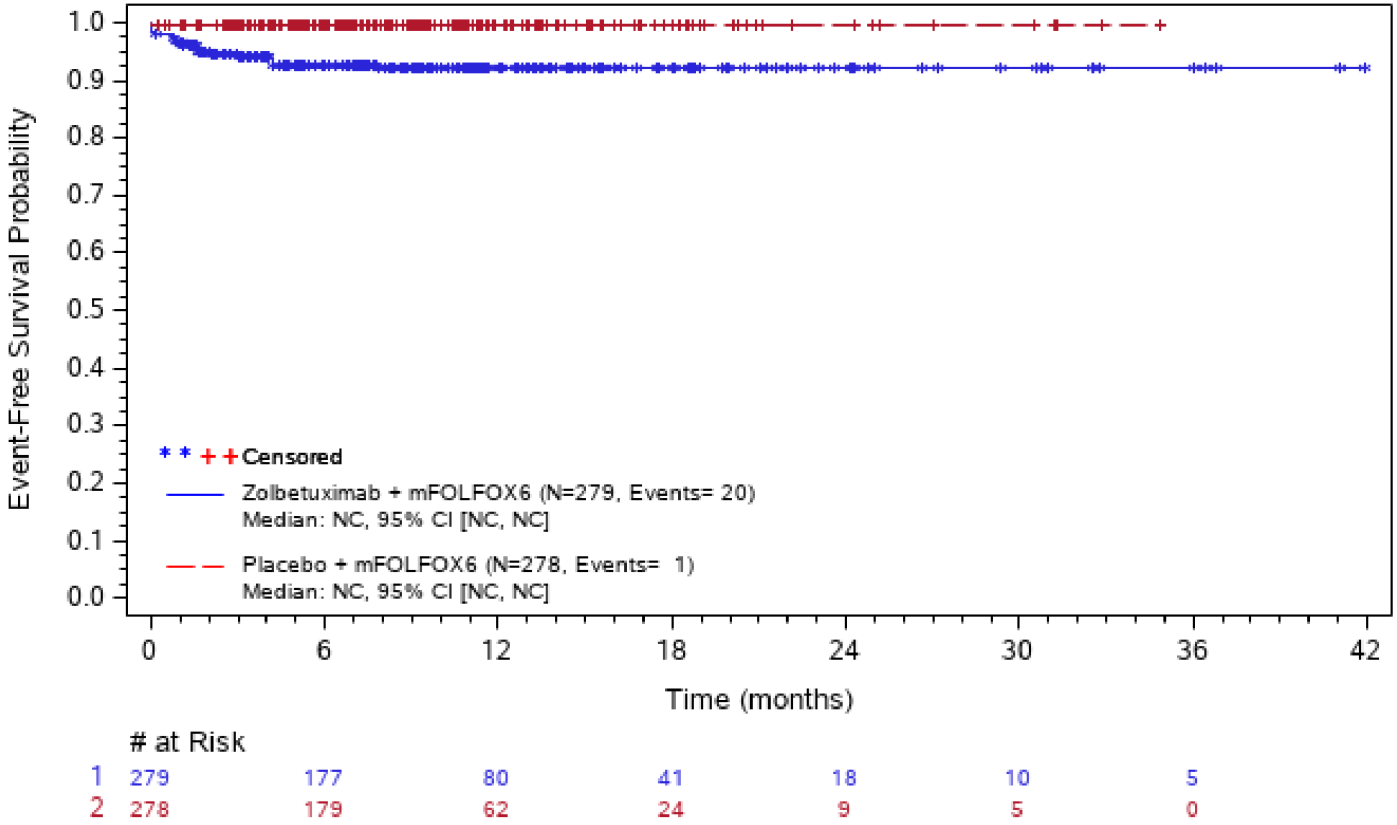
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.238: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set



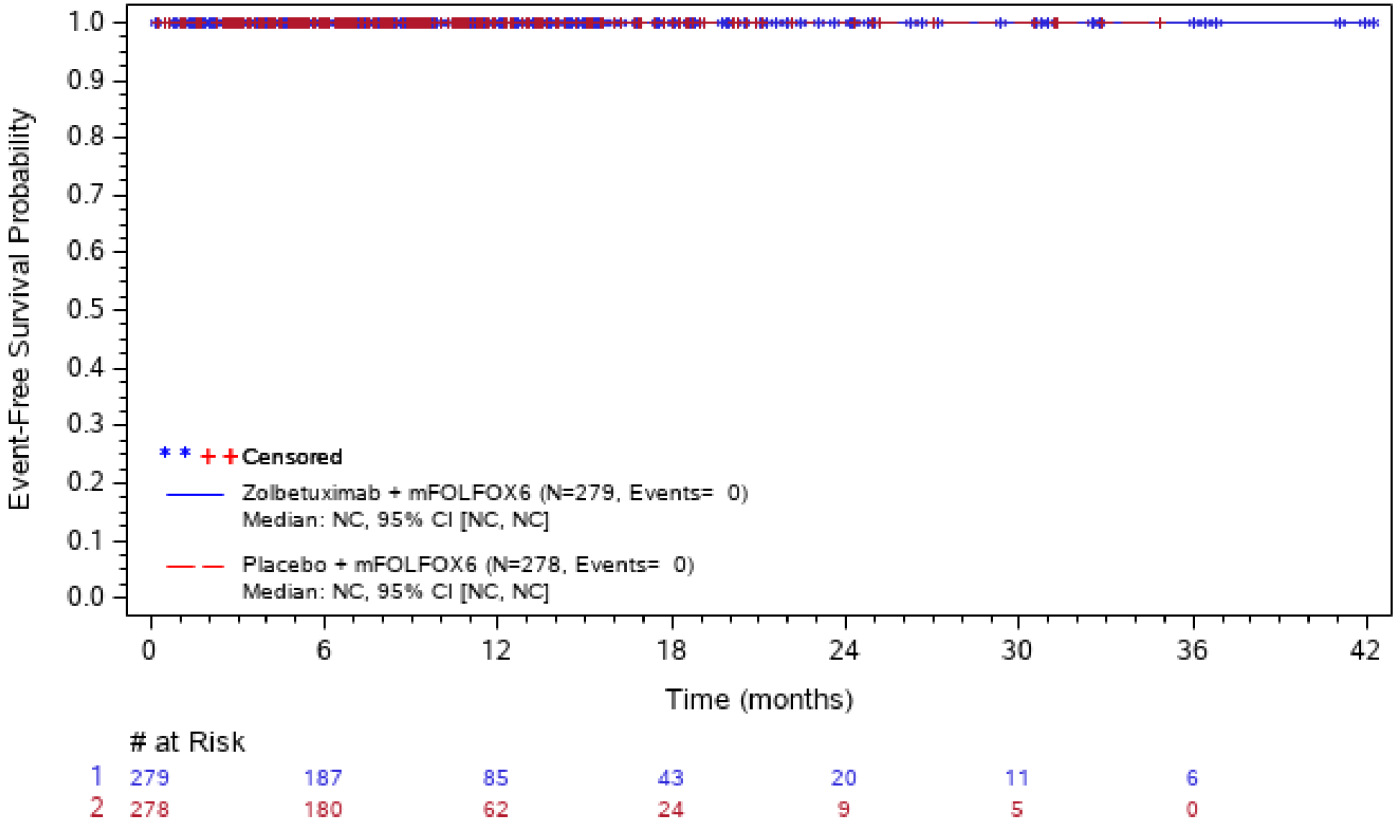
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.239: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set



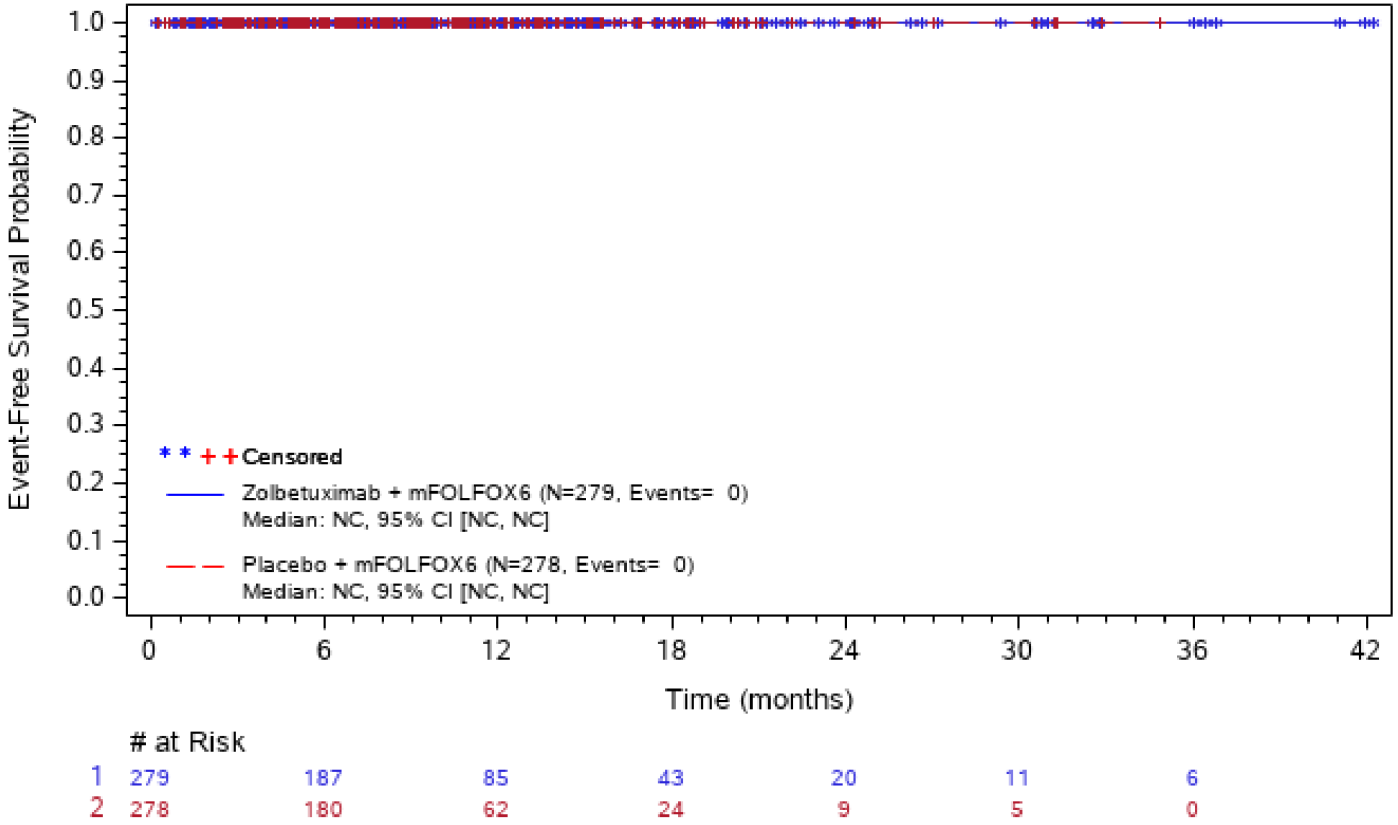
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.261: Kaplan-Meier Plot of Time to first TEAE leading to Death - Abdominal Pain (AESI) - Safety Analysis Set



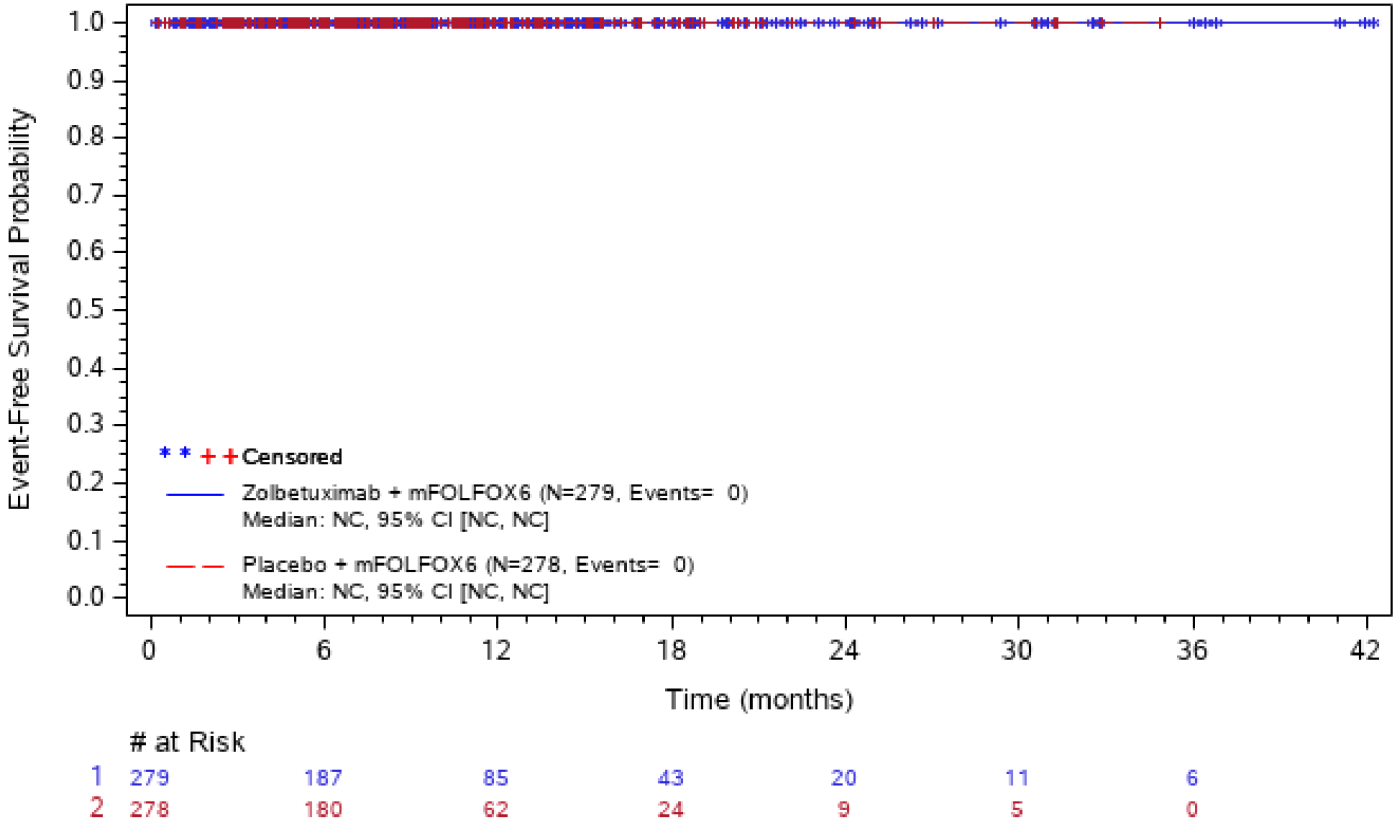
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.262: Kaplan-Meier Plot of Time to first TEAE leading to Death - Anemia (AESI) - Safety Analysis Set



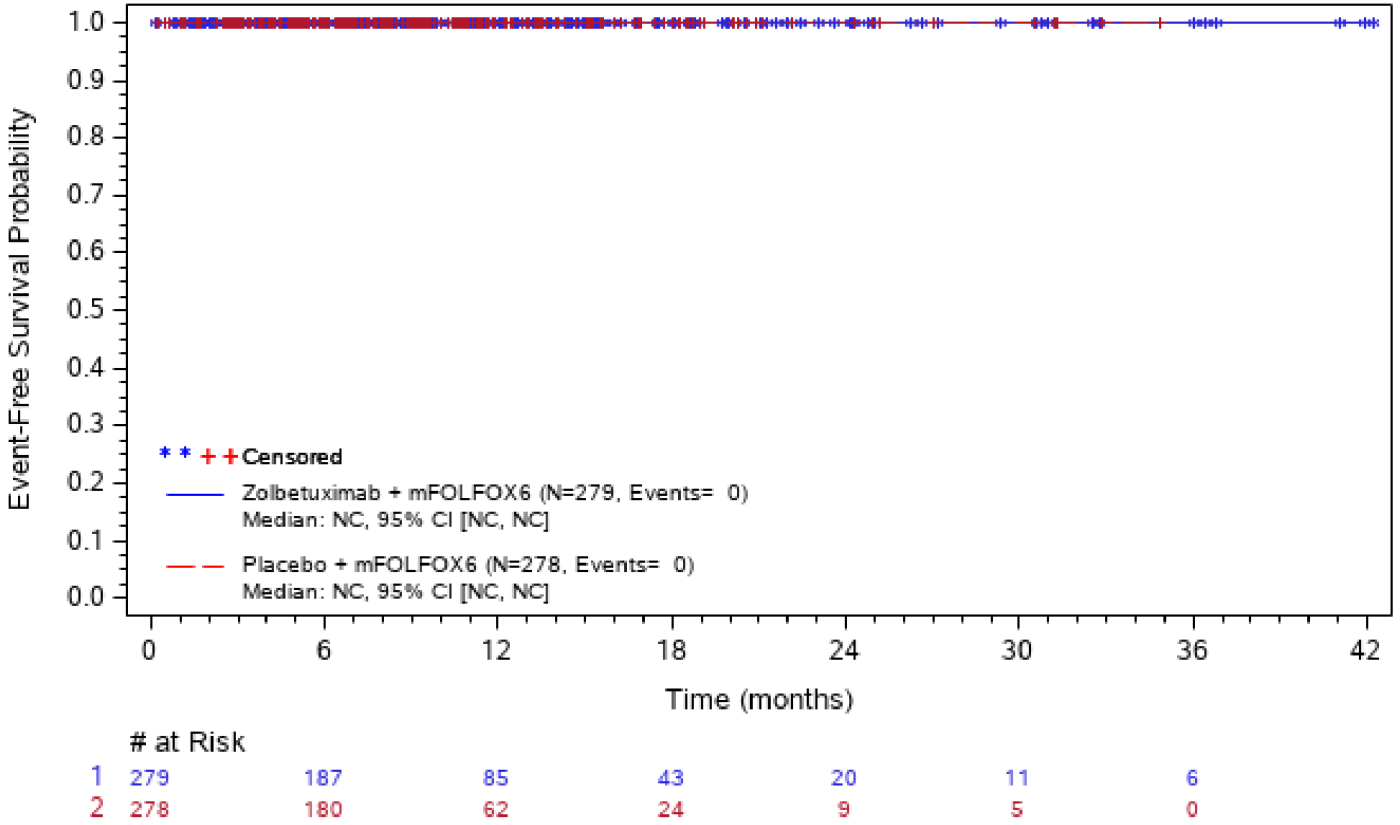
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.263: Kaplan-Meier Plot of Time to first TEAE leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set



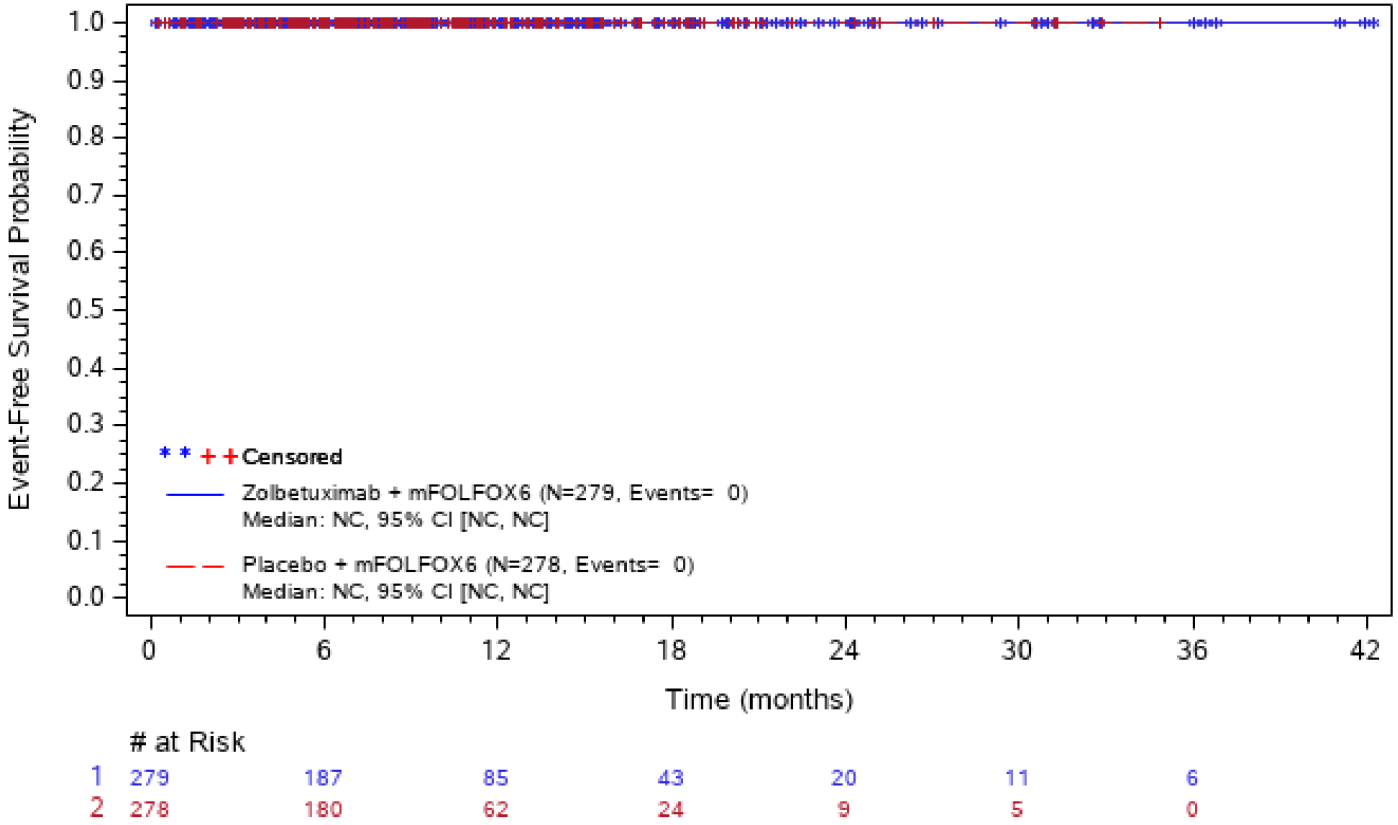
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.264: Kaplan-Meier Plot of Time to first TEAE leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set



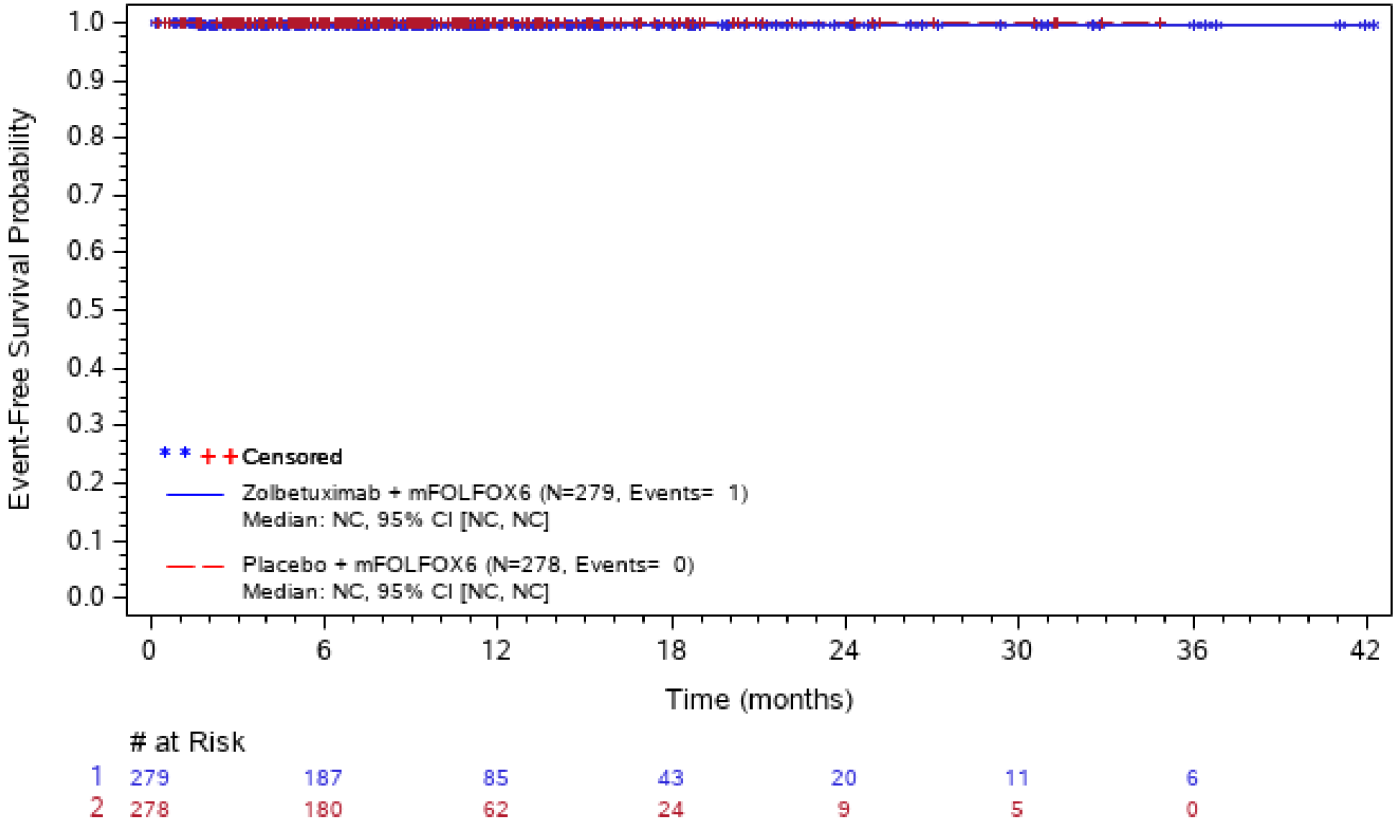
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.265: Kaplan-Meier Plot of Time to first TEAE leading to Death - Nausea (AESI) - Safety Analysis Set



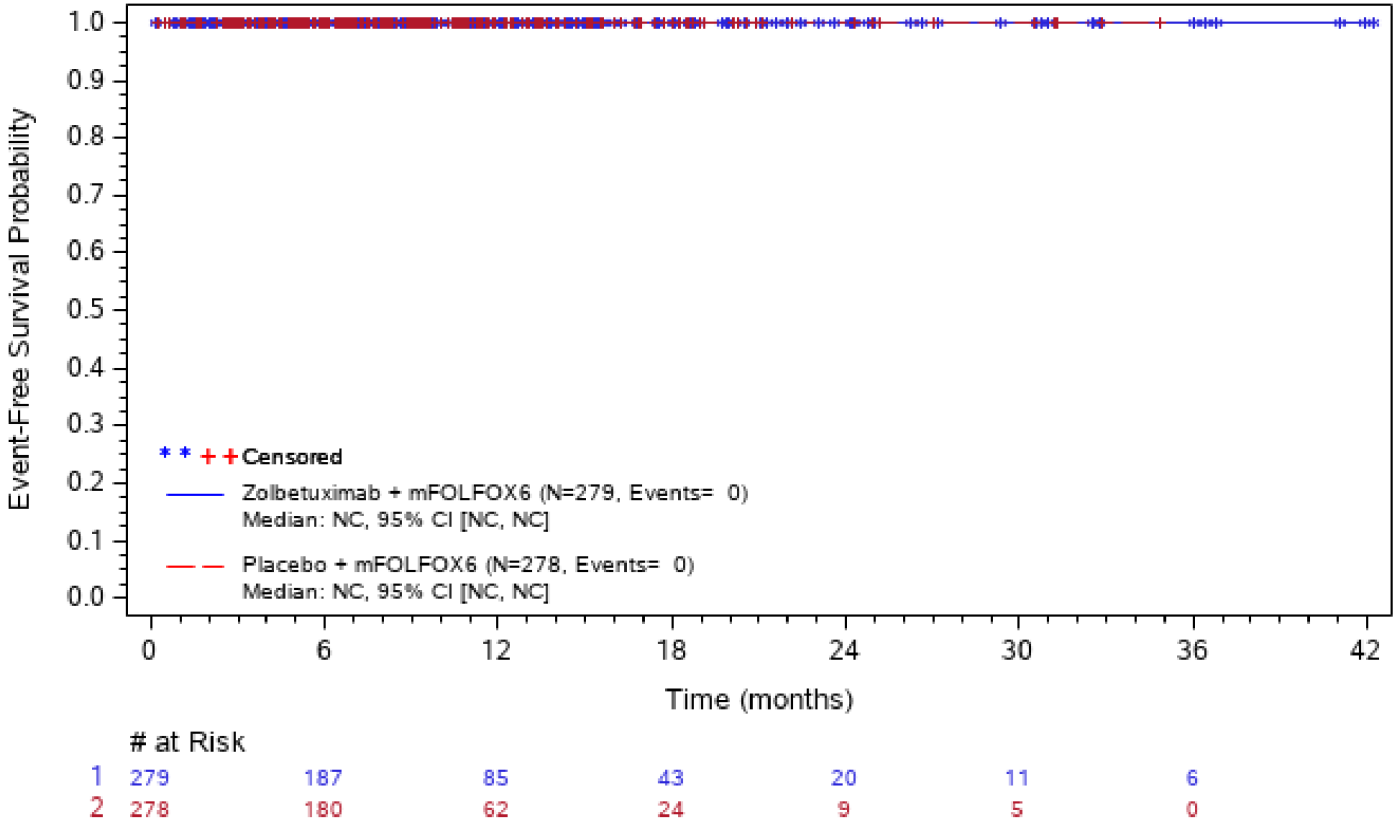
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
ASTELLAS Data Cutoff Date: 09SEP22

Figure 301.1.2001.266: Kaplan-Meier Plot of Time to first TEAE leading to Death - Neutropenia (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: 09SEP22

Figure 301.1.2001.267: 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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022

Anhang 4-G4 Weitere Analysen

Anhang 4-G4 Beobachtungsdauern

Table 301.1.1001.2.1: Summary of Duration of Observation Time of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	14.3 (9.73)	13.2 (8.09)
Median	12.3	11.7
Q1-Q3	7.2 - 19.8	6.9 - 17.6
Range	0 - 42	0 - 37

Abbreviations: 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: 09SEP22

Table 301.1.1001.2.2: Summary of Duration of Observation Time of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	9.3 (7.47)	8.1 (5.84)
Median	8.1	6.5
Q1-Q3	4.2 - 12.4	4.2 - 10.4
Range	0 - 40	0 - 32

Abbreviations: IRC=independent review committee; 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: 09SEP22

Table 301.1.1001.2.3: Summary of Duration of Observation Time of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	9.3 (7.68)	8.1 (5.74)
Median	6.9	6.5
Q1-Q3	4.2 - 12.4	4.2 - 10.5
Range	0 - 40	0 - 32

Abbreviations: INV=investigator; 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: 09SEP22

Table 301.1.3000.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	9.8 (7.89)	8.7 (6.10)
Median	7.9	7.9
Q1-Q3	4.5 - 13.6	4.7 - 11.9
Range	0 - 41	0 - 33

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; 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: 09SEP22

Table 301.1.3000.2: EORTC QLQ-OG25 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	9.8 (7.88)	8.7 (6.10)
Median	7.9	7.9
Q1-Q3	4.5 - 13.6	4.7 - 11.9
Range	0 - 41	0 - 33

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; 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-OG25 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-OG25 questionnaire.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3000.3: EQ-5D-5L Visual Analog Scale - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	9.8 (7.89)	8.8 (6.11)
Median	7.9	7.9
Q1-Q3	4.5 - 13.6	4.7 - 11.9
Range	0 - 41	0 - 33

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EQ-5D VAS includes the time from randomisation until the last date data were collected for EQ-5D VAS.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.3000.4: Global Pain - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	9.8 (7.88)	8.7 (6.09)
Median	7.9	7.9
Q1-Q3	4.5 - 13.5	4.7 - 11.8
Range	0 - 41	0 - 33

Abbreviations: N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for Global Pain questionnaire includes the time from randomisation until the last date data were collected for Global Pain questionnaire.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.2000.6.1: Summary of Duration of Observation Time for Safety Endpoints - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of observation period (months)		
n	279	278
Mean (SD)	11.2 (7.68)	10.3 (5.80)
Median	9.4	9.1
Q1-Q3	5.4 - 14.8	6.3 - 13.4
Range	0 - 43	0 - 34

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: 09SEP22

Table 301.1.2000.6.2: Summary of Duration of Observation Time for any TEAE - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of observation period (months)		
n	279	278
Mean (SD)	10.0 (7.78)	9.1 (5.82)
Median	8.1	7.9
Q1-Q3	4.5 - 13.1	5.2 - 11.7
Range	0 - 41	0 - 34

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: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Begleitmedikationen

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Overall	278 (98.2%)	277 (98.2%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	52 (18.4%)	62 (22.0%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	24 (8.5%)	11 (3.9%)
ANALGESICS	179 (63.3%)	189 (67.0%)
ANESTHETICS	25 (8.8%)	23 (8.2%)
ANTHELMINTICS	1 (0.4%)	1 (0.4%)
ANTI-ACNE PREPARATIONS	3 (1.1%)	3 (1.1%)
ANTI-PARKINSON DRUGS	1 (0.4%)	1 (0.4%)
ANTIANEMIC PREPARATIONS	64 (22.6%)	72 (25.5%)
ANTIBACTERIALS FOR SYSTEMIC USE	103 (36.4%)	91 (32.3%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	9 (3.2%)	9 (3.2%)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	74 (26.1%)	73 (25.9%)
ANTIEMETICS AND ANTINAUSEANTS	197 (69.6%)	178 (63.1%)
ANTIEPILEPTICS	9 (3.2%)	8 (2.8%)
ANTIFUNGALS FOR DERMATOLOGICAL USE	4 (1.4%)	6 (2.1%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
ANTIGOUT PREPARATIONS	8 (2.8%)	8 (2.8%)
ANTIHEMORRHAGICS	14 (4.9%)	17 (6.0%)
ANTIHISTAMINES FOR SYSTEMIC USE	111 (39.2%)	82 (29.1%)
ANTIHYPERTENSIVES	4 (1.4%)	6 (2.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	64 (22.6%)	44 (15.6%)
ANTIMYCOTICS FOR SYSTEMIC USE	7 (2.5%)	5 (1.8%)
ANTINEOPLASTIC AGENTS	1 (0.4%)	2 (0.7%)
ANTIPROTOZOALS	8 (2.8%)	5 (1.8%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	23 (8.1%)	16 (5.7%)
ANTIPSORIATICS	1 (0.4%)	1 (0.4%)
ANTISEPTICS AND DISINFECTANTS	6 (2.1%)	4 (1.4%)
ANTITHROMBOTIC AGENTS	100 (35.3%)	81 (28.7%)
ANTIVIRALS FOR SYSTEMIC USE	6 (2.1%)	5 (1.8%)
APPETITE STIMULANTS	15 (5.3%)	6 (2.1%)
BETA BLOCKING AGENTS	26 (9.2%)	32 (11.3%)
BILE AND LIVER THERAPY	24 (8.5%)	21 (7.4%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	100 (35.3%)	74 (26.2%)
CALCIUM CHANNEL BLOCKERS	45 (15.9%)	40 (14.2%)
CALCIUM HOMEOSTASIS	0	1 (0.4%)
CARDIAC THERAPY	11 (3.9%)	19 (6.7%)
CONTRAST MEDIA	4 (1.4%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	117 (41.3%)	89 (31.6%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	34 (12.0%)	19 (6.7%)
COUGH AND COLD PREPARATIONS	35 (12.4%)	31 (11.0%)
DERMATOLOGICALS	1 (0.4%)	4 (1.4%)
DIAGNOSTIC AGENTS	0	3 (1.1%)
DIGESTIVES, INCL. ENZYMES	12 (4.2%)	7 (2.5%)
DIURETICS	50 (17.7%)	33 (11.7%)
DRUGS FOR ACID RELATED DISORDERS	228 (80.6%)	200 (70.9%)
DRUGS FOR CONSTIPATION	106 (37.5%)	115 (40.8%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	205 (72.4%)	164 (58.2%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	21 (7.4%)	19 (6.7%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
DRUGS FOR TREATMENT OF BONE DISEASES	20 (7.1%)	10 (3.5%)
DRUGS USED IN DIABETES	37 (13.1%)	43 (15.2%)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	1 (0.4%)	1 (0.4%)
EMOLLIENTS AND PROTECTIVES	22 (7.8%)	26 (9.2%)
ENDOCRINE THERAPY	20 (7.1%)	16 (5.7%)
GENERAL NUTRIENTS	52 (18.4%)	41 (14.5%)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	3 (1.1%)	0
HOMEOPATHIC PREPARATION	15 (5.3%)	3 (1.1%)
IMMUNOSTIMULANTS	93 (32.9%)	92 (32.6%)
IMMUNOSUPPRESSANTS	1 (0.4%)	0
LIPID MODIFYING AGENTS	36 (12.7%)	50 (17.7%)
MEDICATED DRESSINGS	5 (1.8%)	1 (0.4%)
MINERAL SUPPLEMENTS	74 (26.1%)	55 (19.5%)
MUSCLE RELAXANTS	13 (4.6%)	7 (2.5%)
NASAL PREPARATIONS	12 (4.2%)	4 (1.4%)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	19 (6.7%)	27 (9.6%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
OPHTHALMOLOGICALS	101 (35.7%)	86 (30.5%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	18 (6.4%)	16 (5.7%)
OTHER DERMATOLOGICAL PREPARATIONS	15 (5.3%)	4 (1.4%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.4%)	1 (0.4%)
OTHER HEMATOLOGICAL AGENTS	2 (0.7%)	1 (0.4%)
OTHER NERVOUS SYSTEM DRUGS	14 (4.9%)	8 (2.8%)
OTHER RESPIRATORY SYSTEM PRODUCTS	2 (0.7%)	0
OTOLOGICALS	35 (12.4%)	19 (6.7%)
PANCREATIC HORMONES	1 (0.4%)	2 (0.7%)
PERIPHERAL VASODILATORS	3 (1.1%)	3 (1.1%)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	3 (1.1%)	1 (0.4%)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	4 (1.4%)	2 (0.7%)
PSYCHOANALEPTICS	35 (12.4%)	37 (13.1%)
PSYCHOLEPTICS	177 (62.5%)	146 (51.8%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	3 (1.1%)	6 (2.1%)
STOMATOLOGICAL PREPARATIONS	62 (21.9%)	51 (18.1%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
THROAT PREPARATIONS	9 (3.2%)	9 (3.2%)
THYROID THERAPY	23 (8.1%)	18 (6.4%)
TONICS	1 (0.4%)	2 (0.7%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	12 (4.2%)	10 (3.5%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	20 (7.1%)	19 (6.7%)
UROLOGICALS	45 (15.9%)	38 (13.5%)
VACCINES	55 (19.4%)	53 (18.8%)
VASOPROTECTIVES	15 (5.3%)	5 (1.8%)
VITAMINS	70 (24.7%)	65 (23.0%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Studienmedikation - Exposition

Table 301.1.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of Zolbetuximab/Placebo (days)		
n	279	278
Mean (SD)	260.6 (242.0)	237.0 (182.1)
Median	190.0	195.0
Range	1 - 1246	1 - 1016
Duration of Oxaliplatin (days)		
n	274	278
Mean (SD)	131.3 (56.47)	130.0 (51.71)
Median	150.0	148.0
Range	1 - 267	1 - 253
Duration of Leucovorin (days)		
n	178	186
Mean (SD)	234.2 (233.2)	204.0 (176.9)
Median	180.5	169.0
Range	1 - 1254	1 - 1030
Duration of Levo-Folinic Acid (days)		
n	127	112
Mean (SD)	245.5 (214.5)	218.5 (179.0)
Median	183.0	178.5
Range	1 - 911	1 - 919
Duration of Fluorouracil Bolus (days)		
n	272	277
Mean (SD)	204.8 (203.6)	185.0 (163.5)
Median	160.0	149.0
Range	1 - 1212	1 - 962

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.
Zolbetuximab + mFOLFOX6 components: Zolbetuximab, Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
Placebo + mFOLFOX6 components: Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of Fluorouracil (days)		
n	273	278
Mean (SD)	267.0 (225.4)	225.9 (175.2)
Median	198.0	178.0
Range	2 - 1256	3 - 1032

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.
Zolbetuximab + mFOLFOX6 components: Zolbetuximab, Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
Placebo + mFOLFOX6 components: Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, primärer Datenschnitt 09.09.2022
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Patientenfluss

Table 301.1.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + mFOLFOX6	Placebo + mFOLFOX6	Total
Number of Subjects with Informed Consent			2735
Discontinued Before Randomization to Treatment			2170 (79.3%)
Randomized to Treatment			565 (20.7%)
Number of Randomized Patients	283	282	565
Safety Analysis Set	279 (98.6%)	278 (98.6%)	557 (98.6%)
Full Analysis Set	283 (100.0%)	282 (100.0%)	565 (100.0%)
Pharmacokinetics Analysis Set	275 (97.2%)	0	275 (48.7%)
Overall Treatment Discontinuation [1]			
Yes	222 (78.4%)	236 (83.7%)	458 (81.1%)
No	61 (21.6%)	46 (16.3%)	107 (18.9%)
Reason for Overall Treatment Discontinuation [2]			
Adverse Event	27 (9.5%)	13 (4.6%)	40 (7.1%)
Death	13 (4.6%)	17 (6.0%)	30 (5.3%)
Lost to Follow-Up	1 (0.4%)	0	1 (0.2%)
Other	21 (7.4%)	18 (6.4%)	39 (6.9%)
Pregnancy	0	0	0
Progressive Disease	133 (47.0%)	177 (62.8%)	310 (54.9%)
Protocol Deviation	1 (0.4%)	0	1 (0.2%)
Withdrawal by Subject	30 (10.6%)	18 (6.4%)	48 (8.5%)
Post-Treatment Follow-Up Discontinuation			
Yes	228 (80.6%)	240 (85.1%)	468 (82.8%)
No	55 (19.4%)	42 (14.9%)	97 (17.2%)
Primary Post-Treatment Follow-Up Status			
Adverse Event	4 (1.4%)	2 (0.7%)	6 (1.1%)
Death	80 (28.3%)	95 (33.7%)	175 (31.0%)
Lost to Follow-Up	1 (0.4%)	2 (0.7%)	3 (0.5%)

[1] Of both treatments.
[2] Reason for overall treatment discontinuation is summarized using the reason of the latest discontinued compound.
If the subject discontinued from both treatments on the same day, all different reasons of discontinuation are summarized.
ASTELLAS Data Cutoff Date: 09SEP22

Table 301.1.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + mFOLFOX6	Placebo + mFOLFOX6	Total
Other	51 (18.0%)	53 (18.8%)	104 (18.4%)
Pregnancy	0	0	0
Progressive Disease	64 (22.6%)	63 (22.3%)	127 (22.5%)
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	28 (9.9%)	25 (8.9%)	53 (9.4%)
Survival Follow-Up Discontinuation			
Yes	176 (62.2%)	195 (69.1%)	371 (65.7%)
No	107 (37.8%)	87 (30.9%)	194 (34.3%)
Primary Survival Follow-Up Status			
Death	150 (53.0%)	177 (62.8%)	327 (57.9%)
Lost to Follow-Up	1 (0.4%)	2 (0.7%)	3 (0.5%)
Other	2 (0.7%)	0	2 (0.4%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	23 (8.1%)	16 (5.7%)	39 (6.9%)

[1] Of both treatments.
[2] Reason for overall treatment discontinuation is summarized using the reason of the latest discontinued compound.
If the subject discontinued from both treatments on the same day, all different reasons of discontinuation are summarized.
ASTELLAS Data Cutoff Date: 09SEP22

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Baseline Charakteristika

Table 301.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Sex		
Male	176 (62.2%)	175 (62.1%)
Female	107 (37.8%)	107 (37.9%)
Unknown	0	0
Age (years)		
n	283	282
Mean (SD)	59.74 (11.75)	58.77 (12.96)
Median	62.0	60.0
Range	27.0 - 83.0	20.0 - 86.0
Age (years)		
>=18 to <=64	171 (60.4%)	174 (61.7%)
>=65 to <85	112 (39.6%)	106 (37.6%)
>=85	0	2 (0.7%)
Age Group 1 (years)		
<=65	181 (64.0%)	181 (64.2%)
>65	102 (36.0%)	101 (35.8%)
Age Group 2 (years)		
<=75	267 (94.3%)	260 (92.2%)
>75	16 (5.7%)	22 (7.8%)
Race		
White	140 (53.6%)	134 (53.0%)
Black or African American	5 (1.9%)	2 (0.8%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Asian	96 (36.8%)	97 (38.3%)
American Indian or Alaska Native	9 (3.4%)	8 (3.2%)
Native Hawaiian or Other Pacific Islander	0	0
Other	11 (4.2%)	12 (4.7%)
Missing	22	29
Ethnicity		
Hispanic or Latino	36 (13.8%)	37 (14.8%)
Not Hispanic or Latino	225 (86.2%)	213 (85.2%)
Missing	22	32
Country 1		
Japan	32 (11.3%)	33 (11.7%)
Non-Japan	251 (88.7%)	249 (88.3%)
Country 2		
China	19 (6.7%)	17 (6.0%)
Non-China	264 (93.3%)	265 (94.0%)
Height (cm)		
n	279	277
Mean (SD)	167.17 (9.25)	166.87 (10.33)
Median	168.0	167.5
Range	145.0 - 188.0	143.0 - 196.0
Weight (kg)		
n	279	278

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Mean (SD)	64.66 (14.47)	65.43 (16.39)
Median	63.0	64.8
Range	38.0 - 110.6	28.5 - 128.3
BMI (kg/m^2)		
<18.5	34 (12.2%)	27 (9.7%)
>=18.5 to <25	168 (60.2%)	169 (61.0%)
>=25 to <30	61 (21.9%)	61 (22.0%)
>=30	16 (5.7%)	20 (7.2%)
Missing	4	5
BSA (m^2)		
n	279	277
Mean (SD)	1.73 (0.23)	1.74 (0.25)
Median	1.7	1.7
Range	1.2 - 2.4	1.1 - 2.5
BSA (m^2)		
<1.7	128 (45.9%)	127 (45.8%)
>=1.7	151 (54.1%)	150 (54.2%)
Missing	4	5
Tobacco History		
Never	142 (50.5%)	137 (48.9%)
Current	26 (9.3%)	25 (8.9%)
Former	113 (40.2%)	118 (42.1%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Missing	2	2
Baseline ECOG Status		
0	125 (44.8%)	115 (41.4%)
>=1	154 (55.2%)	163 (58.6%)
Missing	4	4
Region (IRT)		
Asia	88 (31.1%)	89 (31.6%)
Non-Asia	195 (68.9%)	193 (68.4%)
Region (eCRF)		
Asia	88 (31.1%)	89 (31.6%)
Non-Asia	195 (68.9%)	193 (68.4%)
Number of Organs with Metastatic Sites (IRT)		
0-2	219 (77.4%)	219 (77.7%)
>=3	64 (22.6%)	63 (22.3%)
Number of Organs with Metastatic Sites (eCRF)		
0-2	220 (77.7%)	222 (78.7%)
>=3	63 (22.3%)	60 (21.3%)
Prior Gastrectomy (IRT)		
Yes	84 (29.7%)	82 (29.1%)
No	199 (70.3%)	200 (70.9%)
Prior Gastrectomy (eCRF)		
Yes	82 (29.0%)	83 (29.4%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.1: Summary of Baseline Demographics - Full Analysis Set

Parameter and Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
No	201 (71.0%)	199 (70.6%)
CPS Status		
<5	170 (60.1%)	173 (61.3%)
>=5	27 (9.5%)	24 (8.5%)
Unknown	86 (30.4%)	85 (30.1%)

Abbreviations: BMI=body mass index; BSA=body surface area; CPS=combined positive score; ECOG=eastern cooperative oncology group; eCRF=electronic case report form; IRT=interactive response technology; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Medical Condition	Gastric Adenocarcinoma	219 (77.4%)	210 (74.5%)
	Gastro-Esophageal Junction Adenocarcinoma	64 (22.6%)	72 (25.5%)
Duration Since Initial Diagnosis (days)	n	273	275
	Mean (SD)	270.36 (478.45)	297.63 (675.21)
	Median	56.0	56.0
	Range	2 - 3010	7 - 5366
Tumor Location			
All	Proximal	103 (36.8%)	85 (30.2%)
	Distal	110 (39.3%)	118 (42.0%)
	Unknown	67 (23.9%)	78 (27.8%)
	Missing	3	1
Gastric	n	219	210
	Proximal	73 (33.6%)	59 (28.1%)
	Distal	91 (41.9%)	87 (41.4%)
	Unknown	53 (24.4%)	64 (30.5%)
	Missing	2	0
GEJ	n	64	72
	Proximal	30 (47.6%)	26 (36.6%)
	Distal	19 (30.2%)	31 (43.7%)
	Unknown	14 (22.2%)	14 (19.7%)
	Missing	1	1
Tumor Type	Diffuse	82 (29.1%)	117 (42.1%)
	Intestinal	70 (24.8%)	66 (23.7%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastasic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Mixed	31 (11.0%)	13 (4.7%)
	Other	50 (17.7%)	42 (15.1%)
	Unknown	49 (17.4%)	40 (14.4%)
	Missing	1	4
Primary Tumor	TX	62 (22.1%)	46 (16.4%)
	T0	0	0
	Tis	1 (0.4%)	2 (0.7%)
	T1	2 (0.7%)	4 (1.4%)
	T1a	2 (0.7%)	1 (0.4%)
	T1b	2 (0.7%)	6 (2.1%)
	T2	15 (5.3%)	16 (5.7%)
	T3	86 (30.6%)	98 (34.9%)
	T4	32 (11.4%)	35 (12.5%)
	T4a	56 (19.9%)	56 (19.9%)
	T4b	23 (8.2%)	17 (6.0%)
	Missing	2	1
Regional Lymph Nodes	NX	66 (23.7%)	60 (21.4%)
	N0	40 (14.3%)	38 (13.6%)
	N1	56 (20.1%)	66 (23.6%)
	N2	44 (15.8%)	51 (18.2%)
	N3	42 (15.1%)	32 (11.4%)
	N3a	17 (6.1%)	19 (6.8%)
	N3b	14 (5.0%)	14 (5.0%)
	Missing	4	2
Distant Metastasis [1]	M0	85 (30.4%)	70 (24.8%)
	M1	195 (69.6%)	212 (75.2%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastasic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Missing	3	0
Tumor Metastatic [1]	Yes	239 (84.5%)	238 (84.4%)
	No	44 (15.5%)	44 (15.6%)
Metastasis Location	Abdominal Cavity	19 (6.7%)	17 (6.0%)
	Adrenal Gland	7 (2.5%)	6 (2.1%)
	Bladder	1 (0.4%)	0
	Bone	28 (9.9%)	23 (8.2%)
	Brain	0	1 (0.4%)
	Breast	1 (0.4%)	0
	Chest	4 (1.4%)	1 (0.4%)
	Colon	2 (0.7%)	3 (1.1%)
	Esophagus	3 (1.1%)	4 (1.4%)
	Gallbladder	0	1 (0.4%)
	Heart	2 (0.7%)	1 (0.4%)
	Kidney	2 (0.7%)	0
	Liver	62 (21.9%)	75 (26.6%)
	Lung	36 (12.7%)	33 (11.7%)
	Lymph Node	101 (35.7%)	109 (38.7%)
	Mediastinum	5 (1.8%)	2 (0.7%)
	Neck	0	1 (0.4%)
	Omentum	10 (3.5%)	12 (4.3%)
	Other	23 (8.1%)	17 (6.0%)
	Ovary	16 (5.7%)	19 (6.7%)
	Pancreas	2 (0.7%)	4 (1.4%)
	Pelvis	2 (0.7%)	3 (1.1%)
	Pericardium	1 (0.4%)	0

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastasic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.3: Summary of Primary Diagnosis - Full Analysis Set

Parameter	Category/Statistic	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
	Peritoneum	94 (33.2%)	76 (27.0%)
	Pleura	4 (1.4%)	5 (1.8%)
	Rectum	3 (1.1%)	0
	Retroperitoneum	7 (2.5%)	9 (3.2%)
	Skin	1 (0.4%)	0
	Spleen	2 (0.7%)	3 (1.1%)
	Stomach	5 (1.8%)	5 (1.8%)
History of Helicobacter pylori Infection	Yes	31 (11.0%)	45 (16.0%)
	No	139 (49.1%)	136 (48.2%)
	Unknown	113 (39.9%)	101 (35.8%)
Barrett's Esophagus Diagnosed	Yes	7 (2.5%)	11 (3.9%)
	No	166 (58.7%)	173 (61.3%)
	Unknown	110 (38.9%)	98 (34.8%)
CLDN18.2 Testing Result	<75%	0	0
	>=75%	283 (100.0%)	282 (100.0%)
	Not Applicable	0	0
HER2 Status	Positive	0	0
	Negative	283 (100.0%)	282 (100.0%)
	Not Applicable	0	0
Measurable Disease based on Central	Yes	211 (74.6%)	210 (74.5%)
	No	72 (25.4%)	72 (25.5%)
Measurable Disease based on Local	Yes	235 (83.0%)	227 (80.5%)
	No	48 (17.0%)	55 (19.5%)

Abbreviations: GEJ=gastro-esophageal junction; N=number of patients; n=number of patients with non-missing values; SD=standard deviation.
[1] Distant metastases (M1) and Tumor Metastasic (Yes) may differ depending on date of initial diagnosis.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Overall	259 (91.5%)	251 (89.0%)	510 (90.3%)
Blood And Lymphatic System Disorders	50 (17.7%)	49 (17.4%)	99 (17.5%)
Anaemia	44 (15.5%)	44 (15.6%)	88 (15.6%)
Iron Deficiency Anaemia	4 (1.4%)	5 (1.8%)	9 (1.6%)
Blood Loss Anaemia	1 (0.4%)	0	1 (0.2%)
Hypochromic Anaemia	1 (0.4%)	0	1 (0.2%)
Lymphadenopathy Mediastinal	1 (0.4%)	0	1 (0.2%)
Microcytic Anaemia	0	1 (0.4%)	1 (0.2%)
Pernicious Anaemia	1 (0.4%)	0	1 (0.2%)
Splenic Vein Thrombosis	1 (0.4%)	0	1 (0.2%)
Splenomegaly	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	32 (11.3%)	30 (10.6%)	62 (11.0%)
Atrial Fibrillation	6 (2.1%)	7 (2.5%)	13 (2.3%)
Angina Pectoris	1 (0.4%)	6 (2.1%)	7 (1.2%)
Coronary Artery Disease	1 (0.4%)	6 (2.1%)	7 (1.2%)
Bradycardia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Myocardial Ischaemia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Palpitations	2 (0.7%)	2 (0.7%)	4 (0.7%)
Arrhythmia	2 (0.7%)	1 (0.4%)	3 (0.5%)
Myocardial Infarction	2 (0.7%)	1 (0.4%)	3 (0.5%)
Sinus Bradycardia	3 (1.1%)	0	3 (0.5%)
Sinus Tachycardia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Tachycardia	0	3 (1.1%)	3 (0.5%)
Atrial Flutter	2 (0.7%)	0	2 (0.4%)
Cardiovascular Disorder	2 (0.7%)	0	2 (0.4%)
Ischaemic Cardiomyopathy	2 (0.7%)	0	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Mitral Valve Incompetence	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pericardial Effusion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinus Arrhythmia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Myocardial Infarction	1 (0.4%)	0	1 (0.2%)
Aortic Valve Incompetence	0	1 (0.4%)	1 (0.2%)
Arteriosclerosis Coronary Artery	0	1 (0.4%)	1 (0.2%)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Cardiac Flutter	0	1 (0.4%)	1 (0.2%)
Cardiac Tamponade	1 (0.4%)	0	1 (0.2%)
Cardiomegaly	1 (0.4%)	0	1 (0.2%)
Coronary Artery Stenosis	1 (0.4%)	0	1 (0.2%)
Diastolic Dysfunction	1 (0.4%)	0	1 (0.2%)
Hypertensive Heart Disease	1 (0.4%)	0	1 (0.2%)
Pericarditis	1 (0.4%)	0	1 (0.2%)
Supraventricular Extrasystoles	1 (0.4%)	0	1 (0.2%)
Ventricular Extrasystoles	0	1 (0.4%)	1 (0.2%)
Congenital, Familial And Genetic Disorders	3 (1.1%)	10 (3.5%)	13 (2.3%)
Gilbert's Syndrome	1 (0.4%)	2 (0.7%)	3 (0.5%)
Brugada Syndrome	0	1 (0.4%)	1 (0.2%)
Congenital Musculoskeletal Disorder Of Limbs	1 (0.4%)	0	1 (0.2%)
Deafness Congenital	0	1 (0.4%)	1 (0.2%)
Dermoid Cyst	0	1 (0.4%)	1 (0.2%)
Gene Mutation	0	1 (0.4%)	1 (0.2%)
Porokeratosis	0	1 (0.4%)	1 (0.2%)
Sturge-Weber Syndrome	1 (0.4%)	0	1 (0.2%)
Thalassaemia Minor	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Type V Hyperlipidaemia	0	1 (0.4%)	1 (0.2%)
Ventricular Septal Defect	0	1 (0.4%)	1 (0.2%)
Ear And Labyrinth Disorders	5 (1.8%)	10 (3.5%)	15 (2.7%)
Deafness	0	4 (1.4%)	4 (0.7%)
Hypoacusis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Vertigo	1 (0.4%)	2 (0.7%)	3 (0.5%)
Meniere's Disease	2 (0.7%)	0	2 (0.4%)
Tinnitus	0	2 (0.7%)	2 (0.4%)
Deafness Neurosensory	0	1 (0.4%)	1 (0.2%)
Mastoid Disorder	0	1 (0.4%)	1 (0.2%)
Presbyacusis	0	1 (0.4%)	1 (0.2%)
Endocrine Disorders	24 (8.5%)	19 (6.7%)	43 (7.6%)
Hypothyroidism	18 (6.4%)	16 (5.7%)	34 (6.0%)
Hyperthyroidism	2 (0.7%)	0	2 (0.4%)
Thyroid Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Autoimmune Thyroiditis	1 (0.4%)	0	1 (0.2%)
Goitre	1 (0.4%)	0	1 (0.2%)
Hyperparathyroidism Primary	0	1 (0.4%)	1 (0.2%)
Hyperplasia Adrenal	0	1 (0.4%)	1 (0.2%)
Thyroiditis	1 (0.4%)	0	1 (0.2%)
Eye Disorders	11 (3.9%)	17 (6.0%)	28 (5.0%)
Glaucoma	5 (1.8%)	3 (1.1%)	8 (1.4%)
Cataract	4 (1.4%)	3 (1.1%)	7 (1.2%)
Dry Eye	0	3 (1.1%)	3 (0.5%)
Diabetic Retinopathy	0	2 (0.7%)	2 (0.4%)
Macular Degeneration	0	2 (0.7%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Retinal Degeneration	0	2 (0.7%)	2 (0.4%)
Retinal Detachment	0	2 (0.7%)	2 (0.4%)
Vision Blurred	0	2 (0.7%)	2 (0.4%)
Visual Impairment	1 (0.4%)	1 (0.4%)	2 (0.4%)
Blepharitis	0	1 (0.4%)	1 (0.2%)
Chalazion	1 (0.4%)	0	1 (0.2%)
Chorioretinal Scar	1 (0.4%)	0	1 (0.2%)
Epiretinal Membrane	0	1 (0.4%)	1 (0.2%)
Lacrimation Decreased	0	1 (0.4%)	1 (0.2%)
Macular Oedema	0	1 (0.4%)	1 (0.2%)
Optic Neuropathy	0	1 (0.4%)	1 (0.2%)
Visual Field Defect	0	1 (0.4%)	1 (0.2%)
Vitreous Detachment	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorders	146 (51.6%)	157 (55.7%)	303 (53.6%)
Abdominal Pain	33 (11.7%)	46 (16.3%)	79 (14.0%)
Gastrooesophageal Reflux Disease	35 (12.4%)	44 (15.6%)	79 (14.0%)
Constipation	31 (11.0%)	39 (13.8%)	70 (12.4%)
Dysphagia	34 (12.0%)	31 (11.0%)	65 (11.5%)
Nausea	24 (8.5%)	39 (13.8%)	63 (11.2%)
Abdominal Pain Upper	21 (7.4%)	21 (7.4%)	42 (7.4%)
Vomiting	10 (3.5%)	16 (5.7%)	26 (4.6%)
Dyspepsia	10 (3.5%)	12 (4.3%)	22 (3.9%)
Diarrhoea	7 (2.5%)	12 (4.3%)	19 (3.4%)
Abdominal Distension	6 (2.1%)	11 (3.9%)	17 (3.0%)
Ascites	7 (2.5%)	9 (3.2%)	16 (2.8%)
Gastric Ulcer	4 (1.4%)	12 (4.3%)	16 (2.8%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Gastritis	7 (2.5%)	9 (3.2%)	16 (2.8%)
Abdominal Discomfort	7 (2.5%)	6 (2.1%)	13 (2.3%)
Haemorrhoids	6 (2.1%)	6 (2.1%)	12 (2.1%)
Inguinal Hernia	5 (1.8%)	4 (1.4%)	9 (1.6%)
Chronic Gastritis	4 (1.4%)	4 (1.4%)	8 (1.4%)
Hiatus Hernia	4 (1.4%)	3 (1.1%)	7 (1.2%)
Umbilical Hernia	4 (1.4%)	3 (1.1%)	7 (1.2%)
Diverticulum	1 (0.4%)	5 (1.8%)	6 (1.1%)
Flatulence	1 (0.4%)	4 (1.4%)	5 (0.9%)
Abdominal Pain Lower	2 (0.7%)	2 (0.7%)	4 (0.7%)
Eructation	0	4 (1.4%)	4 (0.7%)
Intestinal Obstruction	1 (0.4%)	3 (1.1%)	4 (0.7%)
Melaena	1 (0.4%)	3 (1.1%)	4 (0.7%)
Peptic Ulcer	2 (0.7%)	2 (0.7%)	4 (0.7%)
Diverticulum Intestinal	1 (0.4%)	2 (0.7%)	3 (0.5%)
Dumping Syndrome	0	3 (1.1%)	3 (0.5%)
Irritable Bowel Syndrome	0	3 (1.1%)	3 (0.5%)
Large Intestine Polyp	3 (1.1%)	0	3 (0.5%)
Barrett's Oesophagus	2 (0.7%)	0	2 (0.4%)
Colitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Duodenal Ulcer	2 (0.7%)	0	2 (0.4%)
Haematochezia	0	2 (0.7%)	2 (0.4%)
Odynophagia	0	2 (0.7%)	2 (0.4%)
Oesophagitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper Gastrointestinal Haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Hernia	0	1 (0.4%)	1 (0.2%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Anal Fistula	1 (0.4%)	0	1 (0.2%)
Anal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Aphthous Ulcer	0	1 (0.4%)	1 (0.2%)
Diaphragmatic Hernia	0	1 (0.4%)	1 (0.2%)
Discoloured Vomit	0	1 (0.4%)	1 (0.2%)
Dry Mouth	0	1 (0.4%)	1 (0.2%)
Duodenitis	1 (0.4%)	0	1 (0.2%)
Epigastric Discomfort	1 (0.4%)	0	1 (0.2%)
Gastritis Erosive	0	1 (0.4%)	1 (0.2%)
Gastritis Hypertrophic	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Hyperchlorhydria	1 (0.4%)	0	1 (0.2%)
Impaired Gastric Emptying	0	1 (0.4%)	1 (0.2%)
Intestinal Cyst	1 (0.4%)	0	1 (0.2%)
Obstruction Gastric	0	1 (0.4%)	1 (0.2%)
Pancreatic Failure	1 (0.4%)	0	1 (0.2%)
Pancreatitis Acute	1 (0.4%)	0	1 (0.2%)
Proctalgia	1 (0.4%)	0	1 (0.2%)
Proctitis Ulcerative	1 (0.4%)	0	1 (0.2%)
Pylorospasm	0	1 (0.4%)	1 (0.2%)
Rectal Polyp	1 (0.4%)	0	1 (0.2%)
Regurgitation	0	1 (0.4%)	1 (0.2%)
Retching	0	1 (0.4%)	1 (0.2%)
Subileus	1 (0.4%)	0	1 (0.2%)
Tongue Coated	1 (0.4%)	0	1 (0.2%)
Toothache	0	1 (0.4%)	1 (0.2%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
General Disorders And Administration Site Conditions	46 (16.3%)	55 (19.5%)	101 (17.9%)
Fatigue	23 (8.1%)	32 (11.3%)	55 (9.7%)
Asthenia	6 (2.1%)	8 (2.8%)	14 (2.5%)
Early Satiety	4 (1.4%)	5 (1.8%)	9 (1.6%)
Pain	5 (1.8%)	3 (1.1%)	8 (1.4%)
Chest Pain	1 (0.4%)	5 (1.8%)	6 (1.1%)
Non-Cardiac Chest Pain	3 (1.1%)	3 (1.1%)	6 (1.1%)
Oedema Peripheral	4 (1.4%)	2 (0.7%)	6 (1.1%)
Pyrexia	3 (1.1%)	2 (0.7%)	5 (0.9%)
Hernia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Malaise	1 (0.4%)	2 (0.7%)	3 (0.5%)
Catheter Site Pain	0	2 (0.7%)	2 (0.4%)
Medical Device Pain	2 (0.7%)	0	2 (0.4%)
Chills	0	1 (0.4%)	1 (0.2%)
Complication Associated With Device	1 (0.4%)	0	1 (0.2%)
Granuloma	1 (0.4%)	0	1 (0.2%)
Impaired Healing	0	1 (0.4%)	1 (0.2%)
Localised Oedema	1 (0.4%)	0	1 (0.2%)
Peripheral Swelling	0	1 (0.4%)	1 (0.2%)
Swelling	1 (0.4%)	0	1 (0.2%)
Temperature Intolerance	0	1 (0.4%)	1 (0.2%)
Hepatobiliary Disorders	17 (6.0%)	9 (3.2%)	26 (4.6%)
Cholelithiasis	4 (1.4%)	2 (0.7%)	6 (1.1%)
Cholecystitis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatic Function Abnormal	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatic Steatosis	2 (0.7%)	1 (0.4%)	3 (0.5%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Hepatic Cyst	1 (0.4%)	1 (0.4%)	2 (0.4%)
Bile Duct Stone	1 (0.4%)	0	1 (0.2%)
Biliary Dilatation	1 (0.4%)	0	1 (0.2%)
Biliary Obstruction	1 (0.4%)	0	1 (0.2%)
Gallbladder Polyp	1 (0.4%)	0	1 (0.2%)
Hepatic Cirrhosis	0	1 (0.4%)	1 (0.2%)
Hepatitis	1 (0.4%)	0	1 (0.2%)
Hepatotoxicity	1 (0.4%)	0	1 (0.2%)
Hyperbilirubinaemia	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	1 (0.4%)	0	1 (0.2%)
Non-Alcoholic Fatty Liver	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	12 (4.2%)	18 (6.4%)	30 (5.3%)
Drug Hypersensitivity	5 (1.8%)	7 (2.5%)	12 (2.1%)
Seasonal Allergy	5 (1.8%)	7 (2.5%)	12 (2.1%)
Hypersensitivity	1 (0.4%)	1 (0.4%)	2 (0.4%)
Allergy To Animal	0	1 (0.4%)	1 (0.2%)
Allergy To Arthropod Sting	0	1 (0.4%)	1 (0.2%)
Food Allergy	0	1 (0.4%)	1 (0.2%)
Hypogammaglobulinaemia	1 (0.4%)	0	1 (0.2%)
Immunodeficiency Common Variable	1 (0.4%)	0	1 (0.2%)
Mite Allergy	0	1 (0.4%)	1 (0.2%)
Rubber Sensitivity	0	1 (0.4%)	1 (0.2%)
Infections And Infestations	38 (13.4%)	31 (11.0%)	69 (12.2%)
Helicobacter Infection	4 (1.4%)	4 (1.4%)	8 (1.4%)
Upper Respiratory Tract Infection	1 (0.4%)	4 (1.4%)	5 (0.9%)
Urinary Tract Infection	3 (1.1%)	2 (0.7%)	5 (0.9%)

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ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Helicobacter Gastritis	4 (1.4%)	0	4 (0.7%)
Pneumonia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Bronchitis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatitis A	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hepatitis B	3 (1.1%)	0	3 (0.5%)
Pulmonary Tuberculosis	3 (1.1%)	0	3 (0.5%)
Chronic Sinusitis	0	2 (0.7%)	2 (0.4%)
Covid-19	1 (0.4%)	1 (0.4%)	2 (0.4%)
Meningitis Viral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rhinitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tuberculosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Abscess	1 (0.4%)	0	1 (0.2%)
Appendicitis	1 (0.4%)	0	1 (0.2%)
Appendicitis Perforated	0	1 (0.4%)	1 (0.2%)
Cellulitis	0	1 (0.4%)	1 (0.2%)
Citrobacter Sepsis	1 (0.4%)	0	1 (0.2%)
Conjunctivitis	1 (0.4%)	0	1 (0.2%)
Covid-19 Pneumonia	0	1 (0.4%)	1 (0.2%)
Cryptococcosis	0	1 (0.4%)	1 (0.2%)
Device Related Infection	0	1 (0.4%)	1 (0.2%)
Encephalitis Viral	0	1 (0.4%)	1 (0.2%)
Endocarditis	0	1 (0.4%)	1 (0.2%)
Enterobacter Infection	1 (0.4%)	0	1 (0.2%)
Epiglottitis	0	1 (0.4%)	1 (0.2%)
Furuncle	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Candidiasis	1 (0.4%)	0	1 (0.2%)

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Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Herpes Simplex	0	1 (0.4%)	1 (0.2%)
Infected Dermal Cyst	0	1 (0.4%)	1 (0.2%)
Infective Aneurysm	0	1 (0.4%)	1 (0.2%)
Labyrinthitis	1 (0.4%)	0	1 (0.2%)
Nasopharyngitis	0	1 (0.4%)	1 (0.2%)
Onychomycosis	0	1 (0.4%)	1 (0.2%)
Oral Candidiasis	0	1 (0.4%)	1 (0.2%)
Oral Herpes	0	1 (0.4%)	1 (0.2%)
Papilloma Viral Infection	1 (0.4%)	0	1 (0.2%)
Parotitis	1 (0.4%)	0	1 (0.2%)
Periodontitis	1 (0.4%)	0	1 (0.2%)
Peritonitis	0	1 (0.4%)	1 (0.2%)
Peritonsillar Abscess	0	1 (0.4%)	1 (0.2%)
Pilonidal Disease	1 (0.4%)	0	1 (0.2%)
Pyelonephritis Acute	1 (0.4%)	0	1 (0.2%)
Sinusitis	0	1 (0.4%)	1 (0.2%)
Tonsillitis	0	1 (0.4%)	1 (0.2%)
Viral Hepatitis Carrier	0	1 (0.4%)	1 (0.2%)
Viral Myocarditis	0	1 (0.4%)	1 (0.2%)
Injury, Poisoning And Procedural Complications	13 (4.6%)	18 (6.4%)	31 (5.5%)
Procedural Pain	3 (1.1%)	2 (0.7%)	5 (0.9%)
Gun Shot Wound	0	3 (1.1%)	3 (0.5%)
Stoma Site Pain	1 (0.4%)	2 (0.7%)	3 (0.5%)
Upper Limb Fracture	2 (0.7%)	1 (0.4%)	3 (0.5%)
Ankle Fracture	1 (0.4%)	1 (0.4%)	2 (0.4%)
Fibula Fracture	2 (0.7%)	0	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Scar	2 (0.7%)	0	2 (0.4%)
Anastomotic Complication	0	1 (0.4%)	1 (0.2%)
Aortic Injury	0	1 (0.4%)	1 (0.2%)
Bone Contusion	1 (0.4%)	0	1 (0.2%)
Contusion	0	1 (0.4%)	1 (0.2%)
Exposure To Chemical Pollution	0	1 (0.4%)	1 (0.2%)
Exposure To Radiation	0	1 (0.4%)	1 (0.2%)
Femur Fracture	1 (0.4%)	0	1 (0.2%)
Foot Fracture	0	1 (0.4%)	1 (0.2%)
Head Injury	0	1 (0.4%)	1 (0.2%)
Infusion Related Reaction	0	1 (0.4%)	1 (0.2%)
Joint Dislocation	0	1 (0.4%)	1 (0.2%)
Meniscus Injury	1 (0.4%)	0	1 (0.2%)
Reactive Gastropathy	1 (0.4%)	0	1 (0.2%)
Rib Fracture	0	1 (0.4%)	1 (0.2%)
Skin Abrasion	0	1 (0.4%)	1 (0.2%)
Spinal Compression Fracture	1 (0.4%)	0	1 (0.2%)
Tibia Fracture	1 (0.4%)	0	1 (0.2%)
Wound Complication	0	1 (0.4%)	1 (0.2%)
Investigations	25 (8.8%)	39 (13.8%)	64 (11.3%)
Weight Decreased	12 (4.2%)	20 (7.1%)	32 (5.7%)
Alanine Aminotransferase Increased	2 (0.7%)	4 (1.4%)	6 (1.1%)
Blood Cholesterol Increased	3 (1.1%)	3 (1.1%)	6 (1.1%)
Aspartate Aminotransferase Increased	2 (0.7%)	3 (1.1%)	5 (0.9%)
Blood Alkaline Phosphatase Increased	2 (0.7%)	3 (1.1%)	5 (0.9%)
Arthroscopy	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Blood Creatinine Increased	0	2 (0.7%)	2 (0.4%)
Cardiac Murmur	0	2 (0.7%)	2 (0.4%)
Lymphocyte Count Decreased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Oesophagogastroduodenoscopy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Biopsy Fallopian Tube	0	1 (0.4%)	1 (0.2%)
Blood Bilirubin Increased	1 (0.4%)	0	1 (0.2%)
Blood Creatinine Decreased	0	1 (0.4%)	1 (0.2%)
Blood Testosterone Decreased	0	1 (0.4%)	1 (0.2%)
Creatinine Renal Clearance Decreased	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Abnormal	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Q Wave Abnormal	0	1 (0.4%)	1 (0.2%)
Electrocardiogram Qt Prolonged	1 (0.4%)	0	1 (0.2%)
Endoscopic Retrograde Cholangiopancreatography	1 (0.4%)	0	1 (0.2%)
Gamma-Glutamyltransferase Increased	0	1 (0.4%)	1 (0.2%)
Glomerular Filtration Rate Decreased	1 (0.4%)	0	1 (0.2%)
Haemoglobin Decreased	1 (0.4%)	0	1 (0.2%)
Helicobacter Test Positive	1 (0.4%)	0	1 (0.2%)
Neutrophil Count Increased	0	1 (0.4%)	1 (0.2%)
Occult Blood	0	1 (0.4%)	1 (0.2%)
Occult Blood Positive	1 (0.4%)	0	1 (0.2%)
Oesophagogastroscopy	0	1 (0.4%)	1 (0.2%)
Platelet Count Decreased	1 (0.4%)	0	1 (0.2%)
Platelet Count Increased	0	1 (0.4%)	1 (0.2%)
Prostatic Specific Antigen Increased	0	1 (0.4%)	1 (0.2%)
Protein Urine Present	0	1 (0.4%)	1 (0.2%)
Stress Echocardiogram Abnormal	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
White Blood Cell Count Decreased	1 (0.4%)	0	1 (0.2%)
White Blood Cell Count Increased	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	103 (36.4%)	107 (37.9%)	210 (37.2%)
Decreased Appetite	32 (11.3%)	35 (12.4%)	67 (11.9%)
Diabetes Mellitus	22 (7.8%)	23 (8.2%)	45 (8.0%)
Hyperlipidaemia	16 (5.7%)	19 (6.7%)	35 (6.2%)
Dyslipidaemia	13 (4.6%)	16 (5.7%)	29 (5.1%)
Type 2 Diabetes Mellitus	13 (4.6%)	14 (5.0%)	27 (4.8%)
Hypercholesterolaemia	10 (3.5%)	11 (3.9%)	21 (3.7%)
Gout	4 (1.4%)	5 (1.8%)	9 (1.6%)
Hyperuricaemia	4 (1.4%)	5 (1.8%)	9 (1.6%)
Hypoalbuminaemia	7 (2.5%)	2 (0.7%)	9 (1.6%)
Glucose Tolerance Impaired	2 (0.7%)	4 (1.4%)	6 (1.1%)
Vitamin D Deficiency	3 (1.1%)	3 (1.1%)	6 (1.1%)
Hyperglycaemia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Hypokalaemia	3 (1.1%)	1 (0.4%)	4 (0.7%)
Obesity	0	4 (1.4%)	4 (0.7%)
Dehydration	1 (0.4%)	2 (0.7%)	3 (0.5%)
Lactose Intolerance	2 (0.7%)	1 (0.4%)	3 (0.5%)
Vitamin B12 Deficiency	0	3 (1.1%)	3 (0.5%)
Abnormal Loss Of Weight	0	2 (0.7%)	2 (0.4%)
Hypoglycaemia	0	2 (0.7%)	2 (0.4%)
Hypomagnesaemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyponatraemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Impaired Fasting Glucose	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cachexia	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Hypercalcaemia	0	1 (0.4%)	1 (0.2%)
Hyperkalaemia	1 (0.4%)	0	1 (0.2%)
Hypertriglyceridaemia	1 (0.4%)	0	1 (0.2%)
Hypocalcaemia	1 (0.4%)	0	1 (0.2%)
Hypoproteinaemia	1 (0.4%)	0	1 (0.2%)
Hypotriglyceridaemia	0	1 (0.4%)	1 (0.2%)
Iron Deficiency	0	1 (0.4%)	1 (0.2%)
Malnutrition	0	1 (0.4%)	1 (0.2%)
Type 1 Diabetes Mellitus	1 (0.4%)	0	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	58 (20.5%)	60 (21.3%)	118 (20.9%)
Back Pain	19 (6.7%)	21 (7.4%)	40 (7.1%)
Arthralgia	9 (3.2%)	5 (1.8%)	14 (2.5%)
Osteoarthritis	5 (1.8%)	6 (2.1%)	11 (1.9%)
Intervertebral Disc Protrusion	5 (1.8%)	3 (1.1%)	8 (1.4%)
Osteoporosis	3 (1.1%)	5 (1.8%)	8 (1.4%)
Spinal Osteoarthritis	3 (1.1%)	4 (1.4%)	7 (1.2%)
Spinal Pain	4 (1.4%)	2 (0.7%)	6 (1.1%)
Arthritis	1 (0.4%)	4 (1.4%)	5 (0.9%)
Neck Pain	1 (0.4%)	4 (1.4%)	5 (0.9%)
Musculoskeletal Pain	2 (0.7%)	2 (0.7%)	4 (0.7%)
Spinal Stenosis	3 (1.1%)	1 (0.4%)	4 (0.7%)
Fibromyalgia	0	3 (1.1%)	3 (0.5%)
Lumbar Spinal Stenosis	1 (0.4%)	2 (0.7%)	3 (0.5%)
Pain In Extremity	2 (0.7%)	1 (0.4%)	3 (0.5%)
Bone Pain	2 (0.7%)	0	2 (0.4%)
Flank Pain	1 (0.4%)	1 (0.4%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Joint Swelling	2 (0.7%)	0	2 (0.4%)
Muscle Spasms	1 (0.4%)	1 (0.4%)	2 (0.4%)
Musculoskeletal Chest Pain	1 (0.4%)	1 (0.4%)	2 (0.4%)
Myalgia	0	2 (0.7%)	2 (0.4%)
Rheumatoid Arthritis	2 (0.7%)	0	2 (0.4%)
Tendonitis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ankylosing Spondylitis	1 (0.4%)	0	1 (0.2%)
Bursitis	0	1 (0.4%)	1 (0.2%)
Cervical Spinal Stenosis	0	1 (0.4%)	1 (0.2%)
Chondrocalcinosis	0	1 (0.4%)	1 (0.2%)
Diffuse Idiopathic Skeletal Hyperostosis	0	1 (0.4%)	1 (0.2%)
Dupuytren's Contracture	1 (0.4%)	0	1 (0.2%)
Exostosis	0	1 (0.4%)	1 (0.2%)
Gouty Arthritis	0	1 (0.4%)	1 (0.2%)
Greater Trochanteric Pain Syndrome	1 (0.4%)	0	1 (0.2%)
Intervertebral Disc Degeneration	0	1 (0.4%)	1 (0.2%)
Mobility Decreased	1 (0.4%)	0	1 (0.2%)
Muscular Weakness	0	1 (0.4%)	1 (0.2%)
Musculoskeletal Discomfort	0	1 (0.4%)	1 (0.2%)
Periarthritis	0	1 (0.4%)	1 (0.2%)
Polymyalgia Rheumatica	1 (0.4%)	0	1 (0.2%)
Rotator Cuff Syndrome	1 (0.4%)	0	1 (0.2%)
Sjogren's Syndrome	1 (0.4%)	0	1 (0.2%)
Spondylolisthesis	1 (0.4%)	0	1 (0.2%)
Spondylolysis	0	1 (0.4%)	1 (0.2%)
Temporomandibular Joint Syndrome	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Thoracic Spinal Stenosis	0	1 (0.4%)	1 (0.2%)
Trigger Finger	0	1 (0.4%)	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	33 (11.7%)	37 (13.1%)	70 (12.4%)
Tumour Pain	4 (1.4%)	4 (1.4%)	8 (1.4%)
Prostate Cancer	2 (0.7%)	5 (1.8%)	7 (1.2%)
Basal Cell Carcinoma	3 (1.1%)	2 (0.7%)	5 (0.9%)
Breast Cancer	3 (1.1%)	2 (0.7%)	5 (0.9%)
Cancer Pain	2 (0.7%)	2 (0.7%)	4 (0.7%)
Colorectal Adenoma	1 (0.4%)	3 (1.1%)	4 (0.7%)
Colon Cancer	1 (0.4%)	2 (0.7%)	3 (0.5%)
Malignant Ascites	1 (0.4%)	2 (0.7%)	3 (0.5%)
Uterine Leiomyoma	1 (0.4%)	2 (0.7%)	3 (0.5%)
Acrochordon	1 (0.4%)	1 (0.4%)	2 (0.4%)
Benign Ovarian Tumour	0	2 (0.7%)	2 (0.4%)
Bladder Transitional Cell Carcinoma	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gastric Cancer	2 (0.7%)	0	2 (0.4%)
Squamous Cell Carcinoma Of Skin	1 (0.4%)	1 (0.4%)	2 (0.4%)
Adenocarcinoma Gastric	0	1 (0.4%)	1 (0.2%)
Benign Neoplasm Of Bladder	1 (0.4%)	0	1 (0.2%)
Benign Neoplasm Of Optic Nerve	1 (0.4%)	0	1 (0.2%)
Benign Neoplasm Of Thyroid Gland	0	1 (0.4%)	1 (0.2%)
Benign Pancreatic Neoplasm	0	1 (0.4%)	1 (0.2%)
Benign Salivary Gland Neoplasm	0	1 (0.4%)	1 (0.2%)
Bowen's Disease	0	1 (0.4%)	1 (0.2%)
Carcinoid Tumour Pulmonary	0	1 (0.4%)	1 (0.2%)
Cardiac Valve Fibroelastoma	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Cervix Carcinoma	1 (0.4%)	0	1 (0.2%)
Fibroadenoma Of Breast	0	1 (0.4%)	1 (0.2%)
Fibroma	1 (0.4%)	0	1 (0.2%)
Haemangioma	1 (0.4%)	0	1 (0.2%)
Haemangioma Of Liver	1 (0.4%)	0	1 (0.2%)
Haemangioma Of Skin	0	1 (0.4%)	1 (0.2%)
Hodgkin's Disease	1 (0.4%)	0	1 (0.2%)
Invasive Ductal Breast Carcinoma	1 (0.4%)	0	1 (0.2%)
Laryngeal Cancer	0	1 (0.4%)	1 (0.2%)
Leiomyoma	0	1 (0.4%)	1 (0.2%)
Malignant Melanoma	1 (0.4%)	0	1 (0.2%)
Melanocytic Naevus	0	1 (0.4%)	1 (0.2%)
Neuroendocrine Tumour	1 (0.4%)	0	1 (0.2%)
Neuroma	1 (0.4%)	0	1 (0.2%)
Non-Hodgkin's Lymphoma	0	1 (0.4%)	1 (0.2%)
Osteochondroma	0	1 (0.4%)	1 (0.2%)
Papillary Thyroid Cancer	1 (0.4%)	0	1 (0.2%)
Pericardial Effusion Malignant	1 (0.4%)	0	1 (0.2%)
Pituitary Tumour	1 (0.4%)	0	1 (0.2%)
Pyogenic Granuloma	0	1 (0.4%)	1 (0.2%)
Rectal Adenocarcinoma	1 (0.4%)	0	1 (0.2%)
Rectal Cancer	0	1 (0.4%)	1 (0.2%)
Renal Cancer	0	1 (0.4%)	1 (0.2%)
Seborrhoeic Keratosis	0	1 (0.4%)	1 (0.2%)
Squamous Cell Carcinoma	0	1 (0.4%)	1 (0.2%)
Testis Cancer	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Nervous System Disorders	36 (12.7%)	38 (13.5%)	74 (13.1%)
Peripheral Sensory Neuropathy	5 (1.8%)	5 (1.8%)	10 (1.8%)
Epilepsy	5 (1.8%)	3 (1.1%)	8 (1.4%)
Headache	4 (1.4%)	4 (1.4%)	8 (1.4%)
Neuropathy Peripheral	3 (1.1%)	3 (1.1%)	6 (1.1%)
Carpal Tunnel Syndrome	2 (0.7%)	3 (1.1%)	5 (0.9%)
Migraine	3 (1.1%)	2 (0.7%)	5 (0.9%)
Transient Ischaemic Attack	2 (0.7%)	2 (0.7%)	4 (0.7%)
Diabetic Neuropathy	2 (0.7%)	1 (0.4%)	3 (0.5%)
Dizziness	2 (0.7%)	1 (0.4%)	3 (0.5%)
Paraesthesia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Sciatica	1 (0.4%)	2 (0.7%)	3 (0.5%)
Carotid Arteriosclerosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebral Infarction	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebrovascular Accident	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysgeusia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Memory Impairment	0	2 (0.7%)	2 (0.4%)
Nerve Compression	0	2 (0.7%)	2 (0.4%)
Neuralgia	0	2 (0.7%)	2 (0.4%)
Polyneuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Tremor	1 (0.4%)	1 (0.4%)	2 (0.4%)
Anosmia	0	1 (0.4%)	1 (0.2%)
Ataxia	1 (0.4%)	0	1 (0.2%)
Cerebellar Infarction	0	1 (0.4%)	1 (0.2%)
Cerebral Small Vessel Ischaemic Disease	0	1 (0.4%)	1 (0.2%)
Cerebral Venous Sinus Thrombosis	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Dystonia	0	1 (0.4%)	1 (0.2%)
Hypoaesthesia	0	1 (0.4%)	1 (0.2%)
Ischaemic Stroke	1 (0.4%)	0	1 (0.2%)
Myelopathy	0	1 (0.4%)	1 (0.2%)
Neurotoxicity	1 (0.4%)	0	1 (0.2%)
Occipital Neuralgia	0	1 (0.4%)	1 (0.2%)
Parkinson's Disease	0	1 (0.4%)	1 (0.2%)
Periodic Limb Movement Disorder	0	1 (0.4%)	1 (0.2%)
Peripheral Motor Neuropathy	1 (0.4%)	0	1 (0.2%)
Peripheral Sensorimotor Neuropathy	0	1 (0.4%)	1 (0.2%)
Peroneal Nerve Palsy	0	1 (0.4%)	1 (0.2%)
Sensory Disturbance	1 (0.4%)	0	1 (0.2%)
Vocal Cord Paresis	0	1 (0.4%)	1 (0.2%)
Pregnancy, Puerperium And Perinatal Conditions	2 (0.7%)	2 (0.7%)	4 (0.7%)
Abortion Spontaneous	1 (0.4%)	0	1 (0.2%)
Abortion Spontaneous Incomplete	0	1 (0.4%)	1 (0.2%)
Cervical Incompetence	1 (0.4%)	0	1 (0.2%)
Delivery	1 (0.4%)	0	1 (0.2%)
Ectopic Pregnancy	0	1 (0.4%)	1 (0.2%)
Gestational Hypertension	1 (0.4%)	0	1 (0.2%)
Postpartum Haemorrhage	0	1 (0.4%)	1 (0.2%)
Product Issues	0	1 (0.4%)	1 (0.2%)
Thrombosis In Device	0	1 (0.4%)	1 (0.2%)
Psychiatric Disorders	51 (18.0%)	59 (20.9%)	110 (19.5%)
Anxiety	16 (5.7%)	30 (10.6%)	46 (8.1%)
Insomnia	17 (6.0%)	28 (9.9%)	45 (8.0%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Depression	16 (5.7%)	11 (3.9%)	27 (4.8%)
Alcoholism	2 (0.7%)	1 (0.4%)	3 (0.5%)
Tobacco Abuse	2 (0.7%)	1 (0.4%)	3 (0.5%)
Mixed Anxiety And Depressive Disorder	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nicotine Dependence	2 (0.7%)	0	2 (0.4%)
Adjustment Disorder	1 (0.4%)	0	1 (0.2%)
Affective Disorder	1 (0.4%)	0	1 (0.2%)
Alcohol Abuse	1 (0.4%)	0	1 (0.2%)
Alcohol Withdrawal Syndrome	1 (0.4%)	0	1 (0.2%)
Anticipatory Anxiety	0	1 (0.4%)	1 (0.2%)
Anxiety Disorder	0	1 (0.4%)	1 (0.2%)
Bipolar Disorder	0	1 (0.4%)	1 (0.2%)
Bruxism	0	1 (0.4%)	1 (0.2%)
Depressed Mood	1 (0.4%)	0	1 (0.2%)
Major Depression	0	1 (0.4%)	1 (0.2%)
Panic Attack	0	1 (0.4%)	1 (0.2%)
Post-Traumatic Stress Disorder	1 (0.4%)	0	1 (0.2%)
Stress	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	27 (9.5%)	28 (9.9%)	55 (9.7%)
Hydronephrosis	3 (1.1%)	7 (2.5%)	10 (1.8%)
Nephrolithiasis	5 (1.8%)	4 (1.4%)	9 (1.6%)
Dysuria	3 (1.1%)	4 (1.4%)	7 (1.2%)
Renal Cyst	3 (1.1%)	4 (1.4%)	7 (1.2%)
Acute Kidney Injury	1 (0.4%)	2 (0.7%)	3 (0.5%)
Chronic Kidney Disease	0	3 (1.1%)	3 (0.5%)
Pollakiuria	1 (0.4%)	2 (0.7%)	3 (0.5%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Proteinuria	2 (0.7%)	1 (0.4%)	3 (0.5%)
Ureterolithiasis	3 (1.1%)	0	3 (0.5%)
Calculus Urinary	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haematuria	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypertonic Bladder	2 (0.7%)	0	2 (0.4%)
Nocturia	0	2 (0.7%)	2 (0.4%)
Urinary Retention	2 (0.7%)	0	2 (0.4%)
Urinary Tract Obstruction	0	2 (0.7%)	2 (0.4%)
Bladder Obstruction	1 (0.4%)	0	1 (0.2%)
Bladder Spasm	0	1 (0.4%)	1 (0.2%)
Calculus Bladder	0	1 (0.4%)	1 (0.2%)
Cystitis Glandularis	1 (0.4%)	0	1 (0.2%)
Renal Impairment	1 (0.4%)	0	1 (0.2%)
Renal Pain	0	1 (0.4%)	1 (0.2%)
Stress Urinary Incontinence	0	1 (0.4%)	1 (0.2%)
Ureteric Obstruction	1 (0.4%)	0	1 (0.2%)
Urge Incontinence	0	1 (0.4%)	1 (0.2%)
Reproductive System And Breast Disorders	25 (8.8%)	34 (12.1%)	59 (10.4%)
Benign Prostatic Hyperplasia	16 (5.7%)	16 (5.7%)	32 (5.7%)
Erectile Dysfunction	3 (1.1%)	5 (1.8%)	8 (1.4%)
Pelvic Pain	1 (0.4%)	3 (1.1%)	4 (0.7%)
Ovarian Cyst	2 (0.7%)	1 (0.4%)	3 (0.5%)
Prostatomegaly	0	3 (1.1%)	3 (0.5%)
Adenomyosis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Prostatic Calcification	0	2 (0.7%)	2 (0.4%)
Breast Cyst	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Cervical Dysplasia	1 (0.4%)	0	1 (0.2%)
Endometrial Hyperplasia	1 (0.4%)	0	1 (0.2%)
Female Genital Tract Fistula	0	1 (0.4%)	1 (0.2%)
Menstruation Irregular	0	1 (0.4%)	1 (0.2%)
Penile Pain	1 (0.4%)	0	1 (0.2%)
Polycystic Ovaries	1 (0.4%)	0	1 (0.2%)
Sexual Dysfunction	0	1 (0.4%)	1 (0.2%)
Testicular Atrophy	0	1 (0.4%)	1 (0.2%)
Vaginal Haemorrhage	0	1 (0.4%)	1 (0.2%)
Vulvovaginal Dryness	0	1 (0.4%)	1 (0.2%)
Vulvovaginal Pruritus	0	1 (0.4%)	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	47 (16.6%)	49 (17.4%)	96 (17.0%)
Cough	7 (2.5%)	13 (4.6%)	20 (3.5%)
Asthma	9 (3.2%)	8 (2.8%)	17 (3.0%)
Dyspnoea	9 (3.2%)	6 (2.1%)	15 (2.7%)
Chronic Obstructive Pulmonary Disease	6 (2.1%)	7 (2.5%)	13 (2.3%)
Rhinitis Allergic	8 (2.8%)	4 (1.4%)	12 (2.1%)
Pulmonary Embolism	4 (1.4%)	5 (1.8%)	9 (1.6%)
Pleural Effusion	2 (0.7%)	4 (1.4%)	6 (1.1%)
Obstructive Sleep Apnoea Syndrome	2 (0.7%)	2 (0.7%)	4 (0.7%)
Pneumothorax	0	4 (1.4%)	4 (0.7%)
Pulmonary Mass	1 (0.4%)	3 (1.1%)	4 (0.7%)
Sleep Apnoea Syndrome	2 (0.7%)	2 (0.7%)	4 (0.7%)
Bronchiectasis	2 (0.7%)	1 (0.4%)	3 (0.5%)
Emphysema	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hiccups	3 (1.1%)	0	3 (0.5%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Rhinorrhoea	2 (0.7%)	1 (0.4%)	3 (0.5%)
Atelectasis	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dysphonia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dyspnoea Exertional	0	2 (0.7%)	2 (0.4%)
Nasal Polyps	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sinus Congestion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Upper-Airway Cough Syndrome	2 (0.7%)	0	2 (0.4%)
Allergic Sinusitis	1 (0.4%)	0	1 (0.2%)
Nasal Cavity Mass	1 (0.4%)	0	1 (0.2%)
Nasal Congestion	0	1 (0.4%)	1 (0.2%)
Nasal Septum Deviation	0	1 (0.4%)	1 (0.2%)
Obstructive Airways Disorder	1 (0.4%)	0	1 (0.2%)
Pleuritic Pain	0	1 (0.4%)	1 (0.2%)
Pneumonitis	0	1 (0.4%)	1 (0.2%)
Pulmonary Congestion	0	1 (0.4%)	1 (0.2%)
Pulmonary Hypertension	0	1 (0.4%)	1 (0.2%)
Pulmonary Thrombosis	0	1 (0.4%)	1 (0.2%)
Rhinitis Hypertrophic	0	1 (0.4%)	1 (0.2%)
Wheezing	1 (0.4%)	0	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	14 (4.9%)	24 (8.5%)	38 (6.7%)
Psoriasis	2 (0.7%)	5 (1.8%)	7 (1.2%)
Dry Skin	1 (0.4%)	5 (1.8%)	6 (1.1%)
Eczema	1 (0.4%)	4 (1.4%)	5 (0.9%)
Pruritus	1 (0.4%)	3 (1.1%)	4 (0.7%)
Actinic Keratosis	0	2 (0.7%)	2 (0.4%)
Alopecia	0	2 (0.7%)	2 (0.4%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Dermatitis Atopic	2 (0.7%)	0	2 (0.4%)
Night Sweats	1 (0.4%)	1 (0.4%)	2 (0.4%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.7%)	0	2 (0.4%)
Skin Lesion	0	2 (0.7%)	2 (0.4%)
Alopecia Areata	1 (0.4%)	0	1 (0.2%)
Dermatitis	0	1 (0.4%)	1 (0.2%)
Hand Dermatitis	1 (0.4%)	0	1 (0.2%)
Hyperhidrosis	0	1 (0.4%)	1 (0.2%)
Itching Scar	0	1 (0.4%)	1 (0.2%)
Lipohypertrophy	0	1 (0.4%)	1 (0.2%)
Rash	1 (0.4%)	0	1 (0.2%)
Seborrhoea	0	1 (0.4%)	1 (0.2%)
Skin Mass	1 (0.4%)	0	1 (0.2%)
Skin Ulcer	1 (0.4%)	0	1 (0.2%)
Vitiligo	1 (0.4%)	0	1 (0.2%)
Social Circumstances	8 (2.8%)	8 (2.8%)	16 (2.8%)
Ex-Tobacco User	4 (1.4%)	1 (0.4%)	5 (0.9%)
Tobacco User	1 (0.4%)	3 (1.1%)	4 (0.7%)
Alcohol Use	1 (0.4%)	2 (0.7%)	3 (0.5%)
Menopause	1 (0.4%)	2 (0.7%)	3 (0.5%)
Social Alcohol Drinker	0	3 (1.1%)	3 (0.5%)
Postmenopause	2 (0.7%)	0	2 (0.4%)
Surgical And Medical Procedures	40 (14.1%)	50 (17.7%)	90 (15.9%)
Appendicectomy	4 (1.4%)	11 (3.9%)	15 (2.7%)
Cholecystectomy	3 (1.1%)	6 (2.1%)	9 (1.6%)
Cataract Operation	1 (0.4%)	5 (1.8%)	6 (1.1%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Gastrectomy	4 (1.4%)	2 (0.7%)	6 (1.1%)
Hysterectomy	2 (0.7%)	3 (1.1%)	5 (0.9%)
Inguinal Hernia Repair	3 (1.1%)	1 (0.4%)	4 (0.7%)
Polypectomy	1 (0.4%)	3 (1.1%)	4 (0.7%)
Caesarean Section	1 (0.4%)	2 (0.7%)	3 (0.5%)
Haemorrhoid Operation	2 (0.7%)	1 (0.4%)	3 (0.5%)
Hysterosalpingo-Oophorectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Intervertebral Disc Operation	1 (0.4%)	2 (0.7%)	3 (0.5%)
Knee Operation	1 (0.4%)	2 (0.7%)	3 (0.5%)
Prostatectomy	2 (0.7%)	1 (0.4%)	3 (0.5%)
Salpingo-Oophorectomy Bilateral	2 (0.7%)	1 (0.4%)	3 (0.5%)
Splenectomy	3 (1.1%)	0	3 (0.5%)
Tonsillectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Vasectomy	1 (0.4%)	2 (0.7%)	3 (0.5%)
Cardiac Pacemaker Insertion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Coronary Arterial Stent Insertion	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hip Arthroplasty	2 (0.7%)	0	2 (0.4%)
Jejunostomy	0	2 (0.7%)	2 (0.4%)
Meniscus Operation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nephrostomy	2 (0.7%)	0	2 (0.4%)
Oesophageal Prosthesis Insertion	2 (0.7%)	0	2 (0.4%)
Oophorectomy	2 (0.7%)	0	2 (0.4%)
Salpingo-Oophorectomy Unilateral	1 (0.4%)	1 (0.4%)	2 (0.4%)
Shoulder Operation	1 (0.4%)	1 (0.4%)	2 (0.4%)
Thyroidectomy	0	2 (0.7%)	2 (0.4%)
Abdominoplasty	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Adenoidectomy	0	1 (0.4%)	1 (0.2%)
Amblyopia Therapy	0	1 (0.4%)	1 (0.2%)
Ankle Operation	0	1 (0.4%)	1 (0.2%)
Apicectomy	1 (0.4%)	0	1 (0.2%)
Bone Graft	0	1 (0.4%)	1 (0.2%)
Brachytherapy To Prostate	0	1 (0.4%)	1 (0.2%)
Brain Operation	0	1 (0.4%)	1 (0.2%)
Breast Conserving Surgery	1 (0.4%)	0	1 (0.2%)
Breast Cyst Excision	0	1 (0.4%)	1 (0.2%)
Cardiac Ablation	1 (0.4%)	0	1 (0.2%)
Central Venous Catheterisation	1 (0.4%)	0	1 (0.2%)
Colectomy	0	1 (0.4%)	1 (0.2%)
Colostomy	0	1 (0.4%)	1 (0.2%)
Coronary Artery Bypass	0	1 (0.4%)	1 (0.2%)
Female Sterilisation	0	1 (0.4%)	1 (0.2%)
Finger Amputation	0	1 (0.4%)	1 (0.2%)
Foot Operation	1 (0.4%)	0	1 (0.2%)
Gallbladder Operation	0	1 (0.4%)	1 (0.2%)
Gastric Bypass	1 (0.4%)	0	1 (0.2%)
Gastric Operation	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Tube Insertion	0	1 (0.4%)	1 (0.2%)
Haematopoietic Stem Cell Mobilisation	1 (0.4%)	0	1 (0.2%)
Hernia Repair	1 (0.4%)	0	1 (0.2%)
Implantable Defibrillator Insertion	0	1 (0.4%)	1 (0.2%)
Internal Fixation Of Fracture	1 (0.4%)	0	1 (0.2%)
Intraocular Lens Implant	0	1 (0.4%)	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Knee Arthroplasty	0	1 (0.4%)	1 (0.2%)
Large Intestinal Polypectomy	0	1 (0.4%)	1 (0.2%)
Lens Extraction	0	1 (0.4%)	1 (0.2%)
Ligament Operation	0	1 (0.4%)	1 (0.2%)
Mammoplasty	1 (0.4%)	0	1 (0.2%)
Mass Excision	0	1 (0.4%)	1 (0.2%)
Mastectomy	0	1 (0.4%)	1 (0.2%)
Mitral Valve Replacement	0	1 (0.4%)	1 (0.2%)
Oesophagoenterostomy	0	1 (0.4%)	1 (0.2%)
Oophorectomy Bilateral	0	1 (0.4%)	1 (0.2%)
Open Reduction Of Fracture	0	1 (0.4%)	1 (0.2%)
Optic Nerve Operation	1 (0.4%)	0	1 (0.2%)
Pituitary Tumour Removal	1 (0.4%)	0	1 (0.2%)
Pleural Decortication	0	1 (0.4%)	1 (0.2%)
Proctectomy	1 (0.4%)	0	1 (0.2%)
Roux Loop Conversion	1 (0.4%)	0	1 (0.2%)
Salpingectomy	0	1 (0.4%)	1 (0.2%)
Skin Neoplasm Excision	1 (0.4%)	0	1 (0.2%)
Spinal Operation	1 (0.4%)	0	1 (0.2%)
Thrombosis Prophylaxis	1 (0.4%)	0	1 (0.2%)
Tooth Extraction	1 (0.4%)	0	1 (0.2%)
Transurethral Bladder Resection	1 (0.4%)	0	1 (0.2%)
Transurethral Prostatectomy	0	1 (0.4%)	1 (0.2%)
Tumour Excision	1 (0.4%)	0	1 (0.2%)
Umbilical Hernia Repair	0	1 (0.4%)	1 (0.2%)
Urethral Stent Insertion	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.4: Summary of Medical History by SOC/PT - Full Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)	Total (N=565)
Wound Closure	0	1 (0.4%)	1 (0.2%)
Vascular Disorders	86 (30.4%)	97 (34.4%)	183 (32.4%)
Hypertension	80 (28.3%)	90 (31.9%)	170 (30.1%)
Deep Vein Thrombosis	2 (0.7%)	2 (0.7%)	4 (0.7%)
Hypotension	1 (0.4%)	3 (1.1%)	4 (0.7%)
Aortic Aneurysm	0	2 (0.7%)	2 (0.4%)
Peripheral Vascular Disorder	0	2 (0.7%)	2 (0.4%)
Peripheral Venous Disease	0	2 (0.7%)	2 (0.4%)
Phlebitis	0	2 (0.7%)	2 (0.4%)
Aortic Stenosis	0	1 (0.4%)	1 (0.2%)
Arteriosclerosis	1 (0.4%)	0	1 (0.2%)
Atheroembolism	0	1 (0.4%)	1 (0.2%)
Embolism Arterial	0	1 (0.4%)	1 (0.2%)
Essential Hypertension	0	1 (0.4%)	1 (0.2%)
Hot Flush	0	1 (0.4%)	1 (0.2%)
Pallor	1 (0.4%)	0	1 (0.2%)
Pelvic Venous Thrombosis	1 (0.4%)	0	1 (0.2%)
Raynaud's Phenomenon	1 (0.4%)	0	1 (0.2%)
Subclavian Artery Stenosis	0	1 (0.4%)	1 (0.2%)
Subclavian Vein Thrombosis	0	1 (0.4%)	1 (0.2%)
Varicose Vein	1 (0.4%)	0	1 (0.2%)
Vena Cava Thrombosis	1 (0.4%)	0	1 (0.2%)
Venous Thrombosis	1 (0.4%)	0	1 (0.2%)

Abbreviations: N=number of patients; PT=preferred term; SOC=system organ class.
Sorting order: alphabetical order by SOC and descending order by the number of subjects of overall group by PT. In case of ties, alphabetical order by PT is applied.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G4 Gesamtüberleben

1. Time-to-Event-Analyse

Table 301.3.1002.1.1: Summary of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	197 (69.6%)	217 (77.0%)	
Number of patients censored	86 (30.4%)	65 (23.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	18.2 [16.1, 20.6]	15.6 [13.7, 16.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.784 [0.644, 0.954]
Log-rank test			
Two-sided stratified log-rank p-value			0.0149

Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.1.2: Type of Events and Censoring of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	197 (69.6%)	217 (77.0%)
Death Before Analysis Cutoff Date	197 (69.6%)	217 (77.0%)
Number of patients censored	86 (30.4%)	65 (23.0%)
Last Known Alive Date Is Before Cutoff Date	75 (26.5%)	52 (18.4%)
Censored At Cutoff Date	11 (3.9%)	13 (4.6%)

Abbreviations: N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.1.3: Summary of Overall Survival by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	126 (69.6)	19.0 [16.7, 22.9]	181	135 (74.6)	15.6 [13.6, 17.7]	0.823 [0.644, 1.050]	0.1177	0.3969
>65 years	102	71 (69.6)	16.2 [12.5, 21.5]	101	82 (81.2)	15.3 [10.6, 16.9]	0.727 [0.527, 1.002]	0.0506	
Age Group2									
<=75 years	267	184 (68.9)	18.6 [16.5, 21.5]	260	200 (76.9)	15.5 [13.6, 17.1]	0.768 [0.628, 0.939]	0.0100	0.3486
>75 years	16	13 (81.3)	10.9 [8.5, 25.3]	22	17 (77.3)	15.7 [9.1, 26.6]	1.200 [0.580, 2.481]	0.6208	
Sex									
Male	176	124 (70.5)	17.2 [15.0, 19.8]	175	139 (79.4)	15.5 [12.4, 16.5]	0.774 [0.607, 0.988]	0.0396	0.7460
Female	107	73 (68.2)	20.7 [17.0, 24.9]	107	78 (72.9)	16.1 [13.4, 19.7]	0.815 [0.591, 1.124]	0.2099	
Race									
White	140	109 (77.9)	16.1 [12.6, 18.6]	134	105 (78.4)	15.3 [13.6, 17.1]	0.940 [0.718, 1.231]	0.6537	0.0819
Asian	96	59 (61.5)	24.8 [19.7, 28.6]	97	72 (74.2)	16.9 [13.2, 19.4]	0.636 [0.450, 0.899]	0.0097	
Tobacco History									
Current	26	17 (65.4)	19.4 [14.3, 26.6]	25	19 (76.0)	15.6 [13.6, 27.5]	0.845 [0.438, 1.634]	0.6136	0.5503
Former	113	83 (73.5)	17.8 [14.1, 22.4]	118	89 (75.4)	15.8 [13.4, 17.7]	0.878 [0.650, 1.187]	0.3987	
Never	142	97 (68.3)	18.2 [14.6, 21.5]	137	108 (78.8)	13.9 [10.7, 17.4]	0.718 [0.545, 0.946]	0.0179	
Region									
Asia	88	55 (62.5)	23.3 [18.2, 30.0]	89	66 (74.2)	17.7 [15.4, 21.2]	0.696 [0.486, 0.996]	0.0468	0.4859
Non-Asia	195	142 (72.8)	16.4 [12.6, 18.9]	193	151 (78.2)	13.9 [11.9, 15.8]	0.833 [0.661, 1.049]	0.1201	
Number of Organs with Metastatic Sites									
0-2	219	145 (66.2)	19.7 [17.5, 23.3]	219	159 (72.6)	16.4 [14.3, 19.0]	0.812 [0.647, 1.018]	0.0704	0.4453
>=3	64	52 (81.3)	14.6 [9.8, 17.4]	63	58 (92.1)	12.0 [9.1, 14.2]	0.682 [0.466, 0.997]	0.0473	
Prior Gastrectomy (total or partial)									
Yes	84	50 (59.5)	25.3 [20.7, 30.0]	82	63 (76.8)	15.7 [13.1, 19.7]	0.567 [0.390, 0.825]	0.0027	0.0410
No	199	147 (73.9)	16.1 [13.5, 17.8]	200	154 (77.0)	15.4 [13.1, 17.1]	0.915 [0.729, 1.147]	0.4395	

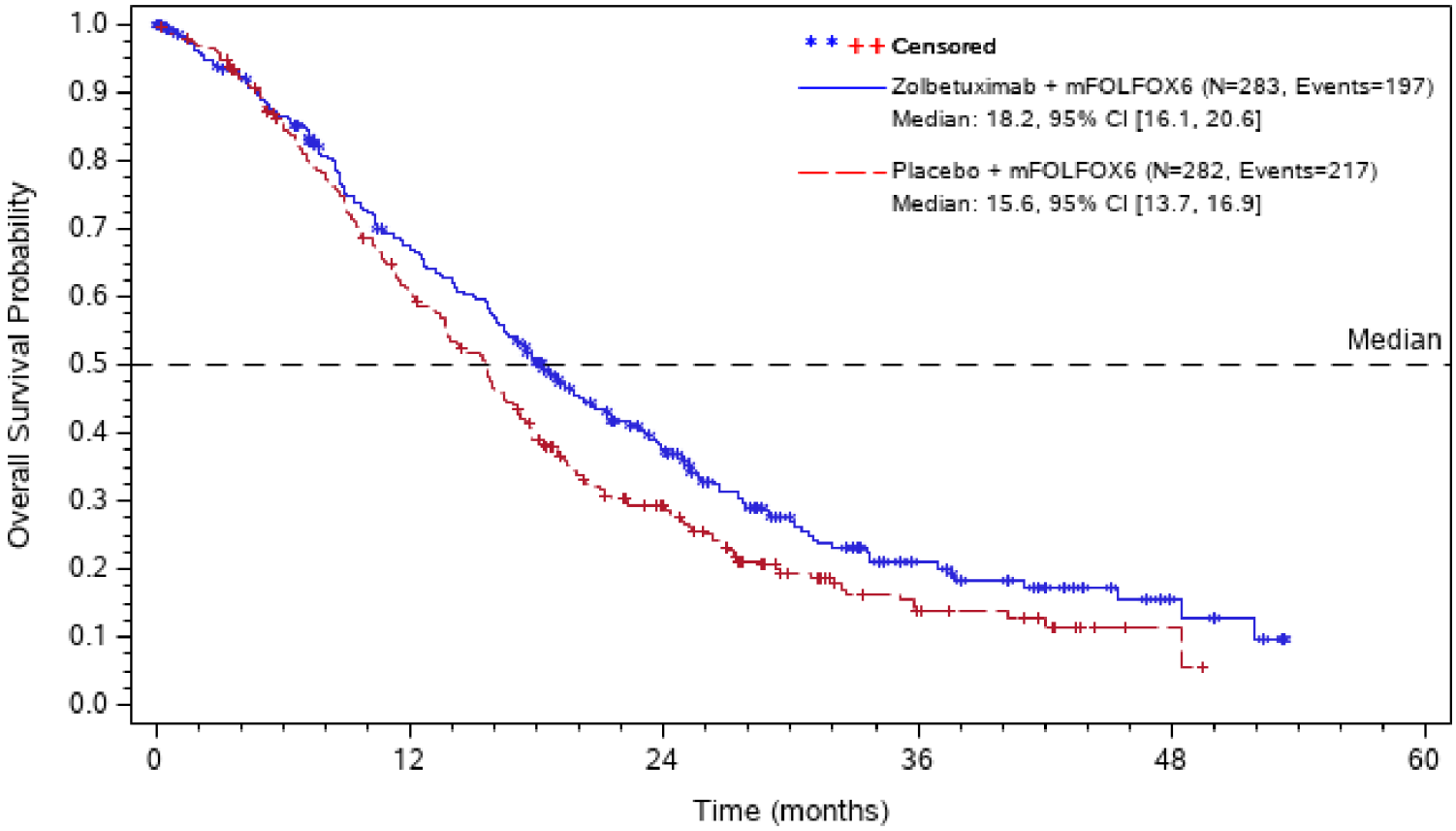
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	82	63 (76.8)	19.7 [17.0, 23.1]	117	86 (73.5)	16.5 [11.9, 19.0]	0.914 [0.660, 1.267]	0.5891	0.1282
Intestinal	70	48 (68.6)	17.9 [14.3, 25.8]	66	57 (86.4)	13.8 [10.3, 17.7]	0.567 [0.382, 0.840]	0.0042	
Mixed/Other	81	57 (70.4)	16.1 [10.4, 21.5]	55	44 (80.0)	14.6 [13.1, 19.2]	0.888 [0.596, 1.322]	0.5551	
Tumor Location 1									
Gastric	219	148 (67.6)	19.8 [17.0, 23.3]	210	161 (76.7)	14.3 [12.3, 16.9]	0.725 [0.579, 0.907]	0.0048	0.1169
GEJ	64	49 (76.6)	15.7 [12.0, 17.8]	72	56 (77.8)	16.4 [13.8, 19.2]	1.022 [0.694, 1.505]	0.9141	
Tumor Location 2									
Gastric Proximal	73	50 (68.5)	17.8 [14.1, 25.6]	59	46 (78.0)	17.6 [13.5, 19.7]	0.767 [0.511, 1.150]	0.1975	0.5992
Gastric Distal	91	56 (61.5)	22.9 [19.0, 28.6]	87	64 (73.6)	13.7 [11.2, 16.5]	0.653 [0.455, 0.937]	0.0197	
Tumor Location 3									
GEJ Proximal	30	22 (73.3)	17.5 [13.2, 25.1]	26	23 (88.5)	15.6 [7.4, 19.2]	0.660 [0.362, 1.205]	0.1731	0.1708
GEJ Distal	19	14 (73.7)	12.6 [8.7, 20.0]	31	23 (74.2)	17.1 [11.6, 27.0]	1.155 [0.593, 2.250]	0.6681	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event.
[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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G4 Gesamtüberleben

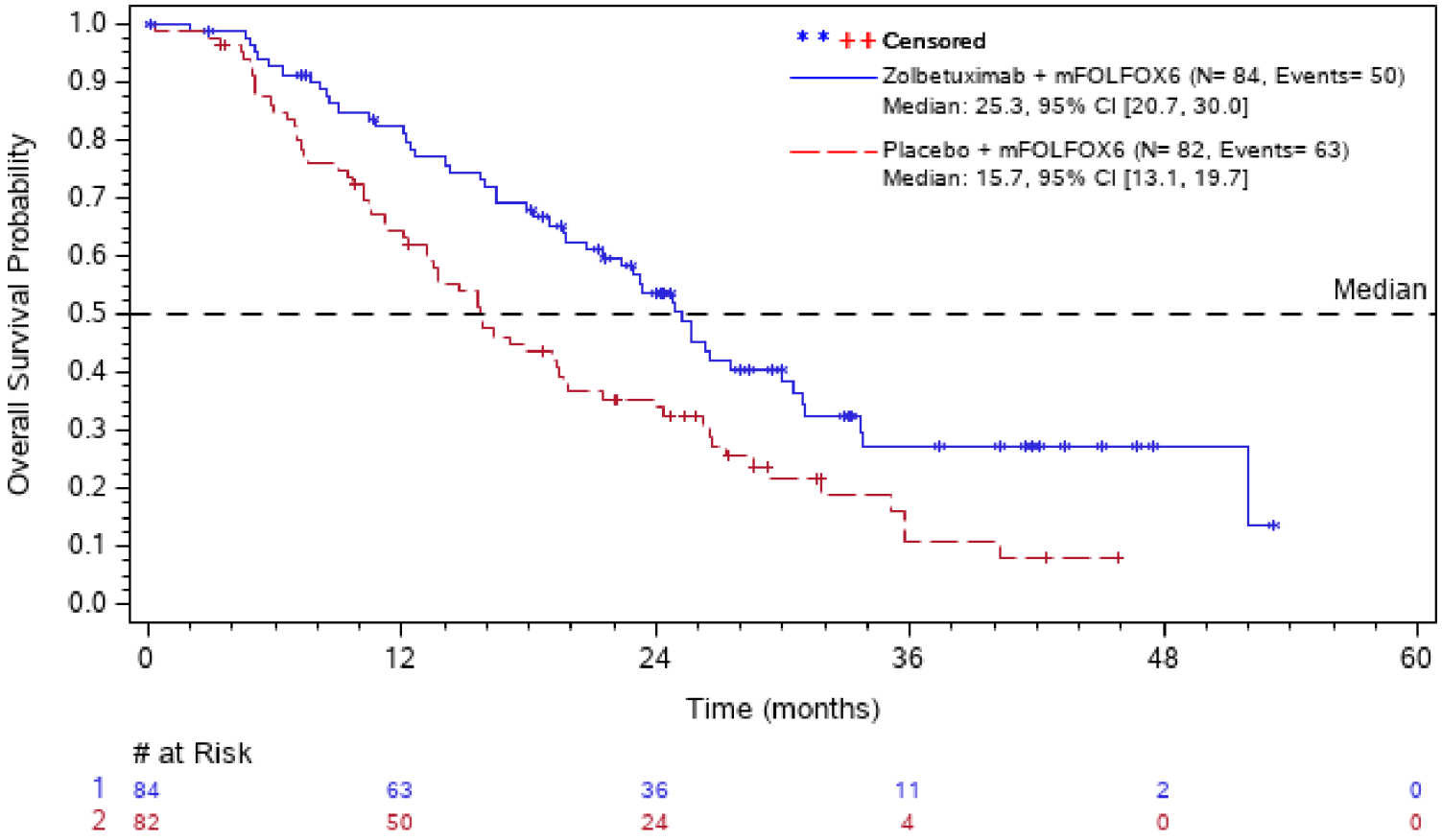
2. Kaplan-Meier-Plots

Figure 301.3.1002.1: Kaplan-Meier Plot of Overall Survival - Full Analysis Set



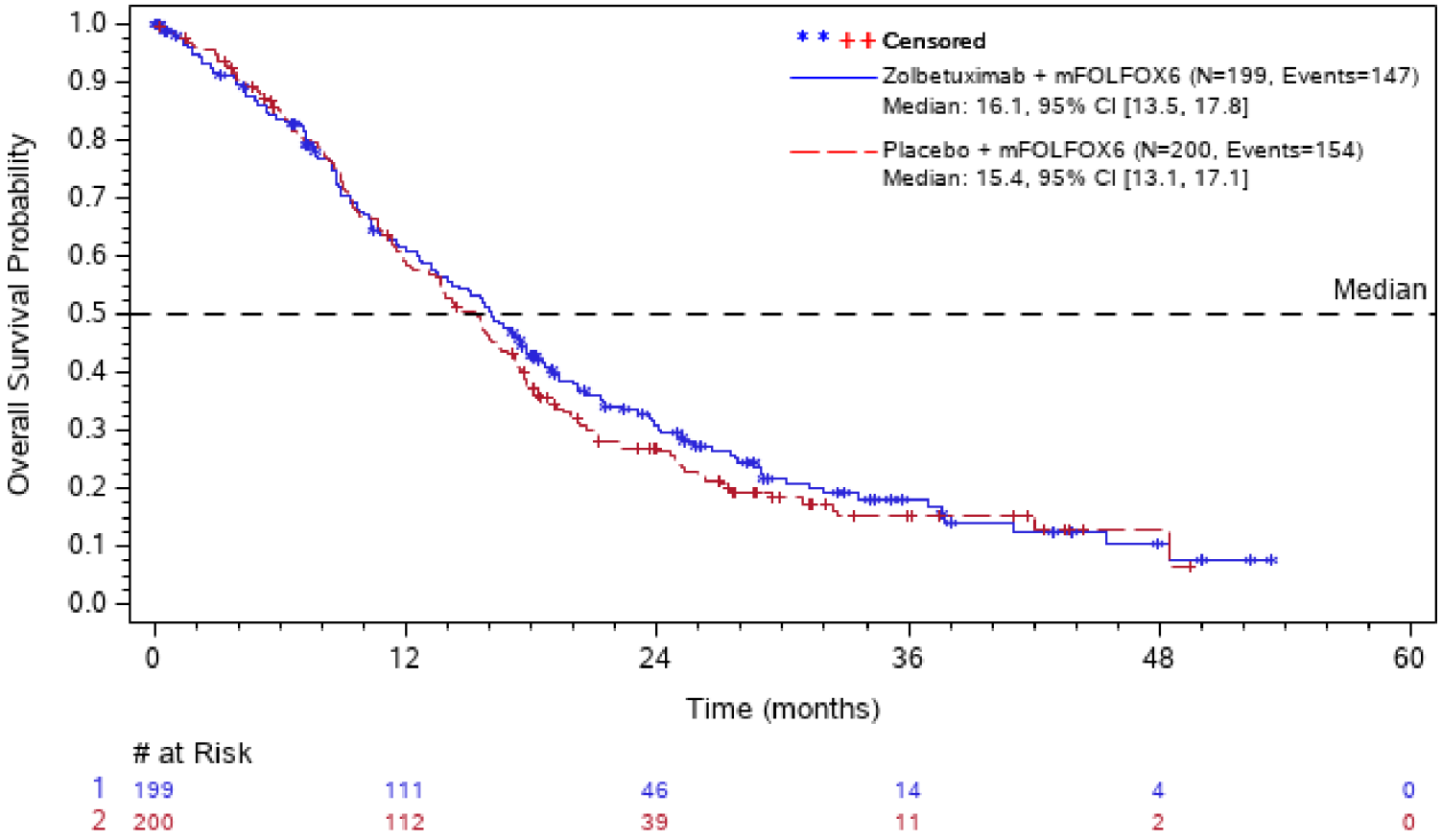
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Figure 301.3.1002.1.8: Kaplan-Meier Plot of Overall Survival by Prior Gastrectomy (total or partial) - Full Analysis Set
IRT- Prior Gastrectomy: Yes



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Figure 301.3.1002.1.8: Kaplan-Meier Plot of Overall Survival by Prior Gastrectomy (total or partial) - Full Analysis Set
IRT- Prior Gastrectomy: No



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben

Anhang 4-G4 Progressionsfreies Überleben (IRC und INV)

1. Time-to-Event-Analysen

Table 301.3.1002.2.1: Summary of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	159 (56.2%)	187 (66.3%)	
Number of patients censored	124 (43.8%)	95 (33.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	11.0 [9.7, 12.5]	8.9 [8.2, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.734 [0.591, 0.910]
Log-rank test			
Two-sided stratified log-rank p-value			0.0048

Abbreviations: CI=confidence interval; HR=hazard ratio; IRC=independent review committee; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.2.2: Type of Events and Censoring of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	159 (56.2%)	187 (66.3%)
rPD	93 (32.9%)	111 (39.4%)
No rPD, but death recorded on eCRF	66 (23.3%)	76 (27.0%)
Number of patients censored	124 (43.8%)	95 (33.7%)

Abbreviations: eCRF=electronic case report form; IRC=independent review committee; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.2.3: Summary of Progression-Free Survival (IRC) by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	102 (56.4)	12.2 [8.8, 15.1]	181	118 (65.2)	10.2 [8.0, 10.7]	0.763 [0.585, 0.996]	0.0459	0.5671
>65 years	102	57 (55.9)	10.6 [8.3, 17.0]	101	69 (68.3)	8.7 [7.4, 10.5]	0.681 [0.479, 0.970]	0.0315	
Age Group2									
<=75 years	267	151 (56.6)	11.2 [9.8, 12.6]	260	169 (65.0)	8.6 [8.1, 10.4]	0.739 [0.593, 0.921]	0.0067	0.8029
>75 years	16	8 (50.0)	9.7 [4.4, NC]	22	18 (81.8)	10.5 [7.1, 14.9]	0.702 [0.303, 1.625]	0.3984	
Sex									
Male	176	103 (58.5)	10.6 [8.7, 12.6]	175	123 (70.3)	9.2 [8.2, 10.6]	0.712 [0.547, 0.926]	0.0107	0.7924
Female	107	56 (52.3)	11.0 [8.9, 18.1]	107	64 (59.8)	8.5 [7.4, 10.8]	0.774 [0.540, 1.110]	0.1615	
Race									
White	140	87 (62.1)	9.3 [8.3, 12.4]	134	98 (73.1)	10.2 [8.4, 12.6]	0.872 [0.653, 1.164]	0.3509	0.0518
Asian	96	48 (50.0)	14.0 [12.3, 20.5]	97	53 (54.6)	8.2 [6.5, 9.1]	0.526 [0.354, 0.781]	0.0013	
Tobacco History									
Current	26	16 (61.5)	12.2 [7.4, 15.8]	25	16 (64.0)	10.2 [4.4, 17.6]	0.822 [0.405, 1.670]	0.5928	0.8906
Former	113	61 (54.0)	12.3 [8.8, 17.4]	118	78 (66.1)	10.2 [8.2, 11.3]	0.694 [0.495, 0.972]	0.0318	
Never	142	82 (57.7)	10.4 [8.3, 12.5]	137	92 (67.2)	8.3 [7.4, 10.4]	0.750 [0.556, 1.011]	0.0577	
Region									
Asia	88	45 (51.1)	13.2 [10.4, 18.1]	89	49 (55.1)	8.2 [6.5, 10.3]	0.553 [0.367, 0.833]	0.0041	0.1226
Non-Asia	195	114 (58.5)	10.2 [8.5, 12.4]	193	138 (71.5)	10.2 [8.2, 11.3]	0.814 [0.635, 1.044]	0.1027	
Number of Organs with Metastatic Sites									
0-2	219	119 (54.3)	12.4 [10.4, 16.1]	219	140 (63.9)	10.2 [8.3, 11.4]	0.712 [0.557, 0.910]	0.0064	0.7285
>=3	64	40 (62.5)	8.2 [6.3, 9.7]	63	47 (74.6)	8.0 [6.3, 9.8]	0.802 [0.525, 1.225]	0.3042	
Prior Gastrectomy (total or partial)									
Yes	84	43 (51.2)	12.4 [10.4, 18.2]	82	58 (70.7)	9.3 [7.2, 11.3]	0.567 [0.381, 0.842]	0.0044	0.1196
No	199	116 (58.3)	10.2 [8.4, 12.5]	200	129 (64.5)	8.7 [8.2, 10.5]	0.819 [0.636, 1.053]	0.1181	

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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]**
Histology (Tumor Type)									
Diffuse	82	45 (54.9)	12.5 [9.3, 18.3]	117	68 (58.1)	10.4 [8.4, 13.7]	0.794 [0.543, 1.160]	0.2312	0.2930
Intestinal	70	44 (62.9)	10.4 [8.3, 12.5]	66	49 (74.2)	7.4 [6.0, 10.3]	0.599 [0.395, 0.909]	0.0147	
Mixed/Other	81	51 (63.0)	9.8 [7.6, 12.6]	55	42 (76.4)	8.7 [6.8, 12.4]	0.848 [0.563, 1.278]	0.4310	
Tumor Location 1									
Gastric	219	118 (53.9)	12.4 [10.2, 15.3]	210	138 (65.7)	8.7 [7.9, 10.4]	0.660 [0.515, 0.845]	0.0009	0.0659
GEJ	64	41 (64.1)	8.7 [7.4, 12.5]	72	49 (68.1)	9.8 [8.2, 12.5]	1.052 [0.694, 1.594]	0.8121	
Tumor Location 2									
Gastric Proximal	73	41 (56.2)	10.2 [8.2, 18.2]	59	36 (61.0)	8.3 [7.6, 14.9]	0.786 [0.500, 1.234]	0.2925	0.3227
Gastric Distal	91	45 (49.5)	15.1 [12.3, 20.5]	87	55 (63.2)	9.4 [6.8, 10.6]	0.546 [0.366, 0.813]	0.0025	
Tumor Location 3									
GEJ Proximal	30	18 (60.0)	11.2 [8.2, 17.8]	26	21 (80.8)	7.4 [4.1, 8.7]	0.553 [0.292, 1.048]	0.0662	0.1277
GEJ Distal	19	12 (63.2)	8.8 [6.4, 12.5]	31	21 (67.7)	10.8 [8.0, 18.0]	1.129 [0.554, 2.299]	0.7379	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; HR=hazard ratio; IRC=independent review committee; KME=Kaplan-Meier Estimate of time to event (months); 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: 08SEP23

Table 301.3.1002.3.1: Summary of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	191 (67.5%)	221 (78.4%)	
Number of patients censored	92 (32.5%)	61 (21.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.5 [9.3, 12.3]	8.4 [7.9, 10.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.713 [0.584, 0.869]
Log-rank test			
Two-sided stratified log-rank p-value			0.0008

Abbreviations: CI=confidence interval; HR=hazard ratio; INV=investigator; N=number of patients.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.3.2: Type of Events and Censoring of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Number of patients at risk	283 (100.0%)	282 (100.0%)
Number of patients with events	191 (67.5%)	221 (78.4%)
rPD	146 (51.6%)	180 (63.8%)
No rPD, but death recorded on eCRF	45 (15.9%)	41 (14.5%)
Number of patients censored	92 (32.5%)	61 (21.6%)

Abbreviations: eCRF= electronic case report form; INV=investigator; N=number of patients; rPD=radiological progressive disease.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1002.3.3: Summary of Progression-Free Survival (INV) by Subgroups - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	125 (69.1)	10.5 [8.4, 12.3]	181	138 (76.2)	8.7 [7.8, 10.3]	0.776 [0.609, 0.990]	0.0404	0.2553
>65 years	102	66 (64.7)	10.6 [8.3, 12.5]	101	83 (82.2)	8.2 [6.3, 9.8]	0.631 [0.454, 0.876]	0.0054	
Age Group2									
<=75 years	267	182 (68.2)	10.6 [8.8, 12.3]	260	204 (78.5)	8.4 [7.8, 10.2]	0.717 [0.586, 0.876]	0.0011	0.9782
>75 years	16	9 (56.3)	9.7 [4.4, NC]	22	17 (77.3)	9.3 [5.9, 13.8]	0.766 [0.339, 1.731]	0.5094	
Sex									
Male	176	121 (68.8)	10.4 [8.4, 12.5]	175	144 (82.3)	8.4 [7.6, 9.8]	0.682 [0.535, 0.871]	0.0020	0.5116
Female	107	70 (65.4)	10.5 [8.3, 14.2]	107	77 (72.0)	8.4 [6.5, 10.6]	0.788 [0.569, 1.091]	0.1495	
Race									
White	140	105 (75.0)	9.7 [6.8, 11.0]	134	112 (83.6)	8.9 [7.8, 10.4]	0.879 [0.673, 1.148]	0.3417	0.0251
Asian	96	61 (63.5)	12.5 [10.4, 15.2]	97	68 (70.1)	8.3 [5.8, 10.2]	0.536 [0.378, 0.762]	0.0004	
Tobacco History									
Current	26	16 (61.5)	11.1 [7.9, 19.6]	25	21 (84.0)	8.4 [4.3, 11.0]	0.660 [0.341, 1.277]	0.2145	0.8878
Former	113	79 (69.9)	10.4 [8.4, 14.0]	118	90 (76.3)	9.3 [7.9, 10.4]	0.742 [0.547, 1.006]	0.0530	
Never	142	95 (66.9)	10.2 [8.1, 12.3]	137	109 (79.6)	8.3 [6.3, 10.2]	0.712 [0.540, 0.940]	0.0161	
Region									
Asia	88	55 (62.5)	12.4 [10.4, 15.2]	89	62 (69.7)	8.4 [6.2, 10.2]	0.551 [0.381, 0.796]	0.0013	0.0867
Non-Asia	195	136 (69.7)	10.2 [8.1, 11.1]	193	159 (82.4)	8.6 [7.8, 10.2]	0.800 [0.635, 1.008]	0.0573	
Number of Organs with Metastatic Sites									
0-2	219	144 (65.8)	11.6 [10.2, 12.5]	219	167 (76.3)	9.4 [8.2, 10.3]	0.705 [0.563, 0.882]	0.0021	0.7348
>=3	64	47 (73.4)	6.5 [6.1, 9.7]	63	54 (85.7)	6.8 [6.0, 8.4]	0.773 [0.519, 1.150]	0.2003	
Prior Gastrectomy (total or partial)									
Yes	84	52 (61.9)	12.4 [10.4, 15.3]	82	66 (80.5)	9.3 [7.1, 12.0]	0.543 [0.376, 0.782]	0.0009	0.0739
No	199	139 (69.8)	9.7 [7.9, 11.1]	200	155 (77.5)	8.4 [7.5, 10.2]	0.816 [0.648, 1.027]	0.0839	

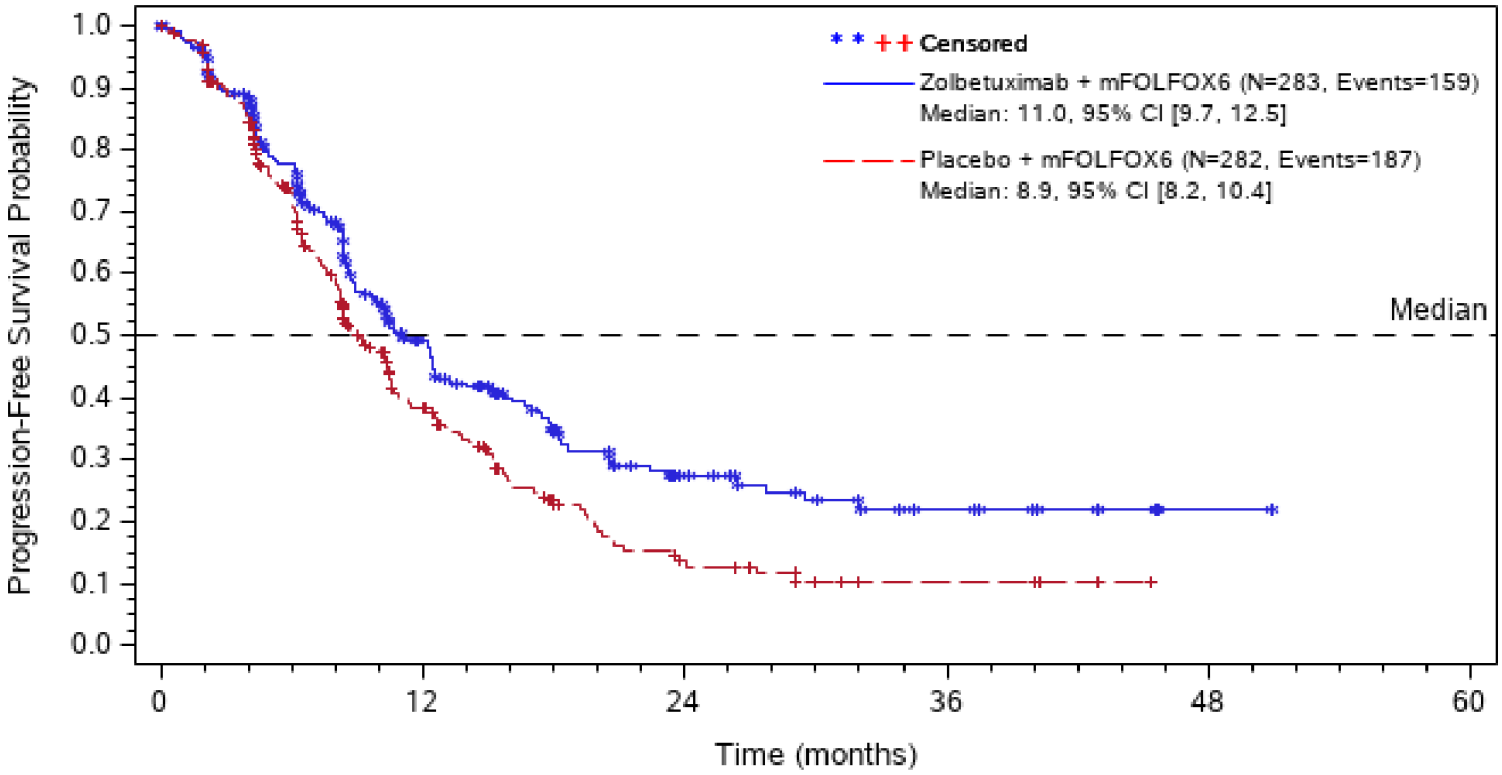
	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
Subgroup	**N**	**n (%)**	**KME [95% CI][a]**	**N**	**n (%)**	**KME [95% CI][a]**	**HR [95% CI][b]**	**Log-rank p-value[c]**	**Test for Interaction p-value[d]**
Histology (Tumor Type)									
Diffuse	82	59 (72.0)	11.0 [8.5, 14.2]	117	84 (71.8)	10.2 [8.3, 11.3]	0.838 [0.600, 1.171]	0.3010	0.1990
Intestinal	70	50 (71.4)	10.4 [6.7, 13.2]	66	54 (81.8)	8.1 [5.7, 10.2]	0.569 [0.381, 0.851]	0.0054	
Mixed/Other	81	57 (70.4)	10.4 [7.7, 12.4]	55	49 (89.1)	8.9 [6.3, 10.3]	0.752 [0.511, 1.107]	0.1465	
Tumor Location 1									
Gastric	219	146 (66.7)	11.3 [10.2, 12.5]	210	160 (76.2)	8.4 [7.8, 10.2]	0.694 [0.553, 0.869]	0.0014	0.4649
GEJ	64	45 (70.3)	8.3 [6.2, 11.0]	72	61 (84.7)	8.4 [6.2, 10.3]	0.827 [0.561, 1.219]	0.3346	
Tumor Location 2									
Gastric Proximal	73	51 (69.9)	10.2 [8.0, 12.3]	59	45 (76.3)	8.7 [7.1, 10.7]	0.790 [0.527, 1.184]	0.2508	0.3341
Gastric Distal	91	58 (63.7)	14.0 [10.4, 15.3]	87	64 (73.6)	8.5 [6.3, 10.4]	0.580 [0.405, 0.831]	0.0026	
Tumor Location 3									
GEJ Proximal	30	21 (70.0)	10.4 [6.5, 14.9]	26	24 (92.3)	5.9 [4.1, 8.4]	0.446 [0.243, 0.819]	0.0079	0.0843
GEJ Distal	19	12 (63.2)	8.3 [4.3, 15.1]	31	26 (83.9)	10.2 [6.2, 13.3]	0.955 [0.481, 1.899]	0.8941	

Abbreviations: CI=confidence interval; GEJ=gastro-esophageal junction; HR=hazard ratio; INV=investigator; KME=Kaplan-Meier Estimate of time to event (months); 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Gesamtüberleben und Progressionsfreies Überleben
Anhang 4-G4 Progressionsfreies Überleben (IRC und INV)

2. Kaplan-Meier-Plots

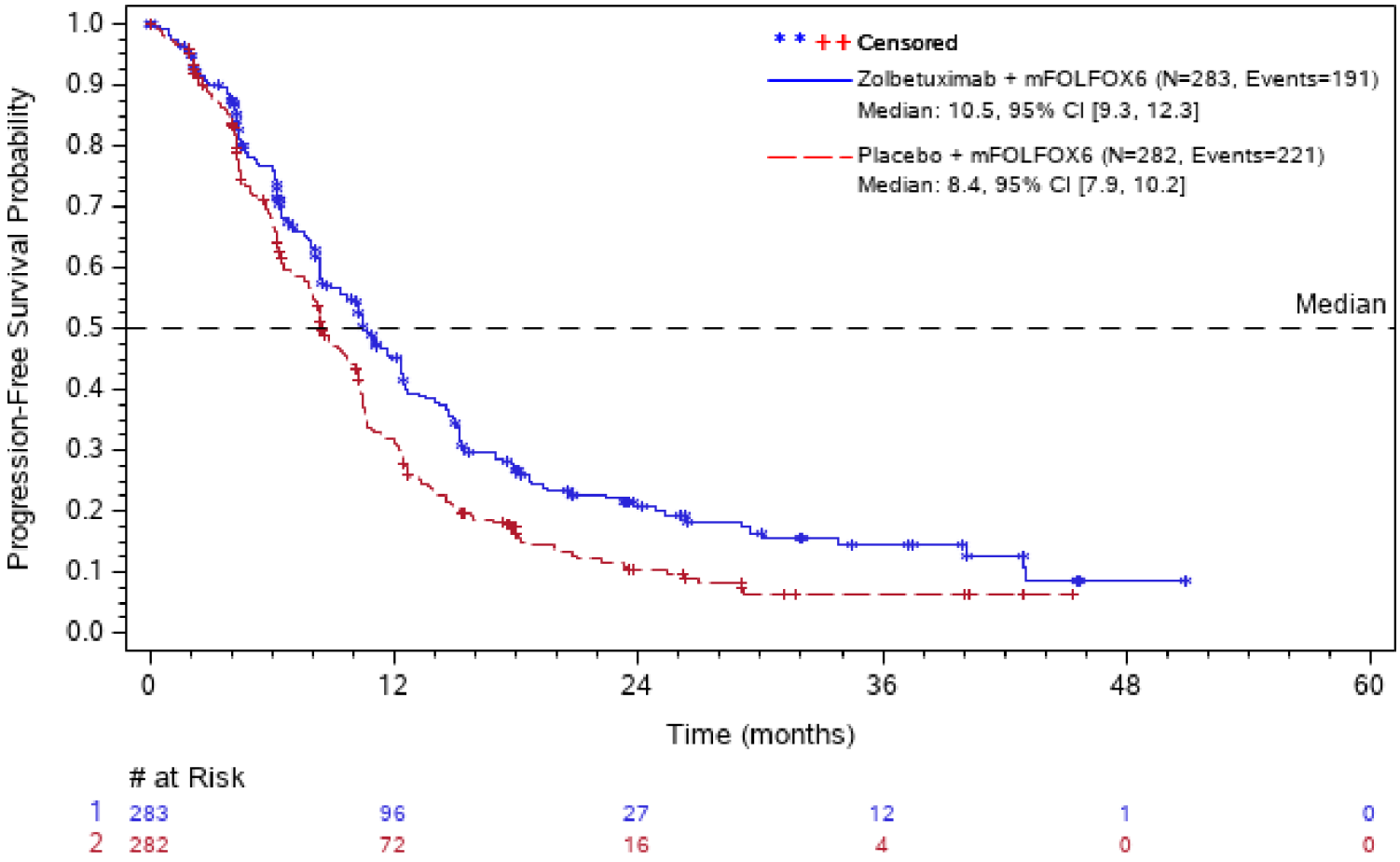
Figure 301.3.1002.2: Kaplan-Meier Plot of Progression-Free Survival (IRC) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; IRC=independent review committee; N=number of patients.

ASTELLAS Data Cutoff Date: 08SEP23

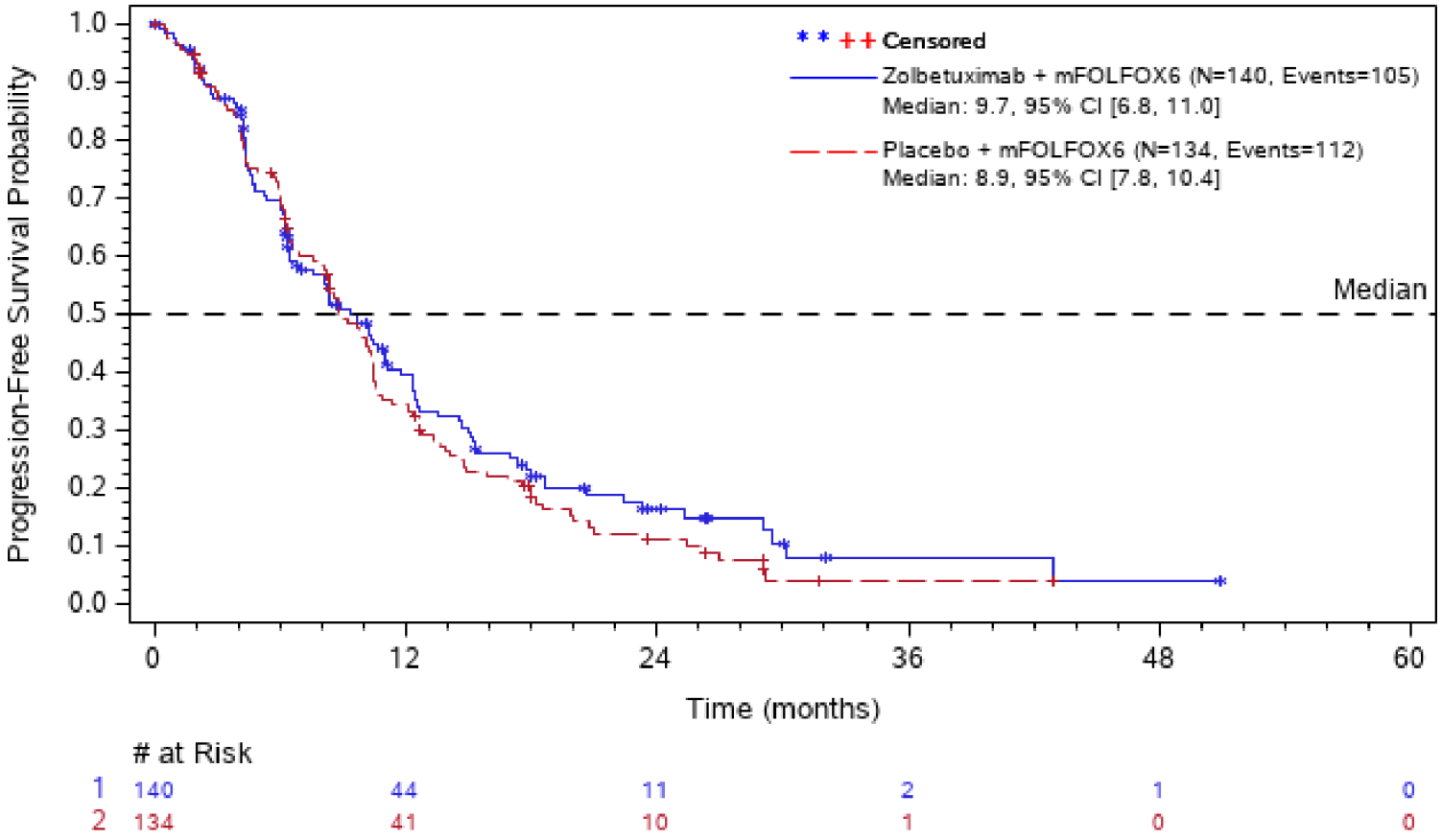
Figure 301.1.1002.3: Kaplan-Meier Plot of Progression-Free Survival (INV) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Figure 301.3.1002.3.4: Kaplan-Meier Plot of Progression-Free Survival (INV) by Race - Full Analysis Set

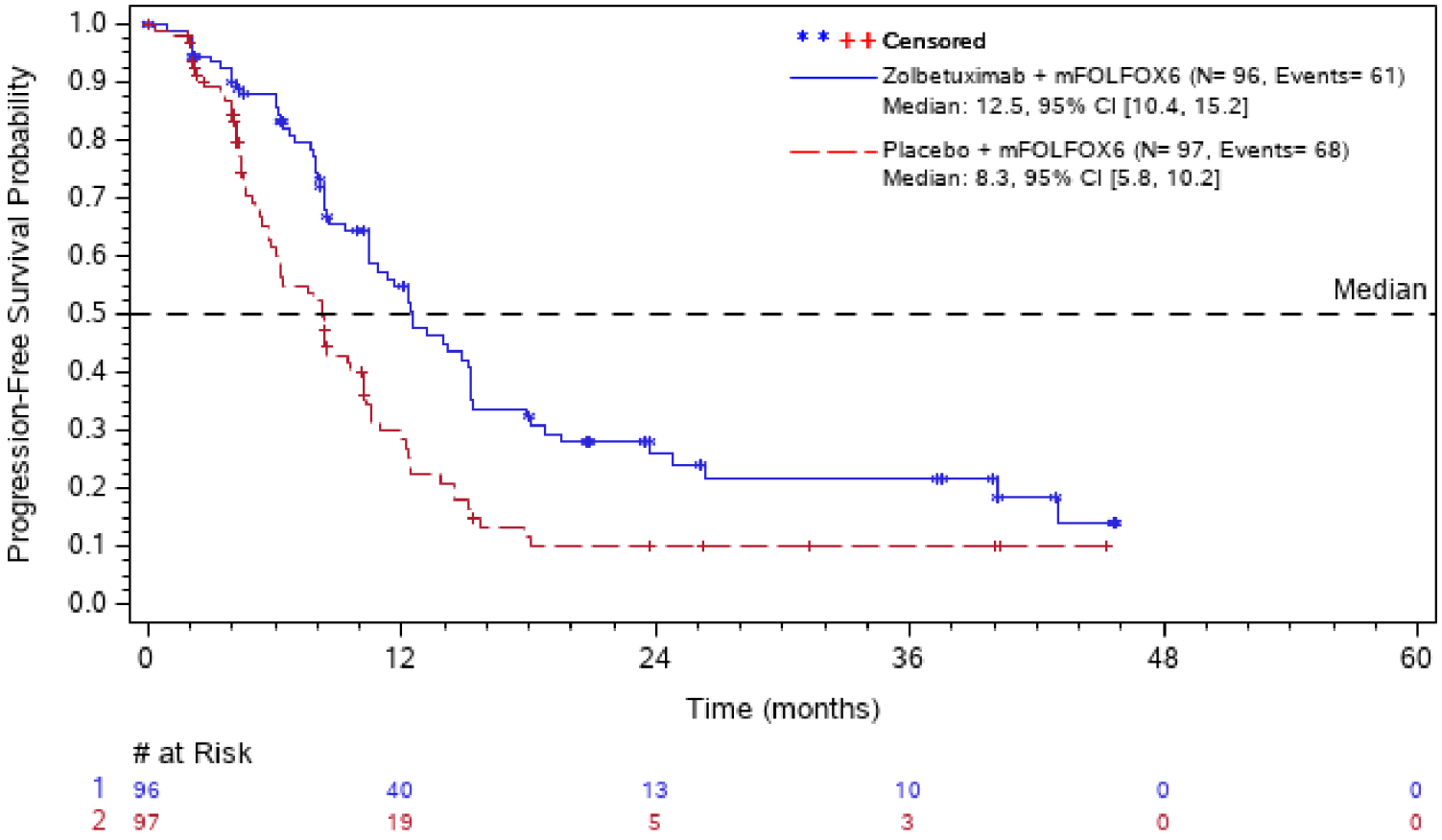
Race: White



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Figure 301.3.1002.3.4: Kaplan-Meier Plot of Progression-Free Survival (INV) by Race - Full Analysis Set

Race: Asian



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; INV=investigator; N=number of patients.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

1. Rücklaufquoten

Table 301.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.1: EORTC QLQ-C30 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.5: EORTC QLQ-C30 - Completion Status of Global Health Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.6: EORTC QLQ-C30 - Completion Status of Physical Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.7: EORTC QLQ-C30 - Completion Status of Role Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.8: EORTC QLQ-C30 - Completion Status of Emotional Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.9: EORTC QLQ-C30 - Completion Status of Cognitive Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.10: EORTC QLQ-C30 - Completion Status of Social Functioning - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.11: EORTC QLQ-C30 - Completion Status of Fatigue - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.12: EORTC QLQ-C30 - Completion Status of Nausea and Vomiting - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.13: EORTC QLQ-C30 - Completion Status of Pain - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.14: EORTC QLQ-C30 - Completion Status of Dyspnoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.15: EORTC QLQ-C30 - Completion Status of Insomnia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.16: EORTC QLQ-C30 - Completion Status of Appetite Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.17: EORTC QLQ-C30 - Completion Status of Constipation - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.18: EORTC QLQ-C30 - Completion Status of Diarrhoea - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	186/257 (72.4%)	187/273 (68.5%)	187/283 (66.1%)	212/266 (79.7%)	212/271 (78.2%)	212/282 (75.2%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	230/263 (87.5%)	231/270 (85.6%)	231/282 (81.9%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	169/192 (88.0%)	174/241 (72.2%)	178/283 (62.9%)	170/202 (84.2%)	170/254 (66.9%)	171/282 (60.6%)
Cycle 4 Day 22	128/179 (71.5%)	128/238 (53.8%)	128/283 (45.2%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	117/156 (75.0%)	118/233 (50.6%)	118/283 (41.7%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	98/128 (76.6%)	98/242 (40.5%)	98/282 (34.8%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	41/ 61 (67.2%)	41/224 (18.3%)	41/283 (14.5%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	43/ 52 (82.7%)	43/222 (19.4%)	44/283 (15.5%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.19: EORTC QLQ-C30 - Completion Status of Financial Difficulties - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 301.3.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	64.20	20.86	0.0	66.67	100.0						
Cycle 1 Day 22	187	60.83	20.24	0.0	66.67	100.0	177	-5.18	20.75	-75.0	0.00	75.0
Cycle 2 Day 1	217	66.78	19.25	16.7	66.67	100.0	207	1.61	20.40	-58.3	0.00	66.7
Cycle 2 Day 22	157	64.38	16.58	16.7	66.67	100.0	150	0.17	18.51	-41.7	0.00	83.3
Cycle 3 Day 1	200	69.63	16.02	16.7	66.67	100.0	190	2.85	17.89	-50.0	0.00	66.7
Cycle 3 Day 22	161	62.84	18.11	0.0	66.67	100.0	152	-3.13	19.10	-75.0	0.00	41.7
Cycle 4 Day 1	178	67.13	17.49	16.7	66.67	100.0	170	0.64	20.49	-58.3	0.00	66.7
Cycle 4 Day 22	128	64.65	17.27	25.0	66.67	100.0	123	-2.78	18.16	-41.7	0.00	50.0
Cycle 5 Day 1	157	65.29	18.77	16.7	66.67	100.0	149	-0.62	20.69	-50.0	0.00	66.7
Cycle 5 Day 22	118	66.24	19.49	8.3	66.67	100.0	111	0.53	21.24	-58.3	0.00	66.7
Cycle 6 Day 1	132	68.50	18.37	16.7	66.67	100.0	123	1.90	20.66	-58.3	0.00	58.3
Cycle 6 Day 22	108	69.21	17.14	33.3	66.67	100.0	103	3.48	18.21	-33.3	0.00	50.0
Cycle 7 Day 1	120	67.50	17.99	25.0	66.67	100.0	114	0.00	20.50	-66.7	0.00	66.7
Cycle 7 Day 22	87	68.68	16.81	33.3	66.67	100.0	81	1.54	18.50	-41.7	0.00	50.0
Cycle 8 Day 1	88	69.89	15.34	25.0	66.67	100.0	80	3.12	19.82	-41.7	0.00	50.0
Cycle 8 Day 22	78	69.34	17.99	0.0	75.00	100.0	72	1.62	19.91	-50.0	0.00	50.0
Cycle 9 Day 1	83	70.28	15.57	33.3	66.67	100.0	75	6.11	18.09	-33.3	0.00	58.3
Cycle 9 Day 22	65	68.46	17.95	0.0	66.67	100.0	60	3.33	19.54	-50.0	0.00	58.3
Cycle 10 Day 1	72	68.98	17.87	16.7	66.67	100.0	66	3.03	18.87	-50.0	0.00	58.3
Cycle 10 Day 22	61	68.03	16.04	16.7	66.67	100.0	57	0.58	19.47	-50.0	0.00	50.0
Cycle 11 Day 1	68	70.83	15.80	16.7	66.67	100.0	63	4.37	16.92	-50.0	0.00	50.0
Cycle 11 Day 22	48	69.97	16.73	33.3	66.67	100.0	44	2.65	18.31	-41.7	0.00	33.3
Cycle 12 Day 1	58	69.11	15.92	16.7	66.67	100.0	53	1.89	18.82	-50.0	0.00	50.0
Cycle 12 Day 22	41	67.89	15.65	25.0	66.67	100.0	38	-0.88	17.41	-33.3	0.00	50.0
Cycle 13 Day 1	51	70.92	16.02	33.3	75.00	100.0	48	3.47	18.18	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	67.05	20.41	16.7	66.67	100.0	41	-2.85	19.24	-41.7	0.00	50.0
Cycle 14 Day 1	41	66.26	18.44	16.7	66.67	100.0	39	-0.85	23.48	-83.3	0.00	50.0
Cycle 14 Day 22	33	67.42	12.90	50.0	66.67	100.0	32	-1.30	19.64	-33.3	0.00	58.3
Cycle 15 Day 1	36	66.90	17.42	0.0	66.67	100.0	35	-0.71	26.69	-100.0	0.00	50.0
Cycle 15 Day 22	30	63.89	14.73	33.3	66.67	83.3	30	-3.89	22.92	-66.7	0.00	50.0
Cycle 16 Day 1	35	69.05	14.09	50.0	66.67	91.7	35	1.90	20.32	-33.3	0.00	50.0
Cycle 16 Day 22	29	63.22	15.03	33.3	66.67	83.3	29	-2.59	20.18	-33.3	0.00	50.0
Cycle 17 Day 1	30	63.61	19.39	16.7	66.67	91.7	30	-3.89	28.68	-83.3	0.00	50.0
Cycle 17 Day 22	23	61.59	15.84	33.3	58.33	100.0	23	-6.88	25.33	-50.0	-8.33	50.0
Cycle 18 Day 1	27	66.98	14.89	33.3	66.67	83.3	27	0.00	24.57	-50.0	0.00	50.0
Cycle 18 Day 22	21	63.10	18.18	33.3	66.67	91.7	21	-7.14	21.94	-41.7	-8.33	41.7
Cycle 19 Day 1	23	65.58	16.34	33.3	66.67	91.7	23	-3.62	24.60	-50.0	0.00	50.0
Cycle 19 Day 22	20	68.33	17.01	33.3	66.67	100.0	20	-4.58	20.32	-41.7	-12.50	33.3
Cycle 20 Day 1	23	67.39	15.06	50.0	66.67	100.0	23	-2.54	24.67	-50.0	-8.33	50.0
Cycle 20 Day 22	18	68.98	14.52	50.0	66.67	100.0	18	-3.70	22.18	-50.0	-4.17	50.0
Cycle 21 Day 1	20	71.67	15.15	50.0	66.67	100.0	20	2.08	20.75	-33.3	0.00	50.0
Cycle 21 Day 22	14	70.24	14.88	50.0	75.00	83.3	14	-4.17	17.83	-41.7	0.00	33.3
Cycle 22 Day 1	15	66.11	12.78	50.0	66.67	83.3	15	-0.56	24.29	-41.7	0.00	50.0
Cycle 22 Day 22	11	60.61	22.39	33.3	66.67	83.3	11	-10.61	29.13	-66.7	0.00	33.3
Cycle 23 Day 1	16	64.06	18.69	33.3	66.67	83.3	16	-4.17	29.03	-66.7	0.00	50.0
Cycle 23 Day 22	11	63.64	12.51	50.0	66.67	83.3	11	-3.79	22.16	-41.7	0.00	33.3
Cycle 24 Day 1	14	66.07	16.81	41.7	66.67	83.3	14	-0.60	26.04	-50.0	0.00	50.0
Cycle 25 Day 1	12	60.42	15.54	41.7	50.00	83.3	12	-6.94	15.82	-41.7	0.00	16.7
Cycle 25 Day 22	11	64.39	18.29	33.3	66.67	83.3	11	-3.03	17.59	-41.7	0.00	33.3
Cycle 26 Day 1	13	71.15	16.18	50.0	83.33	91.7	13	6.41	23.11	-41.7	0.00	50.0
Cycle 27 Day 1	11	68.18	15.28	50.0	75.00	83.3	11	2.27	22.39	-41.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	68.06	20.67	33.3	83.33	83.3	12	0.69	26.93	-58.3	0.00	50.0
Study Disc 1	144	56.77	22.67	0.0	58.33	100.0	136	-8.46	20.18	-50.0	-8.33	58.3
30 D SFU Z/P	77	59.96	21.07	8.3	66.67	100.0	72	-4.98	21.20	-66.7	0.00	41.7
90 D SFU Z/P	89	61.05	19.82	0.0	66.67	100.0	86	-5.72	21.55	-58.3	0.00	33.3
Placebo + mFOLFOX6 (N=282)												
Baseline	258	63.47	20.63	0.0	66.67	100.0						
Cycle 1 Day 22	212	64.27	19.55	0.0	66.67	100.0	210	0.48	17.98	-83.3	0.00	50.0
Cycle 2 Day 1	231	69.44	18.64	0.0	66.67	100.0	225	5.56	18.68	-50.0	0.00	58.3
Cycle 2 Day 22	185	65.77	19.73	0.0	66.67	100.0	181	1.98	20.79	-66.7	0.00	66.7
Cycle 3 Day 1	204	70.18	17.76	8.3	66.67	100.0	198	5.77	19.92	-58.3	0.00	58.3
Cycle 3 Day 22	156	68.64	17.30	16.7	66.67	100.0	149	3.13	18.03	-41.7	0.00	66.7
Cycle 4 Day 1	171	70.66	17.58	16.7	66.67	100.0	163	6.65	21.04	-58.3	0.00	66.7
Cycle 4 Day 22	133	65.85	19.13	16.7	66.67	100.0	128	1.50	22.37	-50.0	0.00	66.7
Cycle 5 Day 1	149	69.24	18.07	8.3	66.67	100.0	145	4.83	20.71	-66.7	0.00	58.3
Cycle 5 Day 22	123	64.91	21.32	0.0	66.67	100.0	116	0.07	21.52	-58.3	0.00	75.0
Cycle 6 Day 1	127	65.88	21.53	0.0	66.67	100.0	122	0.07	21.57	-66.7	0.00	75.0
Cycle 6 Day 22	98	70.07	18.45	33.3	75.00	100.0	94	2.39	18.15	-33.3	0.00	66.7
Cycle 7 Day 1	101	72.36	17.03	33.3	75.00	100.0	98	4.34	17.64	-33.3	0.00	66.7
Cycle 7 Day 22	76	70.94	17.82	25.0	66.67	100.0	74	3.38	20.32	-58.3	0.00	58.3
Cycle 8 Day 1	84	73.81	18.16	16.7	75.00	100.0	83	4.82	17.90	-33.3	0.00	58.3
Cycle 8 Day 22	67	74.50	18.57	33.3	75.00	100.0	65	6.92	18.67	-33.3	8.33	58.3
Cycle 9 Day 1	64	74.61	17.97	16.7	75.00	100.0	62	4.57	15.14	-33.3	0.00	33.3
Cycle 9 Day 22	57	72.08	18.73	0.0	75.00	100.0	55	3.18	17.82	-50.0	0.00	41.7
Cycle 10 Day 1	58	72.84	19.41	25.0	79.17	100.0	56	3.87	19.20	-58.3	0.00	33.3
Cycle 10 Day 22	44	71.97	18.86	33.3	66.67	100.0	43	5.43	17.34	-16.7	0.00	33.3
Cycle 11 Day 1	48	72.92	18.95	33.3	79.17	100.0	46	3.99	15.09	-25.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.5: EORTC QLQ-C30 - Observed Means and Change from Baseline of Global Health Status - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	70.20	21.75	33.3	66.67	100.0	31	1.34	16.12	-33.3	0.00	33.3
Cycle 12 Day 1	43	73.26	18.68	33.3	75.00	100.0	41	2.64	14.00	-25.0	0.00	41.7
Cycle 12 Day 22	27	69.14	18.61	33.3	66.67	100.0	25	-3.33	12.50	-25.0	0.00	25.0
Cycle 13 Day 1	37	72.97	17.83	33.3	83.33	100.0	35	0.95	13.52	-25.0	0.00	33.3
Cycle 13 Day 22	22	68.94	18.75	33.3	66.67	100.0	21	-0.79	13.15	-25.0	0.00	33.3
Cycle 14 Day 1	31	71.51	20.61	0.0	75.00	100.0	30	0.83	20.22	-50.0	0.00	33.3
Cycle 14 Day 22	20	70.00	17.40	33.3	66.67	100.0	19	-1.32	16.26	-33.3	0.00	33.3
Cycle 15 Day 1	27	73.46	18.06	33.3	83.33	100.0	27	0.93	16.88	-33.3	0.00	50.0
Cycle 15 Day 22	17	71.57	15.33	50.0	66.67	100.0	17	-3.43	18.18	-25.0	0.00	50.0
Cycle 16 Day 1	22	75.38	19.67	33.3	83.33	100.0	22	1.89	18.17	-41.7	0.00	41.7
Cycle 16 Day 22	14	73.81	19.02	33.3	83.33	100.0	14	-2.38	14.41	-33.3	0.00	25.0
Cycle 17 Day 1	18	77.78	15.91	50.0	83.33	100.0	18	0.93	13.06	-16.7	0.00	16.7
Cycle 18 Day 1	16	78.65	16.66	41.7	83.33	100.0	16	-1.56	13.68	-25.0	0.00	25.0
Cycle 18 Day 22	11	80.30	12.51	50.0	83.33	100.0	10	-1.67	12.30	-16.7	0.00	16.7
Cycle 19 Day 1	16	75.52	17.07	33.3	83.33	100.0	15	-6.11	14.25	-33.3	0.00	16.7
Cycle 19 Day 22	12	75.00	10.66	50.0	79.17	83.3	11	-7.58	12.05	-33.3	0.00	8.3
Cycle 20 Day 1	16	82.29	15.77	50.0	83.33	100.0	15	1.11	12.94	-25.0	0.00	16.7
Cycle 20 Day 22	11	82.58	14.17	50.0	83.33	100.0	10	-0.83	15.93	-16.7	0.00	25.0
Cycle 21 Day 1	15	80.56	16.57	50.0	83.33	100.0	14	-1.79	15.39	-33.3	0.00	16.7
Cycle 22 Day 1	12	74.31	16.46	41.7	83.33	100.0	12	-6.25	14.70	-33.3	-4.17	16.7
Cycle 23 Day 1	13	78.85	16.88	50.0	83.33	100.0	13	-0.64	15.39	-33.3	0.00	16.7
Study Disc 1	153	59.26	22.39	0.0	66.67	100.0	149	-2.46	23.26	-83.3	0.00	50.0
Study Disc 2	12	54.17	23.97	16.7	62.50	83.3	12	-11.81	29.83	-58.3	-16.67	66.7
30 D SFU Z/P	93	59.50	18.21	16.7	66.67	100.0	91	-4.03	20.99	-66.7	0.00	50.0
90 D SFU Z/P	84	58.93	22.17	0.0	66.67	100.0	83	-4.62	22.32	-66.7	0.00	41.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	79.71	20.37	13.3	86.67	100.0						
Cycle 1 Day 22	187	77.47	20.30	6.7	80.00	100.0	177	-4.22	17.23	-93.3	0.00	40.0
Cycle 2 Day 1	217	79.23	20.35	6.7	86.67	100.0	207	-1.90	18.80	-53.3	0.00	60.0
Cycle 2 Day 22	157	80.47	19.47	13.3	86.67	100.0	150	-0.98	17.69	-73.3	0.00	46.7
Cycle 3 Day 1	200	81.30	18.83	0.0	86.67	100.0	190	-0.84	19.51	-80.0	0.00	60.0
Cycle 3 Day 22	161	79.59	17.60	20.0	80.00	100.0	152	-1.36	17.26	-66.7	0.00	46.7
Cycle 4 Day 1	178	82.40	16.67	20.0	86.67	100.0	170	0.12	19.69	-53.3	0.00	60.0
Cycle 4 Day 22	128	80.89	17.19	20.0	83.33	100.0	123	-2.60	19.87	-60.0	0.00	60.0
Cycle 5 Day 1	157	79.19	20.13	13.3	86.67	100.0	149	-3.00	22.55	-80.0	0.00	60.0
Cycle 5 Day 22	118	80.17	20.04	0.0	86.67	100.0	111	-2.52	22.47	-100.0	0.00	53.3
Cycle 6 Day 1	132	80.96	17.90	13.3	86.67	100.0	123	-1.08	20.91	-80.0	0.00	53.3
Cycle 6 Day 22	108	78.89	20.14	6.7	86.67	100.0	103	-2.01	22.59	-86.7	0.00	46.7
Cycle 7 Day 1	120	81.67	16.76	6.7	86.67	100.0	114	-1.35	21.67	-86.7	0.00	53.3
Cycle 7 Day 22	87	81.30	16.29	26.7	86.67	100.0	81	-2.14	18.67	-73.3	0.00	46.7
Cycle 8 Day 1	88	82.58	18.07	0.0	86.67	100.0	80	0.33	21.87	-93.3	0.00	46.7
Cycle 8 Day 22	78	82.99	14.60	33.3	86.67	100.0	72	1.02	18.84	-46.7	0.00	46.7
Cycle 9 Day 1	83	83.05	17.40	13.3	86.67	100.0	75	2.13	20.33	-60.0	0.00	46.7
Cycle 9 Day 22	65	83.79	15.18	20.0	86.67	100.0	60	2.78	23.46	-80.0	0.00	60.0
Cycle 10 Day 1	72	84.07	14.70	40.0	86.67	100.0	66	2.53	21.65	-60.0	0.00	53.3
Cycle 10 Day 22	61	85.14	13.95	40.0	86.67	100.0	57	3.27	18.61	-53.3	0.00	53.3
Cycle 11 Day 1	68	85.88	14.41	33.3	86.67	100.0	63	3.60	20.17	-66.7	0.00	53.3
Cycle 11 Day 22	48	86.67	15.62	33.3	90.00	100.0	44	3.33	18.72	-66.7	0.00	46.7
Cycle 12 Day 1	58	84.83	15.79	20.0	86.67	100.0	53	2.26	20.08	-60.0	0.00	40.0
Cycle 12 Day 22	41	85.20	15.60	46.7	86.67	100.0	38	2.63	20.65	-53.3	6.67	33.3
Cycle 13 Day 1	51	84.71	15.57	46.7	86.67	100.0	48	3.06	20.35	-53.3	6.67	53.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	84.55	14.00	46.7	86.67	100.0	41	1.46	21.63	-53.3	6.67	46.7
Cycle 14 Day 1	41	83.90	16.53	13.3	86.67	100.0	39	4.27	17.27	-46.7	6.67	46.7
Cycle 14 Day 22	33	83.43	14.15	53.3	86.67	100.0	32	0.42	19.67	-46.7	3.33	46.7
Cycle 15 Day 1	36	83.52	14.21	46.7	86.67	100.0	35	3.24	18.39	-46.7	6.67	46.7
Cycle 15 Day 22	30	85.78	14.19	53.3	86.67	100.0	30	3.56	18.26	-46.7	6.67	53.3
Cycle 16 Day 1	35	83.24	15.96	40.0	86.67	100.0	35	3.43	20.98	-53.3	6.67	46.7
Cycle 16 Day 22	29	85.29	14.63	53.3	86.67	100.0	29	5.29	19.39	-46.7	6.67	60.0
Cycle 17 Day 1	30	82.89	20.39	6.7	86.67	100.0	30	3.78	25.05	-86.7	6.67	46.7
Cycle 17 Day 22	23	81.16	23.75	6.7	86.67	100.0	23	-3.19	26.20	-86.7	6.67	33.3
Cycle 18 Day 1	27	84.20	14.81	53.3	86.67	100.0	27	3.46	21.03	-46.7	6.67	53.3
Cycle 18 Day 22	21	85.71	14.95	53.3	93.33	100.0	21	3.17	20.83	-46.7	6.67	46.7
Cycle 19 Day 1	23	86.67	16.21	46.7	93.33	100.0	23	3.48	17.39	-46.7	6.67	26.7
Cycle 19 Day 22	20	82.33	18.77	33.3	86.67	100.0	20	-1.00	18.39	-40.0	0.00	26.7
Cycle 20 Day 1	23	83.77	20.87	26.7	93.33	100.0	23	0.29	22.43	-46.7	6.67	26.7
Cycle 20 Day 22	18	83.33	18.04	53.3	86.67	100.0	18	-1.48	24.37	-46.7	6.67	33.3
Cycle 21 Day 1	20	87.33	15.58	46.7	93.33	100.0	20	2.33	15.18	-33.3	6.67	20.0
Cycle 21 Day 22	14	82.38	18.42	46.7	86.67	100.0	14	-3.33	18.07	-40.0	3.33	13.3
Cycle 22 Day 1	15	85.33	15.37	66.7	86.67	100.0	15	3.11	18.83	-33.3	6.67	33.3
Cycle 22 Day 22	11	74.55	24.00	33.3	80.00	100.0	11	-5.45	24.00	-60.0	6.67	13.3
Cycle 23 Day 1	16	79.17	17.36	46.7	80.00	100.0	16	-3.33	19.78	-40.0	6.67	20.0
Cycle 23 Day 22	11	81.82	21.10	40.0	80.00	100.0	11	1.82	15.23	-33.3	6.67	13.3
Cycle 24 Day 1	14	77.14	27.26	6.7	83.33	100.0	14	-3.81	21.36	-53.3	6.67	20.0
Cycle 25 Day 1	12	88.89	14.86	53.3	96.67	100.0	12	5.00	11.42	-20.0	6.67	20.0
Cycle 25 Day 22	11	86.67	16.06	53.3	93.33	100.0	11	2.42	15.28	-33.3	6.67	13.3
Cycle 26 Day 1	13	86.67	15.63	53.3	93.33	100.0	13	3.08	14.56	-33.3	6.67	20.0
Cycle 27 Day 1	11	88.48	14.63	60.0	93.33	100.0	11	3.64	15.88	-33.3	6.67	20.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	87.78	13.88	60.0	90.00	100.0	12	1.67	15.86	-33.3	6.67	20.0
Study Disc 1	144	70.69	26.35	0.0	80.00	100.0	136	-10.29	25.37	-93.3	-6.67	46.7
30 D SFU Z/P	77	71.52	24.15	0.0	80.00	100.0	72	-9.26	24.63	-100.0	-6.67	46.7
90 D SFU Z/P	89	70.19	24.54	0.0	80.00	100.0	86	-13.57	23.77	-86.7	-6.67	40.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	78.79	21.13	0.0	86.67	100.0						
Cycle 1 Day 22	212	78.55	20.58	6.7	83.33	100.0	210	-1.49	15.70	-53.3	0.00	46.7
Cycle 2 Day 1	231	81.13	19.06	13.3	86.67	100.0	225	1.69	17.92	-60.0	0.00	60.0
Cycle 2 Day 22	185	81.66	18.41	0.0	86.67	100.0	181	1.73	18.69	-66.7	0.00	53.3
Cycle 3 Day 1	204	82.45	18.57	0.0	86.67	100.0	198	2.66	18.70	-73.3	0.00	66.7
Cycle 3 Day 22	156	83.12	16.86	13.3	86.67	100.0	149	1.52	15.88	-53.3	0.00	53.3
Cycle 4 Day 1	171	82.26	19.00	6.7	86.67	100.0	163	1.47	19.25	-66.7	0.00	66.7
Cycle 4 Day 22	133	80.30	20.85	0.0	86.67	100.0	128	-1.51	19.61	-80.0	0.00	66.7
Cycle 5 Day 1	149	81.83	18.02	0.0	86.67	100.0	145	0.55	18.86	-60.0	0.00	66.7
Cycle 5 Day 22	123	82.06	18.07	20.0	86.67	100.0	116	0.11	19.72	-60.0	0.00	53.3
Cycle 6 Day 1	127	81.73	16.89	33.3	86.67	100.0	122	-1.26	18.92	-66.7	0.00	66.7
Cycle 6 Day 22	98	82.65	17.22	26.7	86.67	100.0	94	-0.92	15.96	-46.7	0.00	40.0
Cycle 7 Day 1	101	83.10	16.91	33.3	86.67	100.0	98	-0.95	15.58	-66.7	0.00	33.3
Cycle 7 Day 22	76	84.65	14.97	40.0	86.67	100.0	74	1.89	19.03	-60.0	0.00	60.0
Cycle 8 Day 1	84	85.56	15.06	40.0	86.67	100.0	83	0.88	15.85	-40.0	0.00	66.7
Cycle 8 Day 22	67	83.88	16.25	20.0	86.67	100.0	65	-0.31	17.66	-46.7	0.00	66.7
Cycle 9 Day 1	64	85.10	15.84	40.0	86.67	100.0	62	0.43	17.24	-60.0	0.00	53.3
Cycle 9 Day 22	57	85.50	15.89	26.7	86.67	100.0	55	1.94	16.61	-53.3	0.00	53.3
Cycle 10 Day 1	58	87.01	16.59	20.0	93.33	100.0	56	0.71	16.26	-60.0	0.00	46.7
Cycle 10 Day 22	44	83.94	20.85	13.3	93.33	100.0	43	-2.48	19.36	-66.7	0.00	46.7
Cycle 11 Day 1	48	83.75	20.85	20.0	93.33	100.0	46	-3.33	16.91	-60.0	0.00	46.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.6: EORTC QLQ-C30 - Observed Means and Change from Baseline of Physical Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	79.60	24.94	0.0	86.67	100.0	31	-6.02	16.18	-53.3	0.00	13.3
Cycle 12 Day 1	43	84.19	17.58	33.3	86.67	100.0	41	-3.58	14.61	-46.7	0.00	40.0
Cycle 12 Day 22	27	82.96	20.45	33.3	93.33	100.0	25	-5.60	14.74	-53.3	0.00	13.3
Cycle 13 Day 1	37	81.62	20.87	40.0	86.67	100.0	35	-6.67	17.26	-60.0	0.00	20.0
Cycle 13 Day 22	22	80.00	22.35	20.0	83.33	100.0	21	-6.98	19.60	-53.3	-6.67	46.7
Cycle 14 Day 1	31	85.38	15.44	40.0	86.67	100.0	30	-3.56	13.30	-33.3	0.00	33.3
Cycle 14 Day 22	20	85.33	15.23	40.0	86.67	100.0	19	-1.75	13.49	-33.3	0.00	33.3
Cycle 15 Day 1	27	83.46	17.87	46.7	86.67	100.0	27	-6.42	18.35	-53.3	0.00	40.0
Cycle 15 Day 22	17	89.80	11.08	66.7	93.33	100.0	17	0.39	14.43	-13.3	0.00	46.7
Cycle 16 Day 1	22	85.15	17.08	40.0	90.00	100.0	22	-4.55	18.79	-60.0	0.00	46.7
Cycle 16 Day 22	14	85.24	17.18	46.7	90.00	100.0	14	-7.14	14.67	-46.7	-3.33	6.7
Cycle 17 Day 1	18	88.52	16.14	46.7	96.67	100.0	18	-3.70	11.93	-40.0	0.00	6.7
Cycle 18 Day 1	16	89.17	13.96	60.0	96.67	100.0	16	-2.92	6.87	-20.0	0.00	6.7
Cycle 18 Day 22	11	91.52	9.47	73.3	93.33	100.0	10	0.00	7.03	-13.3	0.00	6.7
Cycle 19 Day 1	16	90.83	13.53	53.3	100.00	100.0	15	-1.33	8.05	-13.3	0.00	13.3
Cycle 19 Day 22	12	88.33	10.68	66.7	86.67	100.0	11	-4.24	8.58	-20.0	0.00	6.7
Cycle 20 Day 1	16	90.42	15.20	53.3	100.00	100.0	15	-1.78	8.90	-26.7	0.00	6.7
Cycle 20 Day 22	11	89.09	9.08	80.0	86.67	100.0	10	-4.67	7.73	-20.0	-3.33	6.7
Cycle 21 Day 1	15	92.44	10.65	66.7	100.00	100.0	14	-1.43	9.13	-20.0	0.00	13.3
Cycle 22 Day 1	12	88.89	11.49	66.7	90.00	100.0	12	-2.22	6.56	-20.0	0.00	6.7
Cycle 23 Day 1	13	91.79	11.27	73.3	100.00	100.0	13	1.54	9.49	-20.0	0.00	13.3
Study Disc 1	153	74.12	25.72	0.0	80.00	100.0	149	-4.52	21.72	-86.7	0.00	53.3
Study Disc 2	12	60.00	32.91	0.0	60.00	100.0	12	-21.11	33.13	-80.0	-10.00	26.7
30 D SFU Z/P	93	76.70	19.53	6.7	80.00	100.0	91	-6.96	21.73	-86.7	-6.67	40.0
90 D SFU Z/P	84	72.38	26.18	0.0	80.00	100.0	83	-11.49	25.95	-100.0	-6.67	53.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	74.77	27.56	0.0	83.33	100.0						
Cycle 1 Day 22	187	70.77	26.40	0.0	66.67	100.0	177	-6.78	25.09	-100.0	0.00	66.7
Cycle 2 Day 1	217	75.42	25.81	0.0	83.33	100.0	207	-0.64	26.78	-83.3	0.00	83.3
Cycle 2 Day 22	157	75.58	23.38	0.0	83.33	100.0	150	-1.67	25.82	-66.7	0.00	100.0
Cycle 3 Day 1	200	78.42	23.62	0.0	83.33	100.0	190	0.96	28.02	-83.3	0.00	83.3
Cycle 3 Day 22	161	72.88	25.74	0.0	66.67	100.0	152	-3.73	25.96	-66.7	0.00	66.7
Cycle 4 Day 1	178	76.59	24.70	0.0	83.33	100.0	170	-1.18	28.41	-100.0	0.00	83.3
Cycle 4 Day 22	128	76.56	21.06	16.7	66.67	100.0	123	-2.98	28.39	-83.3	0.00	83.3
Cycle 5 Day 1	157	73.67	25.19	0.0	66.67	100.0	149	-4.25	29.71	-100.0	0.00	66.7
Cycle 5 Day 22	118	74.72	25.11	0.0	66.67	100.0	111	-2.70	30.03	-100.0	0.00	66.7
Cycle 6 Day 1	132	75.51	23.70	0.0	66.67	100.0	123	-1.76	29.94	-83.3	0.00	83.3
Cycle 6 Day 22	108	73.46	25.27	0.0	66.67	100.0	103	-4.21	29.59	-66.7	0.00	66.7
Cycle 7 Day 1	120	75.00	23.27	0.0	66.67	100.0	114	-5.56	28.37	-100.0	0.00	66.7
Cycle 7 Day 22	87	75.10	19.83	16.7	66.67	100.0	81	-5.35	29.68	-83.3	0.00	83.3
Cycle 8 Day 1	88	79.17	21.18	16.7	83.33	100.0	80	-2.92	29.62	-83.3	0.00	66.7
Cycle 8 Day 22	78	80.56	19.26	16.7	83.33	100.0	72	-1.39	28.22	-83.3	0.00	66.7
Cycle 9 Day 1	83	83.94	18.12	33.3	83.33	100.0	75	4.89	26.53	-66.7	0.00	66.7
Cycle 9 Day 22	65	79.74	20.09	0.0	66.67	100.0	60	-0.83	30.13	-100.0	0.00	66.7
Cycle 10 Day 1	72	79.63	19.22	33.3	83.33	100.0	66	0.00	29.38	-66.7	0.00	66.7
Cycle 10 Day 22	61	79.78	20.21	33.3	83.33	100.0	57	-0.58	30.37	-66.7	0.00	66.7
Cycle 11 Day 1	68	81.62	21.58	0.0	83.33	100.0	63	1.32	32.56	-100.0	0.00	83.3
Cycle 11 Day 22	48	78.82	20.26	16.7	66.67	100.0	44	-3.79	28.27	-83.3	0.00	50.0
Cycle 12 Day 1	58	79.89	19.69	16.7	75.00	100.0	53	-0.63	26.55	-50.0	0.00	66.7
Cycle 12 Day 22	41	78.46	19.45	33.3	83.33	100.0	38	-5.26	28.24	-66.7	0.00	66.7
Cycle 13 Day 1	51	80.72	20.38	33.3	83.33	100.0	48	-1.04	29.86	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	80.68	19.34	33.3	83.33	100.0	41	-4.88	29.40	-66.7	0.00	83.3
Cycle 14 Day 1	41	78.46	22.12	0.0	66.67	100.0	39	-2.99	26.18	-50.0	0.00	66.7
Cycle 14 Day 22	33	82.83	19.76	33.3	83.33	100.0	32	-3.65	27.67	-50.0	0.00	66.7
Cycle 15 Day 1	36	79.63	19.96	33.3	75.00	100.0	35	-1.90	27.94	-66.7	0.00	83.3
Cycle 15 Day 22	30	81.11	23.05	33.3	91.67	100.0	30	-5.00	31.00	-66.7	0.00	100.0
Cycle 16 Day 1	35	81.90	21.15	33.3	100.00	100.0	35	0.48	30.38	-66.7	0.00	100.0
Cycle 16 Day 22	29	76.44	24.20	33.3	66.67	100.0	29	-6.32	31.94	-66.7	0.00	100.0
Cycle 17 Day 1	30	81.11	23.87	0.0	83.33	100.0	30	-0.56	33.76	-100.0	0.00	83.3
Cycle 17 Day 22	23	78.26	30.75	0.0	100.00	100.0	23	-11.59	36.73	-100.0	0.00	66.7
Cycle 18 Day 1	27	79.01	20.46	33.3	83.33	100.0	27	-4.32	28.72	-66.7	0.00	83.3
Cycle 18 Day 22	21	84.92	17.40	50.0	100.00	100.0	21	-3.17	24.51	-33.3	0.00	83.3
Cycle 19 Day 1	23	83.33	18.80	33.3	83.33	100.0	23	-3.62	24.60	-33.3	0.00	66.7
Cycle 19 Day 22	20	80.83	25.52	0.0	91.67	100.0	20	-8.33	18.34	-33.3	0.00	33.3
Cycle 20 Day 1	23	81.16	22.08	33.3	83.33	100.0	23	-5.80	23.36	-66.7	0.00	50.0
Cycle 20 Day 22	18	83.33	28.01	0.0	100.00	100.0	18	-6.48	33.40	-100.0	0.00	66.7
Cycle 21 Day 1	20	89.17	19.70	33.3	100.00	100.0	20	2.50	21.81	-33.3	0.00	50.0
Cycle 21 Day 22	14	84.52	22.13	33.3	100.00	100.0	14	-5.95	21.29	-33.3	0.00	50.0
Cycle 22 Day 1	15	82.22	22.24	33.3	100.00	100.0	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 22 Day 22	11	72.73	33.56	0.0	83.33	100.0	11	-13.64	36.38	-100.0	0.00	50.0
Cycle 23 Day 1	16	79.17	23.96	33.3	83.33	100.0	16	-6.25	28.46	-66.7	0.00	66.7
Cycle 23 Day 22	11	81.82	25.23	33.3	100.00	100.0	11	-4.55	22.47	-33.3	0.00	50.0
Cycle 24 Day 1	14	76.19	28.28	16.7	83.33	100.0	14	-7.14	26.73	-66.7	0.00	50.0
Cycle 25 Day 1	12	87.50	20.26	33.3	100.00	100.0	12	-4.17	20.26	-33.3	0.00	50.0
Cycle 25 Day 22	11	83.33	26.87	16.7	100.00	100.0	11	-12.12	18.40	-50.0	0.00	0.0
Cycle 26 Day 1	13	78.21	24.89	16.7	66.67	100.0	13	-11.54	19.70	-50.0	0.00	16.7
Cycle 27 Day 1	11	84.85	21.67	33.3	100.00	100.0	11	-6.06	22.70	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	84.72	19.41	50.0	100.00	100.0	12	-6.94	24.06	-33.3	0.00	50.0
Study Disc 1	144	63.08	30.80	0.0	66.67	100.0	136	-13.24	33.95	-100.0	-16.67	83.3
30 D SFU Z/P	77	62.99	29.20	0.0	66.67	100.0	72	-13.19	29.46	-100.0	0.00	66.7
90 D SFU Z/P	89	62.55	27.44	0.0	66.67	100.0	86	-14.53	33.90	-100.0	-16.67	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	75.52	28.02	0.0	83.33	100.0						
Cycle 1 Day 22	212	71.62	28.02	0.0	66.67	100.0	210	-4.13	24.10	-83.3	0.00	66.7
Cycle 2 Day 1	231	76.33	26.15	0.0	83.33	100.0	225	0.30	25.92	-100.0	0.00	66.7
Cycle 2 Day 22	185	75.14	26.30	0.0	83.33	100.0	181	-1.20	28.44	-100.0	0.00	83.3
Cycle 3 Day 1	204	78.35	23.06	0.0	83.33	100.0	198	2.19	26.57	-100.0	0.00	100.0
Cycle 3 Day 22	156	76.18	25.41	0.0	83.33	100.0	149	-0.89	25.98	-83.3	0.00	100.0
Cycle 4 Day 1	171	77.97	24.16	0.0	83.33	100.0	163	1.94	26.92	-66.7	0.00	100.0
Cycle 4 Day 22	133	74.81	26.08	0.0	66.67	100.0	128	-2.73	24.82	-66.7	0.00	66.7
Cycle 5 Day 1	149	74.38	22.39	0.0	66.67	100.0	145	-2.87	27.24	-83.3	0.00	66.7
Cycle 5 Day 22	123	74.66	24.36	0.0	66.67	100.0	116	-2.73	27.88	-83.3	0.00	66.7
Cycle 6 Day 1	127	73.23	25.04	0.0	66.67	100.0	122	-5.46	26.19	-83.3	0.00	100.0
Cycle 6 Day 22	98	76.02	21.94	16.7	66.67	100.0	94	-2.84	25.47	-66.7	0.00	100.0
Cycle 7 Day 1	101	78.22	23.18	16.7	83.33	100.0	98	-2.55	22.75	-66.7	0.00	66.7
Cycle 7 Day 22	76	78.29	24.19	0.0	83.33	100.0	74	-1.58	24.08	-66.7	0.00	83.3
Cycle 8 Day 1	84	81.35	22.47	33.3	100.00	100.0	83	-0.60	23.20	-66.7	0.00	66.7
Cycle 8 Day 22	67	80.85	20.15	33.3	83.33	100.0	65	-1.03	21.83	-66.7	0.00	50.0
Cycle 9 Day 1	64	78.91	22.27	33.3	83.33	100.0	62	-2.96	22.49	-50.0	0.00	33.3
Cycle 9 Day 22	57	80.70	21.08	33.3	83.33	100.0	55	-0.61	22.21	-50.0	0.00	50.0
Cycle 10 Day 1	58	81.03	24.27	0.0	100.00	100.0	56	-3.27	26.10	-100.0	0.00	66.7
Cycle 10 Day 22	44	81.44	24.17	16.7	100.00	100.0	43	-2.71	26.96	-83.3	0.00	66.7
Cycle 11 Day 1	48	83.33	21.47	33.3	100.00	100.0	46	-0.36	21.80	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.7: EORTC QLQ-C30 - Observed Means and Change from Baseline of Role Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	73.23	30.88	0.0	66.67	100.0	31	-9.14	20.11	-66.7	0.00	33.3
Cycle 12 Day 1	43	81.40	20.96	33.3	83.33	100.0	41	-2.85	21.38	-66.7	0.00	33.3
Cycle 12 Day 22	27	80.86	24.33	16.7	100.00	100.0	25	-4.00	24.19	-83.3	0.00	33.3
Cycle 13 Day 1	37	81.53	22.49	33.3	100.00	100.0	35	-2.38	24.30	-66.7	0.00	33.3
Cycle 13 Day 22	22	81.82	22.37	33.3	91.67	100.0	21	0.00	19.00	-33.3	0.00	50.0
Cycle 14 Day 1	31	80.65	21.98	33.3	83.33	100.0	30	-5.56	20.22	-66.7	0.00	33.3
Cycle 14 Day 22	20	79.17	22.86	33.3	83.33	100.0	19	-2.63	20.23	-50.0	0.00	33.3
Cycle 15 Day 1	27	82.72	22.40	33.3	100.00	100.0	27	-5.56	24.46	-66.7	0.00	33.3
Cycle 15 Day 22	17	89.22	17.62	50.0	100.00	100.0	17	5.88	22.00	-33.3	0.00	66.7
Cycle 16 Day 1	22	85.61	19.45	33.3	100.00	100.0	22	0.00	23.00	-33.3	0.00	66.7
Cycle 16 Day 22	14	84.52	24.86	33.3	100.00	100.0	14	-1.19	20.11	-33.3	0.00	33.3
Cycle 17 Day 1	18	88.89	20.61	33.3	100.00	100.0	18	0.00	16.17	-33.3	0.00	33.3
Cycle 18 Day 1	16	87.50	19.72	50.0	100.00	100.0	16	-1.04	14.23	-33.3	0.00	33.3
Cycle 18 Day 22	11	87.88	18.40	50.0	100.00	100.0	10	-1.67	14.59	-33.3	0.00	16.7
Cycle 19 Day 1	16	85.42	22.67	33.3	100.00	100.0	15	-5.56	19.59	-50.0	0.00	33.3
Cycle 19 Day 22	12	87.50	21.47	33.3	100.00	100.0	11	-3.03	19.46	-33.3	0.00	33.3
Cycle 20 Day 1	16	86.46	25.25	33.3	100.00	100.0	15	-4.44	20.38	-50.0	0.00	33.3
Cycle 20 Day 22	11	86.36	16.36	66.7	100.00	100.0	10	-6.67	11.65	-33.3	0.00	0.0
Cycle 21 Day 1	15	91.11	16.51	50.0	100.00	100.0	14	-1.19	17.86	-33.3	0.00	33.3
Cycle 22 Day 1	12	87.50	21.47	33.3	100.00	100.0	12	-2.78	18.58	-33.3	0.00	33.3
Cycle 23 Day 1	13	89.74	17.40	50.0	100.00	100.0	13	1.28	12.66	-16.7	0.00	33.3
Study Disc 1	153	66.01	30.82	0.0	66.67	100.0	149	-8.72	31.16	-100.0	0.00	66.7
Study Disc 2	12	58.33	37.94	0.0	66.67	100.0	12	-18.06	32.92	-66.7	-16.67	33.3
30 D SFU Z/P	93	67.56	26.39	0.0	66.67	100.0	91	-10.99	30.65	-100.0	0.00	50.0
90 D SFU Z/P	84	63.89	31.35	0.0	66.67	100.0	83	-14.26	29.58	-100.0	-16.67	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	74.64	20.71	0.0	75.00	100.0						
Cycle 1 Day 22	187	75.98	20.91	8.3	75.00	100.0	177	0.85	19.08	-58.3	0.00	66.7
Cycle 2 Day 1	217	79.72	19.64	8.3	83.33	100.0	207	4.55	20.49	-50.0	0.00	83.3
Cycle 2 Day 22	157	81.42	16.56	33.3	83.33	100.0	150	5.78	19.36	-58.3	0.00	66.7
Cycle 3 Day 1	200	82.08	18.32	0.0	83.33	100.0	190	6.27	20.28	-58.3	8.33	83.3
Cycle 3 Day 22	161	78.52	21.50	0.0	83.33	100.0	152	3.62	21.14	-75.0	0.00	91.7
Cycle 4 Day 1	178	81.74	18.32	0.0	83.33	100.0	170	7.40	20.20	-50.0	8.33	91.7
Cycle 4 Day 22	128	79.04	19.81	16.7	83.33	100.0	123	2.71	19.46	-50.0	0.00	58.3
Cycle 5 Day 1	157	78.93	20.38	8.3	83.33	100.0	149	4.19	24.21	-66.7	8.33	91.7
Cycle 5 Day 22	118	78.60	20.51	8.3	83.33	100.0	111	4.35	24.04	-58.3	0.00	66.7
Cycle 6 Day 1	132	80.87	18.67	8.3	83.33	100.0	123	6.44	24.56	-58.3	8.33	83.3
Cycle 6 Day 22	108	81.64	18.29	16.7	83.33	100.0	103	5.50	21.44	-50.0	0.00	83.3
Cycle 7 Day 1	120	81.53	18.18	16.7	83.33	100.0	114	5.70	22.24	-50.0	4.17	83.3
Cycle 7 Day 22	87	79.79	18.31	8.3	83.33	100.0	81	3.70	20.20	-75.0	0.00	58.3
Cycle 8 Day 1	88	81.44	16.94	16.7	83.33	100.0	80	5.21	19.64	-50.0	0.00	58.3
Cycle 8 Day 22	78	82.69	16.65	33.3	83.33	100.0	72	7.29	24.58	-58.3	0.00	91.7
Cycle 9 Day 1	83	80.52	19.71	0.0	83.33	100.0	75	8.67	23.86	-66.7	8.33	75.0
Cycle 9 Day 22	65	78.97	19.38	8.3	75.00	100.0	60	6.11	25.25	-75.0	0.00	75.0
Cycle 10 Day 1	72	80.21	18.99	16.7	83.33	100.0	66	7.20	23.97	-66.7	4.17	75.0
Cycle 10 Day 22	61	81.69	16.09	33.3	83.33	100.0	57	8.04	22.27	-50.0	8.33	83.3
Cycle 11 Day 1	68	82.48	16.55	33.3	83.33	100.0	63	9.13	20.83	-33.3	8.33	66.7
Cycle 11 Day 22	48	82.64	18.18	41.7	83.33	100.0	44	8.33	17.88	-41.7	8.33	41.7
Cycle 12 Day 1	58	82.76	17.02	41.7	83.33	100.0	53	9.59	19.57	-41.7	8.33	50.0
Cycle 12 Day 22	41	79.07	16.99	50.0	83.33	100.0	38	3.95	19.25	-33.3	0.00	50.0
Cycle 13 Day 1	51	82.68	16.57	50.0	91.67	100.0	48	7.99	23.44	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	81.44	17.13	41.7	83.33	100.0	41	3.86	20.34	-41.7	0.00	58.3
Cycle 14 Day 1	41	79.47	19.55	8.3	83.33	100.0	39	6.20	21.61	-41.7	0.00	66.7
Cycle 14 Day 22	33	82.32	18.25	33.3	83.33	100.0	32	3.65	21.27	-41.7	0.00	58.3
Cycle 15 Day 1	36	81.71	16.41	41.7	83.33	100.0	35	6.43	21.49	-33.3	8.33	83.3
Cycle 15 Day 22	30	81.39	16.48	41.7	83.33	100.0	30	4.17	16.63	-33.3	0.00	50.0
Cycle 16 Day 1	35	85.00	16.64	50.0	91.67	100.0	35	9.76	21.81	-33.3	8.33	66.7
Cycle 16 Day 22	29	81.90	17.69	41.7	91.67	100.0	29	6.03	19.02	-41.7	8.33	41.7
Cycle 17 Day 1	30	81.39	21.96	0.0	83.33	100.0	30	7.50	28.90	-91.7	8.33	66.7
Cycle 17 Day 22	23	85.87	20.32	33.3	100.00	100.0	23	7.25	23.21	-58.3	8.33	50.0
Cycle 18 Day 1	27	83.95	16.97	33.3	83.33	100.0	27	8.33	20.28	-33.3	8.33	41.7
Cycle 18 Day 22	21	85.71	15.17	50.0	91.67	100.0	21	5.95	18.47	-25.0	8.33	41.7
Cycle 19 Day 1	23	86.59	17.90	33.3	91.67	100.0	23	8.70	23.09	-41.7	8.33	50.0
Cycle 19 Day 22	20	83.75	20.67	33.3	91.67	100.0	20	4.17	24.26	-41.7	0.00	50.0
Cycle 20 Day 1	23	88.41	15.23	50.0	91.67	100.0	23	10.51	17.27	-16.7	8.33	41.7
Cycle 20 Day 22	18	87.96	15.97	50.0	100.00	100.0	18	8.80	17.26	-16.7	8.33	33.3
Cycle 21 Day 1	20	89.58	13.21	58.3	95.83	100.0	20	11.25	18.39	-16.7	8.33	41.7
Cycle 21 Day 22	14	89.29	15.48	50.0	95.83	100.0	14	6.55	16.40	-16.7	8.33	33.3
Cycle 22 Day 1	15	87.78	15.71	50.0	91.67	100.0	15	11.67	16.61	-16.7	8.33	33.3
Cycle 22 Day 22	11	74.24	22.81	33.3	75.00	100.0	11	-2.27	27.41	-58.3	0.00	33.3
Cycle 23 Day 1	16	84.90	18.81	33.3	91.67	100.0	16	7.81	19.36	-33.3	4.17	33.3
Cycle 23 Day 22	11	85.61	19.75	41.7	91.67	100.0	11	4.55	17.62	-25.0	0.00	33.3
Cycle 24 Day 1	14	89.29	18.32	41.7	100.00	100.0	14	14.88	20.72	-25.0	8.33	50.0
Cycle 25 Day 1	12	84.72	20.97	33.3	95.83	100.0	12	9.03	21.75	-33.3	8.33	41.7
Cycle 25 Day 22	11	78.79	23.38	25.0	83.33	100.0	11	1.52	22.92	-41.7	0.00	33.3
Cycle 26 Day 1	13	85.26	19.29	41.7	91.67	100.0	13	10.90	24.86	-25.0	0.00	50.0
Cycle 27 Day 1	11	87.12	15.53	66.7	100.00	100.0	11	13.64	18.36	-16.7	16.67	41.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	89.58	14.70	58.3	100.00	100.0	12	14.58	21.36	-8.3	8.33	50.0
Study Disc 1	144	71.93	22.21	0.0	75.00	100.0	136	-2.88	21.29	-66.7	0.00	66.7
30 D SFU Z/P	77	72.73	22.07	8.3	75.00	100.0	72	-2.55	22.19	-75.0	0.00	41.7
90 D SFU Z/P	89	75.66	19.99	16.7	75.00	100.0	86	-1.74	22.69	-66.7	0.00	50.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	73.45	21.16	0.0	75.00	100.0						
Cycle 1 Day 22	212	78.69	20.54	8.3	83.33	100.0	210	3.33	15.96	-50.0	0.00	58.3
Cycle 2 Day 1	231	80.74	18.95	0.0	83.33	100.0	225	6.15	17.93	-66.7	8.33	66.7
Cycle 2 Day 22	185	79.59	19.01	8.3	83.33	100.0	181	5.85	18.69	-58.3	0.00	58.3
Cycle 3 Day 1	204	83.58	17.37	8.3	83.33	100.0	198	9.43	18.44	-75.0	8.33	83.3
Cycle 3 Day 22	156	83.44	19.00	8.3	91.67	100.0	149	9.06	19.35	-75.0	8.33	58.3
Cycle 4 Day 1	171	83.14	17.17	16.7	83.33	100.0	163	8.13	18.86	-58.3	8.33	66.7
Cycle 4 Day 22	133	80.45	18.72	8.3	83.33	100.0	128	6.84	20.98	-91.7	0.00	83.3
Cycle 5 Day 1	149	79.59	18.97	16.7	83.33	100.0	145	5.80	20.23	-58.3	0.00	75.0
Cycle 5 Day 22	123	78.12	20.20	8.3	83.33	100.0	116	2.95	18.17	-50.0	0.00	66.7
Cycle 6 Day 1	127	79.07	19.61	16.7	83.33	100.0	122	4.92	17.86	-50.0	0.00	83.3
Cycle 6 Day 22	98	80.78	18.71	25.0	83.33	100.0	94	7.54	17.96	-33.3	8.33	75.0
Cycle 7 Day 1	101	81.35	18.64	25.0	83.33	100.0	98	7.99	19.59	-41.7	8.33	91.7
Cycle 7 Day 22	76	80.81	16.94	25.0	83.33	100.0	74	7.66	18.90	-33.3	4.17	75.0
Cycle 8 Day 1	84	83.04	19.34	8.3	91.67	100.0	83	9.14	19.42	-58.3	8.33	83.3
Cycle 8 Day 22	67	80.72	19.69	8.3	83.33	100.0	65	6.41	20.35	-41.7	0.00	66.7
Cycle 9 Day 1	64	83.07	17.19	25.0	83.33	100.0	62	6.99	16.05	-25.0	4.17	58.3
Cycle 9 Day 22	57	82.60	17.06	25.0	83.33	100.0	55	5.76	18.69	-41.7	0.00	58.3
Cycle 10 Day 1	58	83.19	18.17	25.0	83.33	100.0	56	6.85	18.26	-33.3	0.00	58.3
Cycle 10 Day 22	44	82.01	17.33	25.0	83.33	100.0	43	6.20	20.50	-33.3	0.00	58.3
Cycle 11 Day 1	48	80.38	20.23	8.3	83.33	100.0	46	3.99	21.14	-41.7	0.00	58.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.8: EORTC QLQ-C30 - Observed Means and Change from Baseline of Emotional Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	77.78	19.39	33.3	75.00	100.0	31	1.88	22.64	-41.7	8.33	58.3
Cycle 12 Day 1	43	78.88	19.62	33.3	83.33	100.0	41	2.44	18.66	-41.7	0.00	41.7
Cycle 12 Day 22	27	79.01	18.83	16.7	83.33	100.0	25	4.33	18.65	-33.3	8.33	33.3
Cycle 13 Day 1	37	79.28	24.34	0.0	91.67	100.0	35	1.43	24.38	-66.7	8.33	41.7
Cycle 13 Day 22	22	76.89	23.28	25.0	79.17	100.0	21	-3.17	19.63	-50.0	8.33	25.0
Cycle 14 Day 1	31	81.72	18.69	41.7	83.33	100.0	30	2.22	18.94	-41.7	4.17	33.3
Cycle 14 Day 22	20	79.58	16.10	33.3	79.17	100.0	19	-1.75	18.96	-41.7	0.00	25.0
Cycle 15 Day 1	27	82.41	17.50	33.3	83.33	100.0	27	2.47	18.46	-41.7	8.33	25.0
Cycle 15 Day 22	17	79.90	20.21	25.0	83.33	100.0	17	-2.45	20.99	-50.0	0.00	25.0
Cycle 16 Day 1	22	78.03	20.01	33.3	75.00	100.0	22	-3.41	21.62	-41.7	-4.17	33.3
Cycle 16 Day 22	14	80.36	19.78	41.7	83.33	100.0	14	-4.76	20.60	-33.3	-4.17	25.0
Cycle 17 Day 1	18	87.04	17.67	41.7	95.83	100.0	18	3.70	19.43	-33.3	4.17	33.3
Cycle 18 Day 1	16	84.38	17.45	50.0	91.67	100.0	16	2.60	20.12	-33.3	4.17	33.3
Cycle 18 Day 22	11	80.30	21.82	33.3	75.00	100.0	10	-5.00	21.59	-41.7	4.17	25.0
Cycle 19 Day 1	16	80.73	18.69	50.0	75.00	100.0	15	-2.22	19.02	-33.3	0.00	25.0
Cycle 19 Day 22	12	82.64	16.07	58.3	83.33	100.0	11	-3.79	20.87	-33.3	-8.33	25.0
Cycle 20 Day 1	16	85.42	18.13	50.0	100.00	100.0	15	2.78	20.33	-33.3	8.33	33.3
Cycle 20 Day 22	11	81.06	21.44	41.7	83.33	100.0	10	-6.67	19.95	-33.3	-4.17	25.0
Cycle 21 Day 1	15	82.78	20.77	41.7	91.67	100.0	14	-2.98	24.59	-50.0	0.00	41.7
Cycle 22 Day 1	12	82.64	19.29	41.7	87.50	100.0	12	2.78	21.42	-33.3	4.17	25.0
Cycle 23 Day 1	13	84.62	21.20	33.3	100.00	100.0	13	5.13	21.93	-41.7	8.33	41.7
Study Disc 1	153	70.37	25.84	0.0	75.00	100.0	149	-3.19	22.79	-58.3	0.00	58.3
Study Disc 2	12	64.58	27.78	8.3	75.00	100.0	12	-10.42	27.09	-50.0	-12.50	50.0
30 D SFU Z/P	93	73.75	21.03	8.3	75.00	100.0	91	-2.47	19.90	-50.0	0.00	41.7
90 D SFU Z/P	84	70.63	23.87	0.0	75.00	100.0	83	-4.02	23.65	-66.7	0.00	58.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	87.48	17.62	0.0	100.00	100.0						
Cycle 1 Day 22	187	86.10	17.19	33.3	83.33	100.0	177	-3.01	18.04	-50.0	0.00	100.0
Cycle 2 Day 1	217	87.86	17.31	16.7	100.00	100.0	207	-0.16	19.57	-50.0	0.00	100.0
Cycle 2 Day 22	157	88.11	16.35	16.7	100.00	100.0	150	-1.00	16.75	-50.0	0.00	33.3
Cycle 3 Day 1	200	88.25	17.35	0.0	100.00	100.0	190	-0.61	20.67	-66.7	0.00	100.0
Cycle 3 Day 22	161	85.09	17.54	33.3	83.33	100.0	152	-3.07	18.83	-50.0	0.00	50.0
Cycle 4 Day 1	178	88.39	15.22	33.3	100.00	100.0	170	0.10	19.82	-66.7	0.00	83.3
Cycle 4 Day 22	128	84.24	19.99	16.7	83.33	100.0	123	-5.28	21.59	-83.3	0.00	66.7
Cycle 5 Day 1	157	84.39	19.40	16.7	83.33	100.0	149	-4.03	21.19	-83.3	0.00	50.0
Cycle 5 Day 22	118	84.32	20.71	16.7	100.00	100.0	111	-4.35	23.54	-83.3	0.00	83.3
Cycle 6 Day 1	132	82.70	19.80	0.0	83.33	100.0	123	-5.42	24.00	-100.0	0.00	100.0
Cycle 6 Day 22	108	86.11	19.80	0.0	100.00	100.0	103	-2.27	23.46	-83.3	0.00	100.0
Cycle 7 Day 1	120	86.81	16.58	33.3	100.00	100.0	114	-2.49	19.36	-66.7	0.00	66.7
Cycle 7 Day 22	87	87.16	16.99	33.3	100.00	100.0	81	-2.06	18.33	-66.7	0.00	66.7
Cycle 8 Day 1	88	85.98	18.20	16.7	100.00	100.0	80	-3.75	21.38	-83.3	0.00	50.0
Cycle 8 Day 22	78	88.46	16.62	33.3	100.00	100.0	72	1.16	22.08	-50.0	0.00	100.0
Cycle 9 Day 1	83	85.14	19.13	0.0	100.00	100.0	75	-0.67	22.67	-50.0	0.00	83.3
Cycle 9 Day 22	65	85.13	17.21	33.3	83.33	100.0	60	-1.67	24.10	-50.0	0.00	83.3
Cycle 10 Day 1	72	84.95	16.11	50.0	83.33	100.0	66	-0.25	23.11	-50.0	0.00	100.0
Cycle 10 Day 22	61	87.43	15.41	50.0	100.00	100.0	57	-1.17	19.63	-33.3	0.00	66.7
Cycle 11 Day 1	68	88.97	16.19	33.3	100.00	100.0	63	2.12	19.74	-33.3	0.00	83.3
Cycle 11 Day 22	48	86.46	16.36	50.0	100.00	100.0	44	-2.27	15.91	-33.3	0.00	33.3
Cycle 12 Day 1	58	86.78	15.22	50.0	100.00	100.0	53	0.00	18.20	-50.0	0.00	50.0
Cycle 12 Day 22	41	86.99	14.68	66.7	100.00	100.0	38	-1.75	19.68	-33.3	0.00	33.3
Cycle 13 Day 1	51	87.91	14.56	66.7	100.00	100.0	48	1.04	18.96	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	86.36	15.78	50.0	100.00	100.0	41	-1.22	20.20	-33.3	0.00	50.0
Cycle 14 Day 1	41	84.96	17.40	33.3	83.33	100.0	39	0.43	18.92	-33.3	0.00	66.7
Cycle 14 Day 22	33	83.33	17.18	50.0	83.33	100.0	32	-4.17	21.17	-33.3	0.00	33.3
Cycle 15 Day 1	36	84.72	17.54	50.0	91.67	100.0	35	-1.43	24.04	-50.0	0.00	83.3
Cycle 15 Day 22	30	86.11	16.43	50.0	100.00	100.0	30	-0.56	17.22	-33.3	0.00	33.3
Cycle 16 Day 1	35	86.67	15.02	50.0	83.33	100.0	35	1.43	18.24	-33.3	0.00	50.0
Cycle 16 Day 22	29	85.63	16.50	50.0	100.00	100.0	29	-1.15	18.86	-33.3	0.00	33.3
Cycle 17 Day 1	30	83.89	18.30	33.3	83.33	100.0	30	-0.56	25.70	-66.7	0.00	66.7
Cycle 17 Day 22	23	85.51	19.01	50.0	100.00	100.0	23	-2.17	23.73	-50.0	0.00	33.3
Cycle 18 Day 1	27	86.42	16.04	50.0	100.00	100.0	27	-0.62	19.87	-33.3	0.00	33.3
Cycle 18 Day 22	21	88.89	14.27	66.7	100.00	100.0	21	0.00	20.41	-33.3	0.00	33.3
Cycle 19 Day 1	23	87.68	16.83	50.0	100.00	100.0	23	-1.45	18.74	-33.3	0.00	33.3
Cycle 19 Day 22	20	85.00	16.13	50.0	83.33	100.0	20	-5.00	20.30	-33.3	0.00	33.3
Cycle 20 Day 1	23	86.96	16.63	50.0	100.00	100.0	23	-2.90	19.24	-50.0	0.00	33.3
Cycle 20 Day 22	18	89.81	12.96	66.7	100.00	100.0	18	0.93	17.59	-33.3	0.00	33.3
Cycle 21 Day 1	20	90.00	14.71	50.0	100.00	100.0	20	0.00	15.29	-33.3	0.00	33.3
Cycle 21 Day 22	14	90.48	16.94	50.0	100.00	100.0	14	-2.38	14.41	-33.3	0.00	33.3
Cycle 22 Day 1	15	87.78	14.73	50.0	83.33	100.0	15	0.00	16.67	-33.3	0.00	33.3
Cycle 22 Day 22	11	90.91	13.67	66.7	100.00	100.0	11	4.55	19.85	-33.3	0.00	33.3
Cycle 23 Day 1	16	86.46	16.35	50.0	91.67	100.0	16	-1.04	17.71	-33.3	0.00	33.3
Cycle 23 Day 22	11	87.88	15.08	50.0	83.33	100.0	11	1.52	15.73	-16.7	0.00	33.3
Cycle 24 Day 1	14	89.29	15.48	50.0	100.00	100.0	14	2.38	18.32	-33.3	0.00	33.3
Cycle 25 Day 1	12	90.28	15.01	50.0	100.00	100.0	12	4.17	14.43	-16.7	0.00	33.3
Cycle 25 Day 22	11	84.85	17.41	50.0	83.33	100.0	11	0.00	16.67	-33.3	0.00	33.3
Cycle 26 Day 1	13	87.18	19.43	33.3	100.00	100.0	13	2.56	19.06	-33.3	0.00	33.3
Cycle 27 Day 1	11	92.42	11.46	66.7	100.00	100.0	11	6.06	18.67	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	91.67	11.24	66.7	100.00	100.0	12	4.17	18.97	-33.3	0.00	33.3
Study Disc 1	144	79.98	22.52	0.0	83.33	100.0	136	-7.60	22.94	-100.0	0.00	50.0
30 D SFU Z/P	77	79.65	23.20	0.0	83.33	100.0	72	-8.56	24.54	-100.0	0.00	50.0
90 D SFU Z/P	89	76.40	22.16	16.7	83.33	100.0	86	-11.63	21.25	-83.3	0.00	33.3
Placebo + mFOLFOX6 (N=282)												
Baseline	258	86.69	18.35	16.7	100.00	100.0						
Cycle 1 Day 22	212	87.11	17.67	16.7	100.00	100.0	210	-0.32	14.49	-33.3	0.00	66.7
Cycle 2 Day 1	231	88.24	19.03	0.0	100.00	100.0	225	0.30	15.98	-66.7	0.00	66.7
Cycle 2 Day 22	185	87.21	17.16	16.7	100.00	100.0	181	-1.10	15.38	-50.0	0.00	33.3
Cycle 3 Day 1	204	87.83	17.75	16.7	100.00	100.0	198	-0.17	16.19	-83.3	0.00	33.3
Cycle 3 Day 22	156	89.32	15.95	33.3	100.00	100.0	149	-0.11	13.49	-33.3	0.00	33.3
Cycle 4 Day 1	171	87.33	17.11	33.3	100.00	100.0	163	-1.64	15.85	-66.7	0.00	50.0
Cycle 4 Day 22	133	88.10	17.11	33.3	100.00	100.0	128	-1.82	16.10	-50.0	0.00	50.0
Cycle 5 Day 1	149	85.57	17.18	33.3	83.33	100.0	145	-3.56	17.26	-66.7	0.00	83.3
Cycle 5 Day 22	123	86.86	16.70	33.3	100.00	100.0	116	-3.16	16.14	-50.0	0.00	66.7
Cycle 6 Day 1	127	85.96	18.60	16.7	100.00	100.0	122	-3.55	17.17	-66.7	0.00	66.7
Cycle 6 Day 22	98	88.95	16.91	33.3	100.00	100.0	94	-0.71	14.85	-50.0	0.00	33.3
Cycle 7 Day 1	101	84.49	19.19	16.7	83.33	100.0	98	-3.57	17.46	-50.0	0.00	83.3
Cycle 7 Day 22	76	88.16	18.02	33.3	100.00	100.0	74	-0.45	16.08	-33.3	0.00	83.3
Cycle 8 Day 1	84	86.51	17.25	33.3	83.33	100.0	83	-2.61	16.97	-50.0	0.00	83.3
Cycle 8 Day 22	67	84.33	20.90	16.7	100.00	100.0	65	-5.90	20.92	-66.7	0.00	83.3
Cycle 9 Day 1	64	87.24	18.48	16.7	100.00	100.0	62	-2.15	17.72	-50.0	0.00	83.3
Cycle 9 Day 22	57	89.18	16.21	33.3	100.00	100.0	55	0.91	18.26	-50.0	0.00	83.3
Cycle 10 Day 1	58	86.21	16.85	33.3	83.33	100.0	56	-2.68	17.05	-50.0	0.00	66.7
Cycle 10 Day 22	44	85.98	21.25	33.3	100.00	100.0	43	-3.10	21.60	-66.7	0.00	83.3
Cycle 11 Day 1	48	86.11	18.94	33.3	100.00	100.0	46	-2.90	20.28	-50.0	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.9: EORTC QLQ-C30 - Observed Means and Change from Baseline of Cognitive Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	83.84	23.75	16.7	100.00	100.0	31	-4.30	19.71	-66.7	0.00	33.3
Cycle 12 Day 1	43	87.21	17.00	33.3	100.00	100.0	41	-1.63	18.56	-50.0	0.00	66.7
Cycle 12 Day 22	27	83.33	19.06	16.7	83.33	100.0	25	-6.00	15.87	-33.3	0.00	16.7
Cycle 13 Day 1	37	83.78	22.39	0.0	100.00	100.0	35	-5.24	28.23	-100.0	0.00	83.3
Cycle 13 Day 22	22	87.12	22.96	33.3	100.00	100.0	21	-1.59	25.77	-50.0	0.00	83.3
Cycle 14 Day 1	31	86.02	19.29	33.3	100.00	100.0	30	-3.89	20.85	-66.7	0.00	50.0
Cycle 14 Day 22	20	86.67	18.42	33.3	100.00	100.0	19	-3.51	24.58	-33.3	0.00	83.3
Cycle 15 Day 1	27	90.74	16.23	33.3	100.00	100.0	27	1.23	15.28	-33.3	0.00	50.0
Cycle 15 Day 22	17	91.18	18.74	33.3	100.00	100.0	17	3.92	24.67	-33.3	0.00	83.3
Cycle 16 Day 1	22	86.36	20.34	50.0	100.00	100.0	22	-2.27	26.38	-50.0	0.00	83.3
Cycle 16 Day 22	14	89.29	21.29	33.3	100.00	100.0	14	-1.19	17.86	-50.0	0.00	16.7
Cycle 17 Day 1	18	89.81	19.08	33.3	100.00	100.0	18	-2.78	16.42	-50.0	0.00	16.7
Cycle 18 Day 1	16	89.58	18.13	33.3	100.00	100.0	16	0.00	10.54	-16.7	0.00	16.7
Cycle 18 Day 22	11	86.36	20.84	33.3	100.00	100.0	10	-3.33	10.54	-16.7	0.00	16.7
Cycle 19 Day 1	16	87.50	19.72	33.3	100.00	100.0	15	-2.22	10.67	-16.7	0.00	16.7
Cycle 19 Day 22	12	90.28	19.41	33.3	100.00	100.0	11	1.52	11.68	-16.7	0.00	16.7
Cycle 20 Day 1	16	90.62	18.23	33.3	100.00	100.0	15	1.11	11.73	-16.7	0.00	16.7
Cycle 20 Day 22	11	92.42	8.70	83.3	100.00	100.0	10	0.00	7.86	-16.7	0.00	16.7
Cycle 21 Day 1	15	88.89	18.54	33.3	100.00	100.0	14	-2.38	12.84	-16.7	0.00	16.7
Cycle 22 Day 1	12	90.28	13.22	66.7	100.00	100.0	12	-1.39	13.22	-33.3	0.00	16.7
Cycle 23 Day 1	13	91.03	16.12	50.0	100.00	100.0	13	2.56	9.25	-16.7	0.00	16.7
Study Disc 1	153	80.72	22.95	0.0	83.33	100.0	149	-6.60	21.56	-100.0	0.00	50.0
Study Disc 2	12	72.22	31.25	0.0	83.33	100.0	12	-16.67	29.30	-83.3	-8.33	16.7
30 D SFU Z/P	93	83.15	17.46	33.3	83.33	100.0	91	-6.41	17.70	-50.0	0.00	33.3
90 D SFU Z/P	84	82.14	20.66	16.7	83.33	100.0	83	-7.83	20.22	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	75.36	25.77	0.0	83.33	100.0						
Cycle 1 Day 22	187	74.06	26.72	0.0	66.67	100.0	177	-3.11	24.13	-83.3	0.00	100.0
Cycle 2 Day 1	217	76.73	23.29	0.0	83.33	100.0	207	-0.32	24.24	-66.7	0.00	100.0
Cycle 2 Day 22	157	75.48	22.21	0.0	66.67	100.0	150	-2.44	23.04	-66.7	0.00	66.7
Cycle 3 Day 1	200	78.08	24.76	0.0	83.33	100.0	190	0.53	25.31	-66.7	0.00	66.7
Cycle 3 Day 22	161	71.84	25.43	0.0	66.67	100.0	152	-5.70	25.09	-83.3	0.00	50.0
Cycle 4 Day 1	178	78.37	22.59	16.7	83.33	100.0	170	0.20	24.86	-66.7	0.00	83.3
Cycle 4 Day 22	128	77.08	22.04	33.3	66.67	100.0	123	-0.95	25.28	-66.7	0.00	66.7
Cycle 5 Day 1	157	75.90	25.76	0.0	83.33	100.0	149	-1.57	29.21	-100.0	0.00	83.3
Cycle 5 Day 22	118	76.41	24.68	0.0	83.33	100.0	111	-0.75	28.37	-83.3	0.00	100.0
Cycle 6 Day 1	132	77.27	23.23	0.0	83.33	100.0	123	0.54	24.51	-66.7	0.00	100.0
Cycle 6 Day 22	108	79.78	21.14	0.0	83.33	100.0	103	1.29	24.44	-66.7	0.00	66.7
Cycle 7 Day 1	120	77.08	21.18	0.0	66.67	100.0	114	-1.61	24.49	-66.7	0.00	83.3
Cycle 7 Day 22	87	75.67	22.42	0.0	66.67	100.0	81	-1.03	26.66	-66.7	0.00	83.3
Cycle 8 Day 1	88	79.17	22.78	0.0	83.33	100.0	80	-0.83	21.53	-66.7	0.00	50.0
Cycle 8 Day 22	78	81.20	20.87	0.0	83.33	100.0	72	1.85	21.04	-33.3	0.00	50.0
Cycle 9 Day 1	83	81.12	20.79	0.0	83.33	100.0	75	2.67	21.05	-50.0	0.00	50.0
Cycle 9 Day 22	65	81.54	20.44	0.0	83.33	100.0	60	2.78	21.52	-66.7	0.00	50.0
Cycle 10 Day 1	72	82.41	22.53	0.0	100.00	100.0	66	3.03	23.19	-66.7	0.00	66.7
Cycle 10 Day 22	61	81.69	21.02	0.0	83.33	100.0	57	2.34	21.69	-33.3	0.00	50.0
Cycle 11 Day 1	68	83.33	20.56	16.7	91.67	100.0	63	3.70	21.88	-50.0	0.00	66.7
Cycle 11 Day 22	48	80.90	19.45	16.7	83.33	100.0	44	-0.76	21.55	-50.0	0.00	50.0
Cycle 12 Day 1	58	83.33	19.99	33.3	100.00	100.0	53	4.09	17.87	-33.3	0.00	33.3
Cycle 12 Day 22	41	78.86	24.73	0.0	83.33	100.0	38	-1.32	21.71	-50.0	0.00	33.3
Cycle 13 Day 1	51	80.72	21.44	16.7	83.33	100.0	48	2.43	21.19	-33.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	80.68	23.28	16.7	91.67	100.0	41	1.22	23.39	-66.7	0.00	33.3
Cycle 14 Day 1	41	81.71	24.10	0.0	100.00	100.0	39	2.99	22.25	-50.0	0.00	66.7
Cycle 14 Day 22	33	83.33	19.98	33.3	100.00	100.0	32	0.52	20.52	-33.3	0.00	50.0
Cycle 15 Day 1	36	80.56	23.06	33.3	83.33	100.0	35	2.38	28.34	-66.7	0.00	83.3
Cycle 15 Day 22	30	83.89	22.09	33.3	100.00	100.0	30	3.89	20.38	-33.3	0.00	50.0
Cycle 16 Day 1	35	83.33	22.51	16.7	100.00	100.0	35	3.33	22.43	-50.0	0.00	33.3
Cycle 16 Day 22	29	81.61	19.08	33.3	83.33	100.0	29	1.15	22.24	-33.3	0.00	50.0
Cycle 17 Day 1	30	80.00	25.67	0.0	91.67	100.0	30	1.67	26.75	-100.0	0.00	33.3
Cycle 17 Day 22	23	80.43	19.24	33.3	66.67	100.0	23	-3.62	22.45	-66.7	0.00	33.3
Cycle 18 Day 1	27	83.95	18.77	33.3	100.00	100.0	27	1.85	21.85	-66.7	0.00	33.3
Cycle 18 Day 22	21	86.51	17.97	50.0	100.00	100.0	21	2.38	16.06	-33.3	0.00	33.3
Cycle 19 Day 1	23	86.96	17.38	50.0	100.00	100.0	23	3.62	16.63	-33.3	0.00	33.3
Cycle 19 Day 22	20	85.83	17.33	50.0	100.00	100.0	20	0.83	11.44	-16.7	0.00	33.3
Cycle 20 Day 1	23	86.23	18.57	50.0	100.00	100.0	23	2.17	19.66	-50.0	0.00	33.3
Cycle 20 Day 22	18	87.04	16.72	66.7	100.00	100.0	18	1.85	15.00	-33.3	0.00	33.3
Cycle 21 Day 1	20	91.67	15.77	50.0	100.00	100.0	20	6.67	16.58	-33.3	0.00	33.3
Cycle 21 Day 22	14	91.67	16.98	50.0	100.00	100.0	14	7.14	15.63	-16.7	0.00	33.3
Cycle 22 Day 1	15	85.56	21.70	33.3	100.00	100.0	15	1.11	20.38	-33.3	0.00	33.3
Cycle 22 Day 22	11	80.30	26.69	33.3	100.00	100.0	11	-4.55	21.20	-33.3	0.00	33.3
Cycle 23 Day 1	16	85.42	23.47	33.3	100.00	100.0	16	1.04	17.71	-33.3	0.00	33.3
Cycle 23 Day 22	11	89.39	23.89	33.3	100.00	100.0	11	4.55	19.85	-33.3	0.00	33.3
Cycle 24 Day 1	14	85.71	25.20	33.3	100.00	100.0	14	2.38	23.44	-33.3	0.00	33.3
Cycle 25 Day 1	12	83.33	29.30	16.7	100.00	100.0	12	2.78	29.16	-50.0	0.00	33.3
Cycle 25 Day 22	11	84.85	24.10	33.3	100.00	100.0	11	3.03	19.46	-33.3	0.00	33.3
Cycle 26 Day 1	13	84.62	23.04	33.3	100.00	100.0	13	2.56	21.35	-33.3	0.00	33.3
Cycle 27 Day 1	11	87.88	22.47	33.3	100.00	100.0	11	6.06	23.89	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	88.89	20.52	33.3	100.00	100.0	12	5.56	20.52	-33.3	0.00	33.3
Study Disc 1	144	65.86	30.43	0.0	66.67	100.0	136	-12.01	30.07	-100.0	0.00	66.7
30 D SFU Z/P	77	66.88	28.42	0.0	66.67	100.0	72	-12.73	30.45	-100.0	0.00	33.3
90 D SFU Z/P	89	70.22	26.65	0.0	66.67	100.0	86	-9.88	29.64	-83.3	0.00	50.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	73.26	27.18	0.0	75.00	100.0						
Cycle 1 Day 22	212	73.98	26.52	0.0	83.33	100.0	210	0.48	23.05	-66.7	0.00	100.0
Cycle 2 Day 1	231	77.13	23.93	0.0	83.33	100.0	225	3.11	25.69	-66.7	0.00	100.0
Cycle 2 Day 22	185	77.03	24.12	0.0	83.33	100.0	181	2.76	27.47	-83.3	0.00	100.0
Cycle 3 Day 1	204	75.57	25.05	0.0	83.33	100.0	198	2.44	26.78	-100.0	0.00	83.3
Cycle 3 Day 22	156	77.46	21.74	16.7	83.33	100.0	149	3.80	25.86	-66.7	0.00	83.3
Cycle 4 Day 1	171	78.07	24.29	0.0	83.33	100.0	163	5.62	23.88	-66.7	0.00	100.0
Cycle 4 Day 22	133	76.57	22.00	0.0	83.33	100.0	128	2.73	22.21	-66.7	0.00	66.7
Cycle 5 Day 1	149	74.61	25.30	0.0	83.33	100.0	145	1.38	29.43	-100.0	0.00	100.0
Cycle 5 Day 22	123	76.15	24.34	0.0	66.67	100.0	116	0.86	27.26	-100.0	0.00	100.0
Cycle 6 Day 1	127	75.33	23.84	0.0	66.67	100.0	122	0.27	26.42	-83.3	0.00	83.3
Cycle 6 Day 22	98	78.91	22.14	16.7	83.33	100.0	94	3.01	29.33	-66.7	0.00	100.0
Cycle 7 Day 1	101	78.38	23.75	16.7	83.33	100.0	98	0.00	24.87	-66.7	0.00	100.0
Cycle 7 Day 22	76	81.58	23.66	0.0	91.67	100.0	74	4.50	26.21	-100.0	0.00	100.0
Cycle 8 Day 1	84	82.14	22.22	16.7	91.67	100.0	83	3.01	22.56	-66.7	0.00	66.7
Cycle 8 Day 22	67	81.09	19.66	33.3	83.33	100.0	65	1.03	24.09	-66.7	0.00	66.7
Cycle 9 Day 1	64	82.29	21.18	33.3	83.33	100.0	62	3.23	25.22	-66.7	0.00	66.7
Cycle 9 Day 22	57	80.99	21.23	16.7	83.33	100.0	55	3.33	26.91	-66.7	0.00	66.7
Cycle 10 Day 1	58	79.89	23.73	33.3	83.33	100.0	56	-0.60	28.60	-66.7	0.00	66.7
Cycle 10 Day 22	44	78.79	23.40	33.3	83.33	100.0	43	-1.55	30.82	-66.7	0.00	100.0
Cycle 11 Day 1	48	81.25	23.73	33.3	100.00	100.0	46	1.81	25.87	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.10: EORTC QLQ-C30 - Observed Means and Change from Baseline of Social Functioning - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	75.76	23.23	33.3	66.67	100.0	31	-3.76	22.65	-50.0	0.00	33.3
Cycle 12 Day 1	43	80.23	22.50	33.3	83.33	100.0	41	0.00	26.09	-66.7	0.00	66.7
Cycle 12 Day 22	27	82.72	20.92	33.3	83.33	100.0	25	4.00	22.71	-66.7	0.00	33.3
Cycle 13 Day 1	37	82.43	24.52	0.0	100.00	100.0	35	1.43	26.62	-66.7	0.00	66.7
Cycle 13 Day 22	22	84.85	20.52	33.3	100.00	100.0	21	8.73	22.74	-33.3	0.00	66.7
Cycle 14 Day 1	31	83.87	19.00	33.3	83.33	100.0	30	0.56	25.33	-66.7	0.00	66.7
Cycle 14 Day 22	20	86.67	16.75	50.0	100.00	100.0	19	6.14	23.71	-33.3	0.00	50.0
Cycle 15 Day 1	27	82.10	22.61	33.3	100.00	100.0	27	-6.17	24.96	-66.7	0.00	33.3
Cycle 15 Day 22	17	87.25	16.17	50.0	100.00	100.0	17	0.00	22.05	-33.3	0.00	33.3
Cycle 16 Day 1	22	90.91	15.19	66.7	100.00	100.0	22	3.79	24.09	-33.3	0.00	66.7
Cycle 16 Day 22	14	84.52	23.08	33.3	100.00	100.0	14	3.57	26.29	-50.0	0.00	33.3
Cycle 17 Day 1	18	91.67	15.39	50.0	100.00	100.0	18	4.63	26.69	-50.0	0.00	66.7
Cycle 18 Day 1	16	89.58	20.07	33.3	100.00	100.0	16	-1.04	20.61	-33.3	0.00	33.3
Cycle 18 Day 22	11	83.33	22.36	33.3	100.00	100.0	10	-6.67	11.65	-33.3	0.00	0.0
Cycle 19 Day 1	16	87.50	19.72	33.3	100.00	100.0	15	-5.56	16.27	-33.3	0.00	16.7
Cycle 19 Day 22	12	86.11	22.29	33.3	100.00	100.0	11	-4.55	16.82	-33.3	0.00	16.7
Cycle 20 Day 1	16	89.58	20.07	33.3	100.00	100.0	15	-3.33	19.11	-33.3	0.00	33.3
Cycle 20 Day 22	11	87.88	18.40	50.0	100.00	100.0	10	-5.00	13.72	-33.3	0.00	16.7
Cycle 21 Day 1	15	80.00	25.35	33.3	100.00	100.0	14	-11.90	15.23	-33.3	0.00	0.0
Cycle 22 Day 1	12	88.89	16.41	66.7	100.00	100.0	12	-4.17	16.09	-33.3	0.00	16.7
Cycle 23 Day 1	13	88.46	20.84	33.3	100.00	100.0	13	-2.56	16.45	-33.3	0.00	16.7
Study Disc 1	153	69.83	28.47	0.0	66.67	100.0	149	-3.13	24.15	-100.0	0.00	50.0
Study Disc 2	12	63.89	38.16	0.0	66.67	100.0	12	-8.33	41.13	-83.3	0.00	66.7
30 D SFU Z/P	93	72.40	23.51	0.0	66.67	100.0	91	-2.56	26.98	-66.7	0.00	66.7
90 D SFU Z/P	84	68.06	28.01	0.0	66.67	100.0	83	-6.02	27.74	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	31.13	23.94	0.0	33.33	100.0						
Cycle 1 Day 22	187	38.21	25.01	0.0	33.33	100.0	177	8.47	23.12	-66.7	0.00	100.0
Cycle 2 Day 1	217	32.92	23.10	0.0	33.33	100.0	207	3.81	22.20	-77.8	0.00	66.7
Cycle 2 Day 22	157	32.41	21.27	0.0	33.33	100.0	150	4.00	22.75	-66.7	0.00	66.7
Cycle 3 Day 1	200	30.50	21.86	0.0	33.33	100.0	190	2.11	23.61	-100.0	0.00	77.8
Cycle 3 Day 22	161	37.27	23.78	0.0	33.33	100.0	152	8.48	23.15	-44.4	11.11	77.8
Cycle 4 Day 1	178	30.40	22.14	0.0	33.33	88.9	170	1.70	25.04	-77.8	0.00	66.7
Cycle 4 Day 22	128	33.33	20.78	0.0	33.33	88.9	123	5.96	24.03	-88.9	0.00	66.7
Cycle 5 Day 1	157	33.62	23.84	0.0	33.33	100.0	149	4.85	26.79	-77.8	0.00	77.8
Cycle 5 Day 22	118	32.96	24.00	0.0	33.33	100.0	111	5.61	27.94	-77.8	0.00	77.8
Cycle 6 Day 1	132	28.70	23.22	0.0	33.33	100.0	123	1.08	25.66	-77.8	0.00	77.8
Cycle 6 Day 22	108	29.32	21.29	0.0	33.33	88.9	103	2.05	24.74	-100.0	0.00	66.7
Cycle 7 Day 1	120	27.22	19.58	0.0	33.33	100.0	114	0.78	22.74	-88.9	0.00	66.7
Cycle 7 Day 22	87	30.14	20.33	0.0	33.33	88.9	81	4.53	22.21	-66.7	0.00	66.7
Cycle 8 Day 1	88	25.88	20.82	0.0	33.33	100.0	80	-0.14	23.95	-66.7	0.00	66.7
Cycle 8 Day 22	78	25.64	19.72	0.0	33.33	100.0	72	-0.77	22.71	-66.7	0.00	66.7
Cycle 9 Day 1	83	24.10	20.00	0.0	33.33	100.0	75	-4.30	22.81	-66.7	0.00	66.7
Cycle 9 Day 22	65	27.86	21.79	0.0	33.33	100.0	60	-0.74	24.28	-66.7	0.00	77.8
Cycle 10 Day 1	72	26.54	21.06	0.0	33.33	88.9	66	-1.18	23.88	-66.7	0.00	66.7
Cycle 10 Day 22	61	26.05	18.47	0.0	22.22	77.8	57	-0.39	21.92	-66.7	0.00	44.4
Cycle 11 Day 1	68	22.22	17.49	0.0	22.22	55.6	63	-4.23	20.30	-44.4	0.00	55.6
Cycle 11 Day 22	48	23.15	19.56	0.0	22.22	77.8	44	-3.79	19.31	-33.3	0.00	44.4
Cycle 12 Day 1	58	22.99	17.52	0.0	22.22	77.8	53	-3.98	19.13	-44.4	0.00	33.3
Cycle 12 Day 22	41	26.29	16.99	0.0	33.33	55.6	38	1.17	18.04	-44.4	0.00	33.3
Cycle 13 Day 1	51	24.84	17.58	0.0	22.22	66.7	48	-1.16	21.77	-44.4	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	26.26	19.63	0.0	22.22	66.7	41	1.36	23.07	-44.4	0.00	44.4
Cycle 14 Day 1	41	27.91	20.66	0.0	22.22	100.0	39	0.00	20.71	-44.4	0.00	55.6
Cycle 14 Day 22	33	24.24	18.10	0.0	22.22	66.7	32	0.00	21.49	-44.4	0.00	44.4
Cycle 15 Day 1	36	29.32	23.03	0.0	33.33	100.0	35	3.49	25.25	-44.4	11.11	88.9
Cycle 15 Day 22	30	27.04	18.38	0.0	27.78	77.8	30	2.96	19.12	-44.4	0.00	44.4
Cycle 16 Day 1	35	24.13	19.52	0.0	22.22	66.7	35	-2.22	22.51	-44.4	0.00	55.6
Cycle 16 Day 22	29	27.97	23.50	0.0	33.33	100.0	29	1.53	27.33	-44.4	0.00	88.9
Cycle 17 Day 1	30	28.52	24.18	0.0	22.22	100.0	30	1.85	22.24	-22.2	0.00	77.8
Cycle 17 Day 22	23	31.88	25.58	0.0	33.33	100.0	23	8.70	26.58	-22.2	11.11	88.9
Cycle 18 Day 1	27	23.05	17.68	0.0	22.22	66.7	27	-2.88	18.64	-33.3	0.00	44.4
Cycle 18 Day 22	21	18.52	15.84	0.0	11.11	55.6	21	-4.23	17.73	-33.3	-11.11	33.3
Cycle 19 Day 1	23	22.22	20.92	0.0	22.22	88.9	23	-0.48	23.08	-44.4	0.00	44.4
Cycle 19 Day 22	20	21.11	17.25	0.0	22.22	66.7	20	-1.11	19.71	-33.3	0.00	22.2
Cycle 20 Day 1	23	23.67	22.30	0.0	22.22	100.0	23	1.45	26.65	-33.3	0.00	88.9
Cycle 20 Day 22	18	26.54	26.17	0.0	22.22	100.0	18	4.32	29.80	-33.3	0.00	88.9
Cycle 21 Day 1	20	16.67	15.92	0.0	16.67	55.6	20	-4.44	15.88	-22.2	-5.56	22.2
Cycle 21 Day 22	14	27.78	20.79	0.0	22.22	66.7	14	8.73	21.43	-22.2	11.11	55.6
Cycle 22 Day 1	15	26.67	18.69	0.0	22.22	66.7	15	5.19	20.52	-33.3	11.11	44.4
Cycle 22 Day 22	11	32.32	26.04	0.0	33.33	88.9	11	9.09	29.32	-22.2	11.11	77.8
Cycle 23 Day 1	16	31.94	20.24	0.0	33.33	77.8	16	11.11	22.22	-22.2	16.67	55.6
Cycle 23 Day 22	11	25.25	17.28	0.0	22.22	66.7	11	7.07	18.10	-22.2	11.11	22.2
Cycle 24 Day 1	14	29.37	20.26	0.0	27.78	66.7	14	6.35	22.10	-22.2	5.56	55.6
Cycle 25 Day 1	12	25.93	16.64	0.0	22.22	66.7	12	6.48	15.32	-22.2	11.11	22.2
Cycle 25 Day 22	11	27.27	22.97	0.0	22.22	88.9	11	8.08	20.54	-22.2	11.11	44.4
Cycle 26 Day 1	13	24.79	15.15	0.0	22.22	55.6	13	3.42	17.79	-22.2	11.11	22.2
Cycle 27 Day 1	11	21.21	12.62	0.0	22.22	44.4	11	1.01	14.45	-22.2	0.00	22.2

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	23.15	10.00	0.0	22.22	33.3	12	3.70	15.95	-22.2	5.56	22.2
Study Disc 1	144	42.59	27.94	0.0	33.33	100.0	136	12.17	27.51	-55.6	11.11	88.9
30 D SFU Z/P	77	41.27	26.17	0.0	33.33	100.0	72	8.02	26.32	-44.4	11.11	66.7
90 D SFU Z/P	89	41.45	25.99	0.0	33.33	100.0	86	11.63	29.12	-33.3	0.00	88.9
Placebo + mFOLFOX6 (N=282)												
Baseline	258	32.69	23.71	0.0	33.33	100.0						
Cycle 1 Day 22	212	36.11	25.04	0.0	33.33	100.0	210	4.50	20.34	-55.6	0.00	66.7
Cycle 2 Day 1	231	30.25	22.89	0.0	33.33	100.0	225	-1.48	22.30	-88.9	0.00	66.7
Cycle 2 Day 22	185	31.71	23.36	0.0	33.33	100.0	181	-0.06	21.90	-55.6	0.00	66.7
Cycle 3 Day 1	204	29.19	20.54	0.0	33.33	100.0	198	-2.13	21.92	-55.6	0.00	77.8
Cycle 3 Day 22	156	29.70	21.35	0.0	33.33	100.0	149	-0.37	21.47	-66.7	0.00	55.6
Cycle 4 Day 1	171	28.72	21.04	0.0	33.33	100.0	163	-1.30	23.34	-77.8	0.00	55.6
Cycle 4 Day 22	133	28.91	23.13	0.0	33.33	100.0	128	-1.48	22.80	-55.6	0.00	77.8
Cycle 5 Day 1	149	29.83	21.54	0.0	33.33	88.9	145	0.38	24.82	-55.6	0.00	88.9
Cycle 5 Day 22	123	30.17	21.60	0.0	33.33	100.0	116	1.82	25.12	-66.7	0.00	66.7
Cycle 6 Day 1	127	29.48	19.67	0.0	33.33	77.8	122	2.00	22.86	-55.6	0.00	66.7
Cycle 6 Day 22	98	27.44	19.81	0.0	33.33	77.8	94	-0.35	21.83	-66.7	0.00	55.6
Cycle 7 Day 1	101	24.97	20.51	0.0	22.22	88.9	98	-1.81	21.15	-55.6	0.00	55.6
Cycle 7 Day 22	76	26.32	19.02	0.0	33.33	66.7	74	-1.35	21.21	-55.6	0.00	44.4
Cycle 8 Day 1	84	23.54	20.94	0.0	22.22	77.8	83	-1.34	23.11	-55.6	0.00	77.8
Cycle 8 Day 22	67	24.88	20.20	0.0	22.22	66.7	65	-1.03	23.38	-44.4	0.00	66.7
Cycle 9 Day 1	64	21.35	20.22	0.0	22.22	66.7	62	-3.58	21.55	-44.4	0.00	44.4
Cycle 9 Day 22	57	23.00	19.57	0.0	22.22	66.7	55	-3.23	23.00	-55.6	0.00	44.4
Cycle 10 Day 1	58	19.92	21.20	0.0	11.11	77.8	56	-3.97	23.82	-66.7	0.00	66.7
Cycle 10 Day 22	44	25.51	23.43	0.0	22.22	77.8	43	0.26	22.55	-66.7	0.00	55.6
Cycle 11 Day 1	48	21.76	23.26	0.0	11.11	77.8	46	-1.21	20.45	-44.4	0.00	44.4

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	24.92	25.31	0.0	22.22	77.8	31	-0.36	21.94	-33.3	0.00	55.6
Cycle 12 Day 1	43	23.77	23.33	0.0	22.22	66.7	41	0.54	20.63	-33.3	0.00	44.4
Cycle 12 Day 22	27	26.75	28.12	0.0	11.11	88.9	25	2.67	22.52	-33.3	0.00	66.7
Cycle 13 Day 1	37	26.13	26.09	0.0	22.22	88.9	35	3.17	23.43	-44.4	0.00	55.6
Cycle 13 Day 22	22	28.79	24.88	0.0	33.33	66.7	21	2.65	16.06	-33.3	0.00	33.3
Cycle 14 Day 1	31	24.73	22.90	0.0	33.33	77.8	30	1.48	20.37	-33.3	0.00	55.6
Cycle 14 Day 22	20	25.56	19.45	0.0	22.22	66.7	19	-0.58	20.11	-55.6	0.00	33.3
Cycle 15 Day 1	27	25.93	23.47	0.0	22.22	77.8	27	4.94	23.54	-44.4	0.00	55.6
Cycle 15 Day 22	17	17.65	19.27	0.0	11.11	55.6	17	-7.19	21.50	-55.6	0.00	22.2
Cycle 16 Day 1	22	20.71	21.77	0.0	16.67	55.6	22	0.51	21.54	-44.4	5.56	33.3
Cycle 16 Day 22	14	25.40	24.04	0.0	16.67	77.8	14	2.38	23.13	-33.3	0.00	44.4
Cycle 17 Day 1	18	19.14	22.48	0.0	11.11	66.7	18	-0.62	23.33	-44.4	0.00	44.4
Cycle 18 Day 1	16	15.97	19.86	0.0	5.56	55.6	16	-2.78	21.66	-44.4	0.00	33.3
Cycle 18 Day 22	11	19.19	19.93	0.0	11.11	55.6	10	1.11	20.59	-33.3	5.56	33.3
Cycle 19 Day 1	16	19.44	23.83	0.0	5.56	66.7	15	2.96	25.36	-44.4	0.00	55.6
Cycle 19 Day 22	12	22.22	24.16	0.0	16.67	55.6	11	3.03	26.80	-33.3	0.00	55.6
Cycle 20 Day 1	16	15.28	18.09	0.0	5.56	44.4	15	-1.48	15.64	-33.3	0.00	22.2
Cycle 20 Day 22	11	20.20	15.57	0.0	22.22	44.4	10	2.22	18.74	-22.2	0.00	44.4
Cycle 21 Day 1	15	14.81	19.09	0.0	0.00	55.6	14	-0.79	19.72	-22.2	0.00	55.6
Cycle 22 Day 1	12	19.44	18.43	0.0	11.11	55.6	12	2.78	17.81	-33.3	5.56	33.3
Cycle 23 Day 1	13	16.24	21.57	0.0	0.00	55.6	13	-1.71	19.16	-33.3	0.00	33.3
Study Disc 1	153	38.56	27.31	0.0	33.33	100.0	149	5.67	26.99	-55.6	0.00	66.7
Study Disc 2	12	49.07	32.29	0.0	44.44	100.0	12	16.67	34.00	-33.3	16.67	66.7
30 D SFU Z/P	93	36.80	21.79	0.0	33.33	100.0	91	6.96	25.80	-55.6	11.11	77.8
90 D SFU Z/P	84	41.27	25.32	0.0	33.33	100.0	83	13.25	25.35	-33.3	11.11	77.8

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	30.90	24.41	0.0	33.33	100.0						
	Cycle 1 Day 22	125	34.58	24.12	0.0	33.33	100.0	117	6.93	22.06	-66.7	0.00	100.0
	Cycle 2 Day 1	138	30.76	22.19	0.0	33.33	100.0	130	2.22	19.59	-77.8	0.00	55.6
	Cycle 2 Day 22	103	29.88	22.28	0.0	33.33	100.0	97	3.09	21.44	-66.7	0.00	44.4
	Cycle 3 Day 1	125	28.80	22.09	0.0	33.33	88.9	117	2.75	21.73	-100.0	0.00	66.7
	Cycle 3 Day 22	97	34.82	24.93	0.0	33.33	100.0	90	8.40	22.98	-44.4	11.11	77.8
	Cycle 4 Day 1	112	29.07	22.53	0.0	33.33	88.9	104	2.67	23.40	-77.8	0.00	66.7
	Cycle 4 Day 22	84	33.60	21.54	0.0	33.33	88.9	79	7.45	25.14	-88.9	11.11	66.7
	Cycle 5 Day 1	101	33.77	24.89	0.0	33.33	100.0	94	6.97	26.82	-77.8	0.00	77.8
	Cycle 5 Day 22	72	34.10	25.59	0.0	33.33	100.0	66	7.74	27.07	-77.8	0.00	77.8
	Cycle 6 Day 1	78	28.06	23.60	0.0	27.78	100.0	70	3.49	24.78	-77.8	0.00	55.6
	Cycle 6 Day 22	67	28.52	21.38	0.0	33.33	77.8	63	4.23	25.20	-100.0	0.00	66.7
	Cycle 7 Day 1	76	27.19	21.27	0.0	33.33	100.0	70	3.65	23.91	-88.9	0.00	66.7
	Cycle 7 Day 22	57	31.77	21.66	0.0	33.33	88.9	51	8.06	24.75	-66.7	0.00	66.7
	Cycle 8 Day 1	59	27.12	21.37	0.0	33.33	100.0	51	2.18	24.95	-66.7	0.00	66.7
	Cycle 8 Day 22	48	24.31	21.34	0.0	22.22	100.0	42	0.26	22.69	-33.3	0.00	66.7
	Cycle 9 Day 1	50	24.22	21.73	0.0	33.33	100.0	42	-2.38	24.85	-66.7	0.00	66.7
	Cycle 9 Day 22	38	30.70	24.97	0.0	33.33	100.0	33	3.37	26.28	-66.7	0.00	77.8
	Cycle 10 Day 1	46	29.71	21.98	0.0	33.33	88.9	40	4.17	26.11	-66.7	0.00	66.7
	Cycle 10 Day 22	37	24.62	19.09	0.0	22.22	77.8	33	-0.67	23.56	-66.7	0.00	44.4
	Cycle 11 Day 1	43	23.77	18.40	0.0	22.22	55.6	38	-0.29	21.99	-44.4	0.00	55.6
	Cycle 11 Day 22	30	27.41	20.16	0.0	33.33	77.8	26	-0.85	21.53	-33.3	0.00	44.4
	Cycle 12 Day 1	33	26.26	17.75	0.0	33.33	77.8	28	-1.59	20.45	-44.4	0.00	33.3
	Cycle 12 Day 22	23	28.02	18.00	0.0	33.33	55.6	20	2.22	20.26	-44.4	0.00	33.3
	Cycle 13 Day 1	29	25.29	17.79	0.0	22.22	66.7	26	1.28	22.52	-44.4	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	25	24.44	20.54	0.0	22.22	66.7	22	-0.51	24.36	-44.4	0.00	44.4
	Cycle 14 Day 1	21	29.10	25.45	0.0	22.22	100.0	19	-1.17	21.88	-44.4	0.00	33.3
	Cycle 14 Day 22	20	20.00	19.28	0.0	22.22	66.7	19	-6.43	23.52	-44.4	-11.11	44.4
	Cycle 15 Day 1	19	28.07	22.94	0.0	33.33	66.7	18	0.62	19.98	-33.3	11.11	33.3
	Cycle 15 Day 22	19	26.90	19.71	0.0	22.22	77.8	19	0.58	18.69	-44.4	0.00	33.3
	Cycle 16 Day 1	19	19.30	14.74	0.0	22.22	44.4	19	-7.60	21.29	-44.4	0.00	22.2
	Cycle 16 Day 22	18	24.69	16.42	0.0	27.78	55.6	18	-4.32	20.92	-44.4	-5.56	22.2
	Cycle 17 Day 1	17	28.76	21.18	0.0	22.22	77.8	17	2.61	20.61	-22.2	0.00	33.3
	Cycle 17 Day 22	14	26.19	22.90	0.0	16.67	66.7	14	1.59	20.84	-22.2	0.00	33.3
	Cycle 18 Day 1	16	22.92	18.80	0.0	16.67	66.7	16	-4.17	18.09	-33.3	-5.56	22.2
	Cycle 18 Day 22	13	16.24	15.46	0.0	11.11	55.6	13	-7.69	18.36	-33.3	-11.11	33.3
	Cycle 19 Day 1	14	20.63	24.98	0.0	11.11	88.9	14	-3.17	25.20	-44.4	-5.56	44.4
	Cycle 19 Day 22	13	21.37	18.95	0.0	22.22	66.7	13	-4.27	19.00	-33.3	0.00	22.2
	Cycle 20 Day 1	14	17.46	17.28	0.0	11.11	55.6	14	-6.35	19.35	-33.3	-11.11	22.2
	Cycle 20 Day 22	13	18.80	20.48	0.0	11.11	66.7	13	-6.84	20.05	-33.3	-11.11	22.2
	Cycle 21 Day 1	13	13.68	17.07	0.0	11.11	55.6	13	-8.55	15.81	-22.2	-11.11	22.2
	Cycle 21 Day 22	10	24.44	20.82	0.0	22.22	66.7	10	3.33	18.92	-22.2	11.11	22.2
	Cycle 23 Day 1	10	26.67	21.08	0.0	22.22	77.8	10	5.56	20.45	-22.2	11.11	33.3
	Study Disc 1	93	44.09	28.40	0.0	33.33	100.0	85	14.38	26.77	-44.4	11.11	88.9
	30 D SFU Z/P	50	40.89	26.98	0.0	33.33	100.0	46	7.49	26.30	-44.4	5.56	66.7
	90 D SFU Z/P	52	39.96	28.63	0.0	33.33	100.0	50	10.67	32.22	-33.3	0.00	88.9
	Placebo + mFOLFOX6 (N=175)												
	Baseline	160	30.00	23.14	0.0	33.33	100.0						
	Cycle 1 Day 22	138	33.98	24.34	0.0	33.33	100.0	136	5.72	19.92	-44.4	0.00	66.7
	Cycle 2 Day 1	151	29.80	22.75	0.0	33.33	100.0	145	0.77	19.67	-55.6	0.00	44.4
	Cycle 2 Day 22	128	30.12	22.49	0.0	33.33	100.0	124	0.99	18.03	-44.4	0.00	44.4

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 3 Day 1	130	28.12	20.15	0.0	33.33	77.8	125	0.18	18.56	-55.6	0.00	55.6
	Cycle 3 Day 22	105	29.63	22.94	0.0	33.33	100.0	100	1.33	21.03	-66.7	0.00	55.6
	Cycle 4 Day 1	109	28.44	22.65	0.0	22.22	100.0	102	1.20	22.76	-77.8	0.00	55.6
	Cycle 4 Day 22	88	28.91	24.15	0.0	33.33	100.0	84	0.53	23.64	-55.6	0.00	77.8
	Cycle 5 Day 1	94	28.01	21.23	0.0	33.33	88.9	91	0.61	23.45	-55.6	0.00	88.9
	Cycle 5 Day 22	85	28.37	20.25	0.0	33.33	66.7	79	2.11	23.27	-55.6	0.00	66.7
	Cycle 6 Day 1	77	29.00	20.72	0.0	33.33	77.8	73	3.50	22.44	-55.6	0.00	66.7
	Cycle 6 Day 22	64	25.69	20.18	0.0	33.33	77.8	61	-1.46	22.54	-66.7	0.00	44.4
	Cycle 7 Day 1	63	22.22	19.96	0.0	22.22	66.7	60	-2.59	21.88	-55.6	0.00	33.3
	Cycle 7 Day 22	46	22.95	18.94	0.0	22.22	66.7	44	-2.53	21.81	-55.6	0.00	33.3
	Cycle 8 Day 1	50	21.33	20.31	0.0	22.22	66.7	49	-1.81	22.61	-55.6	0.00	55.6
	Cycle 8 Day 22	39	24.50	19.28	0.0	22.22	66.7	37	-1.20	22.34	-44.4	0.00	44.4
	Cycle 9 Day 1	38	21.35	21.05	0.0	16.67	66.7	36	-2.47	21.43	-44.4	0.00	33.3
	Cycle 9 Day 22	34	23.20	20.17	0.0	22.22	66.7	32	-1.74	23.12	-55.6	0.00	44.4
	Cycle 10 Day 1	31	18.28	20.99	0.0	11.11	66.7	29	-3.45	18.81	-44.4	0.00	33.3
	Cycle 10 Day 22	27	25.51	24.62	0.0	22.22	77.8	26	2.14	19.38	-33.3	0.00	33.3
	Cycle 11 Day 1	28	20.24	23.04	0.0	11.11	77.8	26	-0.43	17.91	-44.4	0.00	33.3
	Cycle 11 Day 22	20	24.44	24.61	0.0	22.22	77.8	18	3.70	22.55	-22.2	0.00	55.6
	Cycle 12 Day 1	23	21.74	24.95	0.0	11.11	66.7	21	1.59	20.27	-33.3	0.00	33.3
	Cycle 12 Day 22	15	22.96	28.32	0.0	0.00	66.7	13	2.56	19.33	-33.3	0.00	33.3
	Cycle 13 Day 1	21	21.69	23.17	0.0	11.11	55.6	19	1.17	16.93	-33.3	0.00	22.2
	Cycle 13 Day 22	11	26.26	25.95	0.0	33.33	66.7	10	3.33	19.63	-33.3	5.56	33.3
	Cycle 14 Day 1	14	17.46	19.35	0.0	11.11	44.4	13	-1.71	17.48	-33.3	0.00	22.2
	Cycle 14 Day 22	10	26.67	20.42	0.0	27.78	66.7	9	6.17	15.82	-22.2	0.00	33.3
	Cycle 15 Day 1	14	24.60	23.13	0.0	22.22	66.7	14	7.14	19.78	-22.2	0.00	44.4
	Cycle 15 Day 22	10	15.56	18.29	0.0	5.56	44.4	10	-4.44	15.89	-33.3	0.00	11.1

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 16 Day 1	14	18.25	21.17	0.0	5.56	55.6	14	0.79	18.21	-33.3	5.56	22.2
	Cycle 17 Day 1	11	19.19	22.27	0.0	11.11	55.6	11	2.02	23.74	-33.3	0.00	44.4
	Cycle 18 Day 1	10	14.44	21.63	0.0	0.00	55.6	10	-3.33	17.41	-33.3	0.00	22.2
	Cycle 19 Day 1	10	17.78	25.23	0.0	0.00	66.7	9	3.70	21.52	-33.3	0.00	33.3
	Cycle 20 Day 1	10	13.33	19.46	0.0	0.00	44.4	9	-1.23	16.14	-33.3	0.00	11.1
	Study Disc 1	94	36.05	26.71	0.0	33.33	100.0	92	6.64	25.57	-55.6	0.00	66.7
	30 D SFU Z/P	65	35.73	21.65	0.0	33.33	100.0	64	7.99	22.96	-44.4	11.11	77.8
	90 D SFU Z/P	57	39.18	24.41	0.0	33.33	100.0	56	12.90	22.90	-22.2	11.11	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	31.50	23.28	0.0	33.33	88.9						
	Cycle 1 Day 22	62	45.52	25.35	0.0	44.44	100.0	60	11.48	24.97	-44.4	11.11	66.7
	Cycle 2 Day 1	79	36.71	24.29	0.0	33.33	100.0	77	6.49	25.95	-66.7	0.00	66.7
	Cycle 2 Day 22	54	37.24	18.46	0.0	33.33	77.8	53	5.66	25.09	-55.6	0.00	66.7
	Cycle 3 Day 1	75	33.33	21.30	0.0	33.33	100.0	73	1.07	26.46	-66.7	0.00	77.8
	Cycle 3 Day 22	64	40.97	21.58	0.0	38.89	100.0	62	8.60	23.58	-33.3	11.11	66.7
	Cycle 4 Day 1	66	32.66	21.43	0.0	33.33	88.9	66	0.17	27.53	-66.7	0.00	66.7
	Cycle 4 Day 22	44	32.83	19.46	0.0	33.33	77.8	44	3.28	21.91	-55.6	0.00	55.6
	Cycle 5 Day 1	56	33.33	22.02	0.0	33.33	88.9	55	1.21	26.59	-66.7	0.00	66.7
	Cycle 5 Day 22	46	31.16	21.42	0.0	33.33	88.9	45	2.47	29.20	-66.7	0.00	66.7
	Cycle 6 Day 1	54	29.63	22.84	0.0	33.33	100.0	53	-2.10	26.69	-66.7	0.00	77.8
	Cycle 6 Day 22	41	30.62	21.34	0.0	33.33	88.9	40	-1.39	23.90	-55.6	0.00	66.7
	Cycle 7 Day 1	44	27.27	16.51	0.0	33.33	77.8	44	-3.79	20.18	-44.4	0.00	55.6
	Cycle 7 Day 22	30	27.04	17.43	0.0	33.33	66.7	30	-1.48	15.64	-33.3	0.00	33.3
	Cycle 8 Day 1	29	23.37	19.77	0.0	22.22	88.9	29	-4.21	21.91	-44.4	0.00	66.7
	Cycle 8 Day 22	30	27.78	16.95	0.0	33.33	66.7	30	-2.22	23.05	-66.7	0.00	33.3
	Cycle 9 Day 1	33	23.91	17.37	0.0	33.33	55.6	33	-6.73	20.02	-66.7	0.00	44.4
	Cycle 9 Day 22	27	23.87	15.92	0.0	22.22	55.6	27	-5.76	20.98	-55.6	0.00	22.2
	Cycle 10 Day 1	26	20.94	18.41	0.0	22.22	66.7	26	-9.40	17.41	-44.4	-11.11	22.2
	Cycle 10 Day 22	24	28.24	17.64	0.0	33.33	55.6	24	0.00	19.93	-33.3	0.00	44.4
	Cycle 11 Day 1	25	19.56	15.80	0.0	22.22	44.4	25	-10.22	16.01	-44.4	-11.11	11.1
	Cycle 11 Day 22	18	16.05	16.71	0.0	11.11	55.6	18	-8.02	15.15	-33.3	-11.11	22.2
	Cycle 12 Day 1	25	18.67	16.58	0.0	11.11	55.6	25	-6.67	17.57	-44.4	0.00	33.3
	Cycle 12 Day 22	18	24.07	15.83	0.0	33.33	44.4	18	0.00	15.71	-33.3	0.00	22.2
	Cycle 13 Day 1	22	24.24	17.70	0.0	22.22	66.7	22	-4.04	21.01	-44.4	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	19	28.65	18.64	0.0	33.33	66.7	19	3.51	21.93	-33.3	11.11	33.3
	Cycle 14 Day 1	20	26.67	14.60	0.0	22.22	66.7	20	1.11	20.04	-33.3	0.00	55.6
	Cycle 14 Day 22	13	30.77	14.45	0.0	33.33	55.6	13	9.40	14.23	-22.2	11.11	22.2
	Cycle 15 Day 1	17	30.72	23.74	0.0	33.33	100.0	17	6.54	30.19	-44.4	0.00	88.9
	Cycle 15 Day 22	11	27.27	16.75	0.0	33.33	55.6	11	7.07	20.04	-22.2	11.11	44.4
	Cycle 16 Day 1	16	29.86	23.21	0.0	33.33	66.7	16	4.17	22.91	-33.3	0.00	55.6
	Cycle 16 Day 22	11	33.33	32.20	0.0	33.33	100.0	11	11.11	34.43	-33.3	0.00	88.9
	Cycle 17 Day 1	13	28.21	28.55	0.0	22.22	100.0	13	0.85	25.04	-22.2	-11.11	77.8
	Cycle 18 Day 1	11	23.23	16.82	0.0	22.22	55.6	11	-1.01	20.16	-33.3	0.00	44.4
	Study Disc 1	51	39.87	27.14	0.0	33.33	100.0	51	8.50	28.60	-55.6	0.00	66.7
	30 D SFU Z/P	27	41.98	25.10	0.0	44.44	88.9	26	8.97	26.85	-44.4	11.11	66.7
	90 D SFU Z/P	37	43.54	21.97	0.0	44.44	88.9	36	12.96	24.56	-22.2	11.11	66.7
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	37.07	24.09	0.0	33.33	100.0						
	Cycle 1 Day 22	74	40.09	26.00	0.0	33.33	100.0	74	2.25	21.05	-55.6	0.00	44.4
	Cycle 2 Day 1	80	31.11	23.28	0.0	33.33	100.0	80	-5.56	26.04	-88.9	0.00	66.7
	Cycle 2 Day 22	57	35.28	25.03	0.0	33.33	100.0	57	-2.34	28.62	-55.6	0.00	66.7
	Cycle 3 Day 1	74	31.08	21.21	0.0	33.33	100.0	73	-6.09	26.39	-55.6	-11.11	77.8
	Cycle 3 Day 22	51	29.85	17.85	0.0	33.33	66.7	49	-3.85	22.17	-66.7	0.00	33.3
	Cycle 4 Day 1	62	29.21	18.02	0.0	33.33	77.8	61	-5.46	23.88	-55.6	0.00	55.6
	Cycle 4 Day 22	45	28.89	21.24	0.0	33.33	88.9	44	-5.30	20.82	-55.6	0.00	33.3
	Cycle 5 Day 1	55	32.93	21.91	0.0	33.33	88.9	54	0.00	27.22	-55.6	0.00	55.6
	Cycle 5 Day 22	38	34.21	24.15	0.0	33.33	100.0	37	1.20	29.02	-66.7	0.00	66.7
	Cycle 6 Day 1	50	30.22	18.10	0.0	33.33	77.8	49	-0.23	23.51	-55.6	0.00	55.6
	Cycle 6 Day 22	34	30.72	18.96	0.0	33.33	77.8	33	1.68	20.62	-44.4	0.00	55.6
	Cycle 7 Day 1	38	29.53	20.87	0.0	22.22	88.9	38	-0.58	20.17	-44.4	0.00	55.6

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.11.2: EORTC QLQ-C30 - Observed Means and Change from Baseline of Fatigue by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	30	31.48	18.24	0.0	33.33	66.7	30	0.37	20.53	-55.6	0.00	44.4
	Cycle 8 Day 1	34	26.80	21.73	0.0	22.22	77.8	34	-0.65	24.15	-44.4	0.00	77.8
	Cycle 8 Day 22	28	25.40	21.78	0.0	27.78	66.7	28	-0.79	25.11	-33.3	-5.56	66.7
	Cycle 9 Day 1	26	21.37	19.35	0.0	22.22	66.7	26	-5.13	22.05	-44.4	-11.11	44.4
	Cycle 9 Day 22	23	22.71	19.09	0.0	22.22	66.7	23	-5.31	23.18	-55.6	0.00	44.4
	Cycle 10 Day 1	27	21.81	21.68	0.0	22.22	77.8	27	-4.53	28.62	-66.7	-11.11	66.7
	Cycle 10 Day 22	17	25.49	22.14	0.0	22.22	55.6	17	-2.61	27.08	-66.7	0.00	55.6
	Cycle 11 Day 1	20	23.89	23.99	0.0	22.22	66.7	20	-2.22	23.80	-44.4	-5.56	44.4
	Cycle 11 Day 22	13	25.64	27.36	0.0	22.22	77.8	13	-5.98	20.60	-33.3	0.00	22.2
	Cycle 12 Day 1	20	26.11	21.71	0.0	22.22	66.7	20	-0.56	21.47	-33.3	0.00	44.4
	Cycle 12 Day 22	12	31.48	28.36	0.0	22.22	88.9	12	2.78	26.43	-33.3	0.00	66.7
	Cycle 13 Day 1	16	31.94	29.22	0.0	33.33	88.9	16	5.56	29.81	-44.4	0.00	55.6
	Cycle 13 Day 22	11	31.31	24.75	0.0	33.33	66.7	11	2.02	12.97	-22.2	0.00	22.2
	Cycle 14 Day 1	17	30.72	24.38	0.0	33.33	77.8	17	3.92	22.55	-33.3	0.00	55.6
	Cycle 14 Day 22	10	24.44	19.46	0.0	22.22	55.6	10	-6.67	22.35	-55.6	-5.56	22.2
	Cycle 15 Day 1	13	27.35	24.69	0.0	22.22	77.8	13	2.56	27.65	-44.4	0.00	55.6
	Study Disc 1	59	42.56	28.00	0.0	33.33	100.0	57	4.09	29.29	-55.6	0.00	66.7
	30 D SFU Z/P	28	39.29	22.32	0.0	33.33	88.9	27	4.53	31.92	-55.6	0.00	77.8
	90 D SFU Z/P	27	45.68	27.10	0.0	44.44	100.0	27	13.99	30.29	-33.3	22.22	77.8

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	15.37	23.90	0.0	0.00	100.0						
Cycle 1 Day 22	187	23.08	22.28	0.0	16.67	100.0	177	9.13	23.77	-66.7	16.67	83.3
Cycle 2 Day 1	217	17.51	19.66	0.0	16.67	100.0	207	3.38	25.90	-83.3	0.00	100.0
Cycle 2 Day 22	157	17.62	20.08	0.0	16.67	83.3	150	4.33	23.76	-66.7	0.00	83.3
Cycle 3 Day 1	200	14.83	19.04	0.0	0.00	83.3	190	0.53	27.43	-100.0	0.00	66.7
Cycle 3 Day 22	161	18.32	21.43	0.0	16.67	100.0	152	4.61	24.28	-66.7	0.00	66.7
Cycle 4 Day 1	178	14.51	18.75	0.0	0.00	100.0	170	0.00	26.46	-83.3	0.00	83.3
Cycle 4 Day 22	128	14.32	17.84	0.0	16.67	83.3	123	2.30	25.46	-83.3	0.00	66.7
Cycle 5 Day 1	157	12.74	18.02	0.0	0.00	100.0	149	-0.22	23.00	-66.7	0.00	66.7
Cycle 5 Day 22	118	13.56	20.55	0.0	0.00	100.0	111	2.40	21.65	-66.7	0.00	66.7
Cycle 6 Day 1	132	10.10	16.95	0.0	0.00	100.0	123	-2.98	19.33	-66.7	0.00	50.0
Cycle 6 Day 22	108	10.03	16.26	0.0	0.00	66.7	103	-1.13	22.54	-66.7	0.00	50.0
Cycle 7 Day 1	120	8.06	13.66	0.0	0.00	66.7	114	-2.63	19.40	-66.7	0.00	50.0
Cycle 7 Day 22	87	11.69	14.40	0.0	0.00	66.7	81	2.06	21.31	-66.7	0.00	66.7
Cycle 8 Day 1	88	7.77	12.87	0.0	0.00	50.0	80	-1.46	18.41	-66.7	0.00	33.3
Cycle 8 Day 22	78	11.32	15.07	0.0	0.00	66.7	72	-1.85	22.12	-66.7	0.00	50.0
Cycle 9 Day 1	83	7.83	15.03	0.0	0.00	83.3	75	-6.22	20.46	-66.7	0.00	33.3
Cycle 9 Day 22	65	10.77	15.71	0.0	0.00	66.7	60	-0.56	20.11	-66.7	0.00	33.3
Cycle 10 Day 1	72	8.56	14.53	0.0	0.00	66.7	66	-2.27	21.26	-66.7	0.00	50.0
Cycle 10 Day 22	61	10.11	13.70	0.0	0.00	50.0	57	-1.17	21.33	-66.7	0.00	33.3
Cycle 11 Day 1	68	7.35	13.32	0.0	0.00	66.7	63	-4.23	20.95	-66.7	0.00	50.0
Cycle 11 Day 22	48	9.38	15.72	0.0	0.00	66.7	44	0.38	17.79	-66.7	0.00	33.3
Cycle 12 Day 1	58	6.61	12.46	0.0	0.00	50.0	53	-3.77	19.51	-66.7	0.00	50.0
Cycle 12 Day 22	41	7.72	14.48	0.0	0.00	66.7	38	-1.75	19.68	-66.7	0.00	50.0
Cycle 13 Day 1	51	8.50	15.05	0.0	0.00	66.7	48	-3.12	19.34	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	8.71	15.46	0.0	0.00	66.7	41	-1.63	23.22	-66.7	0.00	50.0
Cycle 14 Day 1	41	8.94	19.04	0.0	0.00	100.0	39	-5.13	22.99	-66.7	0.00	50.0
Cycle 14 Day 22	33	10.61	15.49	0.0	0.00	50.0	32	-2.08	24.59	-66.7	0.00	50.0
Cycle 15 Day 1	36	7.87	13.50	0.0	0.00	33.3	35	-3.33	23.50	-83.3	0.00	33.3
Cycle 15 Day 22	30	8.33	12.18	0.0	0.00	33.3	30	-3.89	22.18	-66.7	0.00	33.3
Cycle 16 Day 1	35	6.67	10.85	0.0	0.00	33.3	35	-7.62	22.63	-66.7	0.00	33.3
Cycle 16 Day 22	29	12.64	19.75	0.0	0.00	66.7	29	-1.72	29.33	-66.7	0.00	66.7
Cycle 17 Day 1	30	3.89	8.40	0.0	0.00	33.3	30	-10.00	21.71	-66.7	0.00	16.7
Cycle 17 Day 22	23	10.14	13.98	0.0	0.00	33.3	23	-1.45	21.85	-66.7	0.00	33.3
Cycle 18 Day 1	27	4.32	7.44	0.0	0.00	16.7	27	-7.41	20.84	-66.7	0.00	16.7
Cycle 18 Day 22	21	7.94	17.97	0.0	0.00	66.7	21	-3.17	22.12	-66.7	0.00	33.3
Cycle 19 Day 1	23	5.80	11.90	0.0	0.00	50.0	23	-5.07	21.58	-66.7	0.00	33.3
Cycle 19 Day 22	20	5.83	9.79	0.0	0.00	33.3	20	-5.00	22.36	-66.7	0.00	16.7
Cycle 20 Day 1	23	5.07	14.59	0.0	0.00	66.7	23	-4.35	22.60	-66.7	0.00	50.0
Cycle 20 Day 22	18	5.56	16.17	0.0	0.00	66.7	18	-4.63	25.44	-66.7	0.00	50.0
Cycle 21 Day 1	20	5.00	9.52	0.0	0.00	33.3	20	-1.67	16.13	-66.7	0.00	16.7
Cycle 21 Day 22	14	1.19	4.45	0.0	0.00	16.7	14	-4.76	18.98	-66.7	0.00	16.7
Cycle 22 Day 1	15	6.67	12.28	0.0	0.00	33.3	15	-2.22	20.77	-66.7	0.00	33.3
Cycle 22 Day 22	11	6.06	8.41	0.0	0.00	16.7	11	-6.06	25.03	-66.7	0.00	16.7
Cycle 23 Day 1	16	3.13	6.72	0.0	0.00	16.7	16	-5.21	19.92	-66.7	0.00	16.7
Cycle 23 Day 22	11	6.06	11.24	0.0	0.00	33.3	11	-6.06	23.89	-66.7	0.00	16.7
Cycle 24 Day 1	14	1.19	4.45	0.0	0.00	16.7	14	-8.33	21.43	-66.7	0.00	16.7
Cycle 25 Day 1	12	2.78	6.49	0.0	0.00	16.7	12	-8.33	21.90	-66.7	0.00	16.7
Cycle 25 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Cycle 26 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-10.26	21.01	-66.7	0.00	0.0
Cycle 27 Day 1	11	4.55	7.78	0.0	0.00	16.7	11	-1.52	8.99	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	1.39	4.81	0.0	0.00	16.7	12	-4.17	14.43	-33.3	0.00	16.7
Study Disc 1	144	18.17	24.21	0.0	16.67	100.0	136	4.66	27.49	-66.7	0.00	100.0
30 D SFU Z/P	77	17.10	24.18	0.0	0.00	100.0	72	3.24	25.12	-66.7	0.00	66.7
90 D SFU Z/P	89	12.73	19.79	0.0	0.00	100.0	86	0.39	22.28	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	17.18	24.33	0.0	0.00	100.0						
Cycle 1 Day 22	212	19.10	21.78	0.0	16.67	100.0	210	2.70	23.19	-83.3	0.00	66.7
Cycle 2 Day 1	231	12.77	18.37	0.0	0.00	100.0	225	-3.70	23.85	-100.0	0.00	83.3
Cycle 2 Day 22	185	17.12	19.69	0.0	16.67	100.0	181	0.83	26.25	-83.3	0.00	100.0
Cycle 3 Day 1	204	10.62	15.66	0.0	0.00	66.7	198	-5.13	23.70	-100.0	0.00	66.7
Cycle 3 Day 22	156	13.57	17.43	0.0	16.67	83.3	149	-1.68	28.19	-100.0	0.00	83.3
Cycle 4 Day 1	171	10.23	17.36	0.0	0.00	100.0	163	-4.19	23.74	-100.0	0.00	83.3
Cycle 4 Day 22	133	11.53	18.71	0.0	0.00	100.0	128	-3.39	25.48	-100.0	0.00	100.0
Cycle 5 Day 1	149	8.28	15.70	0.0	0.00	83.3	145	-6.78	23.69	-100.0	0.00	83.3
Cycle 5 Day 22	123	9.35	16.96	0.0	0.00	83.3	116	-5.60	22.08	-83.3	0.00	66.7
Cycle 6 Day 1	127	9.71	19.64	0.0	0.00	100.0	122	-3.42	24.24	-83.3	0.00	83.3
Cycle 6 Day 22	98	8.50	16.10	0.0	0.00	100.0	94	-5.14	24.32	-83.3	0.00	66.7
Cycle 7 Day 1	101	7.59	15.55	0.0	0.00	100.0	98	-4.25	21.31	-83.3	0.00	83.3
Cycle 7 Day 22	76	6.58	10.91	0.0	0.00	50.0	74	-6.53	22.21	-83.3	0.00	33.3
Cycle 8 Day 1	84	6.15	11.21	0.0	0.00	50.0	83	-3.61	16.68	-66.7	0.00	50.0
Cycle 8 Day 22	67	7.21	10.94	0.0	0.00	33.3	65	-4.10	21.86	-83.3	0.00	33.3
Cycle 9 Day 1	64	6.77	13.84	0.0	0.00	66.7	62	-4.57	23.80	-83.3	0.00	50.0
Cycle 9 Day 22	57	6.73	10.38	0.0	0.00	33.3	55	-3.94	21.98	-83.3	0.00	33.3
Cycle 10 Day 1	58	6.32	12.02	0.0	0.00	50.0	56	-3.87	19.59	-83.3	0.00	50.0
Cycle 10 Day 22	44	9.47	14.10	0.0	0.00	50.0	43	-2.71	25.18	-83.3	0.00	50.0
Cycle 11 Day 1	48	7.64	15.74	0.0	0.00	66.7	46	-1.81	22.56	-83.3	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.12: EORTC QLQ-C30 - Observed Means and Change from Baseline of Nausea and Vomiting - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	5.56	9.92	0.0	0.00	33.3	31	-3.76	24.23	-83.3	0.00	33.3
Cycle 12 Day 1	43	7.75	13.29	0.0	0.00	50.0	41	-1.63	25.22	-83.3	0.00	50.0
Cycle 12 Day 22	27	8.64	10.71	0.0	0.00	33.3	25	-3.33	24.06	-83.3	0.00	16.7
Cycle 13 Day 1	37	6.76	12.08	0.0	0.00	50.0	35	-3.33	23.50	-83.3	0.00	33.3
Cycle 13 Day 22	22	8.33	9.96	0.0	0.00	33.3	21	-7.14	24.48	-83.3	0.00	16.7
Cycle 14 Day 1	31	8.60	14.19	0.0	0.00	50.0	30	-2.78	22.35	-83.3	0.00	50.0
Cycle 14 Day 22	20	8.33	15.77	0.0	0.00	66.7	19	-7.02	24.42	-83.3	0.00	16.7
Cycle 15 Day 1	27	6.79	11.56	0.0	0.00	50.0	27	-3.09	25.75	-83.3	0.00	50.0
Cycle 15 Day 22	17	8.82	13.33	0.0	0.00	33.3	17	-2.94	31.31	-83.3	0.00	33.3
Cycle 16 Day 1	22	11.36	20.82	0.0	0.00	66.7	22	1.52	33.69	-83.3	0.00	66.7
Cycle 16 Day 22	14	5.95	10.56	0.0	0.00	33.3	14	-7.14	30.46	-83.3	0.00	33.3
Cycle 17 Day 1	18	5.56	9.90	0.0	0.00	33.3	18	-4.63	27.30	-83.3	0.00	33.3
Cycle 18 Day 1	16	6.25	8.33	0.0	0.00	16.7	16	-4.17	26.87	-83.3	0.00	16.7
Cycle 18 Day 22	11	4.55	7.78	0.0	0.00	16.7	10	-8.33	29.66	-83.3	0.00	16.7
Cycle 19 Day 1	16	7.29	10.49	0.0	0.00	33.3	15	-1.11	29.19	-83.3	0.00	33.3
Cycle 19 Day 22	12	4.17	10.36	0.0	0.00	33.3	11	-7.58	31.94	-83.3	0.00	33.3
Cycle 20 Day 1	16	5.21	11.74	0.0	0.00	33.3	15	-3.33	26.87	-83.3	0.00	33.3
Cycle 20 Day 22	11	4.55	7.78	0.0	0.00	16.7	10	-8.33	32.63	-83.3	0.00	16.7
Cycle 21 Day 1	15	6.67	12.28	0.0	0.00	33.3	14	-3.57	30.08	-83.3	0.00	33.3
Cycle 22 Day 1	12	1.39	4.81	0.0	0.00	16.7	12	-9.72	27.94	-83.3	0.00	16.7
Cycle 23 Day 1	13	6.41	10.84	0.0	0.00	33.3	13	-3.85	30.55	-83.3	0.00	33.3
Study Disc 1	153	15.47	23.66	0.0	0.00	100.0	149	-0.67	25.84	-83.3	0.00	83.3
Study Disc 2	12	22.22	22.84	0.0	16.67	66.7	12	-4.17	30.26	-50.0	0.00	66.7
30 D SFU Z/P	93	17.38	22.78	0.0	16.67	100.0	91	-1.10	27.19	-100.0	0.00	66.7
90 D SFU Z/P	84	13.69	19.73	0.0	0.00	66.7	83	-4.42	29.34	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	25.68	25.51	0.0	16.67	100.0						
Cycle 1 Day 22	187	22.01	21.40	0.0	16.67	100.0	177	-2.54	23.40	-66.7	0.00	66.7
Cycle 2 Day 1	217	17.97	22.44	0.0	16.67	100.0	207	-6.36	24.77	-83.3	0.00	83.3
Cycle 2 Day 22	157	16.03	18.77	0.0	16.67	83.3	150	-7.67	24.47	-100.0	0.00	66.7
Cycle 3 Day 1	200	14.75	18.39	0.0	8.33	100.0	190	-9.12	25.92	-100.0	0.00	66.7
Cycle 3 Day 22	161	16.67	18.82	0.0	16.67	83.3	152	-8.44	24.71	-100.0	0.00	50.0
Cycle 4 Day 1	178	15.07	18.38	0.0	16.67	66.7	170	-9.31	24.46	-83.3	0.00	50.0
Cycle 4 Day 22	128	15.23	17.12	0.0	16.67	66.7	123	-5.69	23.94	-66.7	0.00	50.0
Cycle 5 Day 1	157	16.99	20.10	0.0	16.67	83.3	149	-5.82	26.91	-83.3	0.00	66.7
Cycle 5 Day 22	118	16.10	20.89	0.0	0.00	100.0	111	-5.41	26.32	-66.7	0.00	100.0
Cycle 6 Day 1	132	15.15	18.93	0.0	8.33	100.0	123	-7.18	27.25	-100.0	0.00	100.0
Cycle 6 Day 22	108	15.74	19.18	0.0	16.67	83.3	103	-5.34	23.36	-66.7	0.00	50.0
Cycle 7 Day 1	120	14.86	17.92	0.0	16.67	83.3	114	-5.56	24.15	-66.7	0.00	66.7
Cycle 7 Day 22	87	17.62	19.25	0.0	16.67	83.3	81	-1.65	25.22	-66.7	0.00	83.3
Cycle 8 Day 1	88	16.48	19.49	0.0	16.67	83.3	80	-2.92	25.13	-66.7	0.00	66.7
Cycle 8 Day 22	78	13.46	16.79	0.0	0.00	66.7	72	-8.10	23.40	-66.7	0.00	33.3
Cycle 9 Day 1	83	14.46	17.22	0.0	0.00	66.7	75	-8.89	22.48	-66.7	0.00	50.0
Cycle 9 Day 22	65	17.18	17.91	0.0	16.67	83.3	60	-6.11	23.96	-66.7	0.00	33.3
Cycle 10 Day 1	72	16.44	17.36	0.0	16.67	66.7	66	-6.57	24.09	-66.7	0.00	50.0
Cycle 10 Day 22	61	18.03	17.82	0.0	16.67	66.7	57	-2.92	24.42	-66.7	0.00	50.0
Cycle 11 Day 1	68	13.48	16.35	0.0	16.67	66.7	63	-9.26	23.91	-83.3	0.00	50.0
Cycle 11 Day 22	48	13.89	16.96	0.0	0.00	50.0	44	-7.20	22.85	-66.7	0.00	50.0
Cycle 12 Day 1	58	14.66	15.94	0.0	16.67	66.7	53	-7.55	22.54	-83.3	0.00	33.3
Cycle 12 Day 22	41	18.70	21.47	0.0	16.67	100.0	38	-0.88	27.11	-66.7	0.00	100.0
Cycle 13 Day 1	51	15.03	16.42	0.0	16.67	66.7	48	-5.21	25.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	15.15	18.26	0.0	16.67	83.3	41	-2.03	25.87	-66.7	0.00	83.3
Cycle 14 Day 1	41	15.85	19.35	0.0	16.67	83.3	39	-4.27	24.10	-66.7	0.00	66.7
Cycle 14 Day 22	33	11.62	14.12	0.0	0.00	50.0	32	-5.73	18.26	-50.0	0.00	33.3
Cycle 15 Day 1	36	13.43	17.28	0.0	0.00	66.7	35	-4.76	23.07	-66.7	0.00	66.7
Cycle 15 Day 22	30	13.33	17.73	0.0	0.00	66.7	30	-5.00	18.65	-50.0	0.00	33.3
Cycle 16 Day 1	35	15.71	16.14	0.0	16.67	66.7	35	-3.81	24.95	-66.7	0.00	66.7
Cycle 16 Day 22	29	14.94	18.55	0.0	16.67	66.7	29	-6.32	19.11	-50.0	0.00	33.3
Cycle 17 Day 1	30	18.89	23.87	0.0	16.67	100.0	30	0.56	29.84	-50.0	0.00	100.0
Cycle 17 Day 22	23	18.12	25.08	0.0	16.67	100.0	23	2.17	31.90	-50.0	0.00	100.0
Cycle 18 Day 1	27	15.43	23.54	0.0	0.00	100.0	27	-3.09	28.13	-50.0	0.00	100.0
Cycle 18 Day 22	21	13.49	15.47	0.0	16.67	50.0	21	-1.59	17.40	-50.0	0.00	16.7
Cycle 19 Day 1	23	14.49	20.90	0.0	0.00	66.7	23	0.00	20.72	-50.0	0.00	50.0
Cycle 19 Day 22	20	15.00	14.20	0.0	16.67	33.3	20	0.00	16.22	-33.3	0.00	33.3
Cycle 20 Day 1	23	12.32	19.60	0.0	0.00	83.3	23	-2.17	26.26	-33.3	0.00	83.3
Cycle 20 Day 22	18	12.96	15.71	0.0	8.33	50.0	18	-3.70	21.81	-33.3	0.00	50.0
Cycle 21 Day 1	20	8.33	11.47	0.0	0.00	33.3	20	-5.83	18.95	-33.3	0.00	33.3
Cycle 21 Day 22	14	10.71	16.80	0.0	0.00	50.0	14	-2.38	17.12	-33.3	0.00	16.7
Cycle 22 Day 1	15	12.22	16.02	0.0	0.00	50.0	15	-1.11	14.73	-33.3	0.00	16.7
Cycle 22 Day 22	11	15.15	18.94	0.0	0.00	50.0	11	0.00	14.91	-33.3	0.00	16.7
Cycle 23 Day 1	16	13.54	19.45	0.0	0.00	66.7	16	1.04	21.49	-50.0	0.00	33.3
Cycle 23 Day 22	11	13.64	16.36	0.0	16.67	50.0	11	-1.52	17.41	-33.3	0.00	16.7
Cycle 24 Day 1	14	17.86	23.08	0.0	16.67	66.7	14	3.57	26.29	-33.3	0.00	66.7
Cycle 25 Day 1	12	16.67	18.80	0.0	16.67	50.0	12	5.56	14.79	-16.7	0.00	33.3
Cycle 25 Day 22	11	16.67	25.82	0.0	0.00	83.3	11	6.06	23.89	-33.3	0.00	50.0
Cycle 26 Day 1	13	12.82	16.88	0.0	0.00	50.0	13	1.28	14.37	-33.3	0.00	16.7
Cycle 27 Day 1	11	9.09	13.67	0.0	0.00	33.3	11	0.00	18.26	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	11.11	16.41	0.0	0.00	50.0	12	1.39	19.41	-33.3	0.00	33.3
Study Disc 1	144	26.62	26.25	0.0	16.67	100.0	136	0.37	25.86	-66.7	0.00	83.3
30 D SFU Z/P	77	27.49	24.45	0.0	33.33	83.3	72	0.46	29.33	-66.7	0.00	83.3
90 D SFU Z/P	89	28.46	28.89	0.0	33.33	100.0	86	3.49	28.37	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	26.61	25.13	0.0	16.67	100.0						
Cycle 1 Day 22	212	20.28	20.84	0.0	16.67	83.3	210	-5.48	19.23	-66.7	0.00	50.0
Cycle 2 Day 1	231	16.38	20.50	0.0	16.67	100.0	225	-9.19	21.93	-100.0	0.00	83.3
Cycle 2 Day 22	185	16.22	22.55	0.0	0.00	100.0	181	-9.21	23.27	-83.3	0.00	100.0
Cycle 3 Day 1	204	15.60	19.86	0.0	0.00	100.0	198	-9.18	22.56	-66.7	0.00	66.7
Cycle 3 Day 22	156	17.20	22.59	0.0	0.00	100.0	149	-7.61	22.13	-66.7	0.00	50.0
Cycle 4 Day 1	171	13.74	20.32	0.0	0.00	100.0	163	-9.41	21.68	-66.7	0.00	50.0
Cycle 4 Day 22	133	15.54	21.34	0.0	0.00	100.0	128	-7.94	22.91	-66.7	0.00	66.7
Cycle 5 Day 1	149	16.55	21.00	0.0	16.67	100.0	145	-6.55	23.27	-66.7	0.00	100.0
Cycle 5 Day 22	123	19.78	24.08	0.0	16.67	100.0	116	-5.60	24.27	-66.7	0.00	83.3
Cycle 6 Day 1	127	17.85	23.77	0.0	0.00	100.0	122	-4.64	24.17	-66.7	0.00	66.7
Cycle 6 Day 22	98	15.14	20.74	0.0	0.00	83.3	94	-8.16	18.89	-50.0	0.00	33.3
Cycle 7 Day 1	101	13.70	21.52	0.0	0.00	83.3	98	-6.80	20.56	-66.7	0.00	66.7
Cycle 7 Day 22	76	13.38	19.82	0.0	0.00	83.3	74	-6.98	20.65	-66.7	0.00	33.3
Cycle 8 Day 1	84	11.71	20.17	0.0	0.00	100.0	83	-7.83	18.28	-66.7	0.00	33.3
Cycle 8 Day 22	67	13.43	20.56	0.0	0.00	100.0	65	-5.90	17.04	-50.0	0.00	33.3
Cycle 9 Day 1	64	12.50	19.92	0.0	0.00	100.0	62	-6.99	18.74	-50.0	0.00	50.0
Cycle 9 Day 22	57	16.08	19.66	0.0	16.67	83.3	55	-3.94	21.75	-66.7	0.00	33.3
Cycle 10 Day 1	58	14.94	22.01	0.0	0.00	100.0	56	-2.38	25.71	-66.7	0.00	100.0
Cycle 10 Day 22	44	15.91	20.94	0.0	0.00	66.7	43	-2.71	24.65	-66.7	0.00	66.7
Cycle 11 Day 1	48	12.85	19.82	0.0	0.00	66.7	46	-3.62	18.56	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	14.14	24.34	0.0	0.00	100.0	31	-3.23	15.17	-50.0	0.00	16.7
Cycle 12 Day 1	43	15.12	19.18	0.0	0.00	66.7	41	-1.22	19.50	-66.7	0.00	50.0
Cycle 12 Day 22	27	14.20	23.44	0.0	0.00	83.3	25	-5.33	20.25	-50.0	0.00	50.0
Cycle 13 Day 1	37	13.96	22.40	0.0	0.00	100.0	35	-2.86	20.41	-66.7	0.00	50.0
Cycle 13 Day 22	22	14.39	22.59	0.0	0.00	83.3	21	-7.14	21.46	-66.7	0.00	33.3
Cycle 14 Day 1	31	15.05	22.51	0.0	0.00	100.0	30	-1.11	19.54	-33.3	0.00	33.3
Cycle 14 Day 22	20	12.50	16.99	0.0	0.00	50.0	19	-10.53	26.18	-66.7	0.00	50.0
Cycle 15 Day 1	27	14.81	21.85	0.0	0.00	66.7	27	1.85	25.46	-66.7	0.00	66.7
Cycle 15 Day 22	17	9.80	13.25	0.0	0.00	33.3	17	-4.90	28.73	-66.7	0.00	33.3
Cycle 16 Day 1	22	9.85	18.30	0.0	0.00	66.7	22	-4.55	22.53	-66.7	0.00	50.0
Cycle 16 Day 22	14	9.52	15.63	0.0	0.00	50.0	14	-3.57	11.65	-33.3	0.00	16.7
Cycle 17 Day 1	18	7.41	17.36	0.0	0.00	66.7	18	-4.63	15.97	-33.3	0.00	16.7
Cycle 18 Day 1	16	4.17	12.91	0.0	0.00	50.0	16	-6.25	10.32	-33.3	0.00	0.0
Cycle 18 Day 22	11	4.55	10.78	0.0	0.00	33.3	10	-5.00	15.81	-33.3	0.00	16.7
Cycle 19 Day 1	16	9.38	19.21	0.0	0.00	66.7	15	-1.11	13.31	-33.3	0.00	16.7
Cycle 19 Day 22	12	5.56	10.86	0.0	0.00	33.3	11	-4.55	10.78	-33.3	0.00	0.0
Cycle 20 Day 1	16	7.29	17.18	0.0	0.00	66.7	15	-3.33	15.69	-33.3	0.00	16.7
Cycle 20 Day 22	11	7.58	11.46	0.0	0.00	33.3	10	1.67	16.57	-33.3	0.00	33.3
Cycle 21 Day 1	15	3.33	9.34	0.0	0.00	33.3	14	-4.76	15.23	-33.3	0.00	16.7
Cycle 22 Day 1	12	5.56	19.25	0.0	0.00	66.7	12	-4.17	12.56	-33.3	0.00	16.7
Cycle 23 Day 1	13	5.13	18.49	0.0	0.00	66.7	13	-6.41	14.50	-33.3	0.00	16.7
Study Disc 1	153	28.98	26.68	0.0	33.33	100.0	149	2.13	28.89	-66.7	0.00	83.3
Study Disc 2	12	40.28	28.83	0.0	33.33	100.0	12	16.67	21.32	0.0	8.33	66.7
30 D SFU Z/P	93	28.85	25.67	0.0	33.33	100.0	91	7.33	27.24	-50.0	0.00	66.7
90 D SFU Z/P	84	27.18	28.31	0.0	16.67	100.0	83	6.02	29.51	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Asia	Zolbetuximab + mFOLFOX6 (N= 88)												
	Baseline	84	16.67	22.26	0.0	8.33	100.0						
	Cycle 1 Day 22	65	18.46	21.47	0.0	16.67	66.7	64	3.13	20.11	-33.3	0.00	66.7
	Cycle 2 Day 1	78	15.60	22.04	0.0	0.00	100.0	76	-1.97	21.42	-66.7	0.00	83.3
	Cycle 2 Day 22	61	13.66	18.64	0.0	0.00	66.7	60	-4.44	21.23	-66.7	0.00	66.7
	Cycle 3 Day 1	77	13.20	15.37	0.0	0.00	50.0	75	-4.67	18.90	-66.7	0.00	50.0
	Cycle 3 Day 22	61	14.48	16.80	0.0	16.67	66.7	59	-3.67	19.34	-66.7	0.00	33.3
	Cycle 4 Day 1	68	12.75	15.54	0.0	0.00	50.0	66	-6.57	21.46	-83.3	0.00	50.0
	Cycle 4 Day 22	55	15.76	16.17	0.0	16.67	50.0	55	0.61	20.28	-66.7	0.00	50.0
	Cycle 5 Day 1	65	16.92	19.43	0.0	16.67	83.3	64	-0.52	24.48	-66.7	0.00	66.7
	Cycle 5 Day 22	47	15.60	19.48	0.0	16.67	83.3	47	1.06	20.38	-50.0	0.00	66.7
	Cycle 6 Day 1	52	19.23	21.99	0.0	16.67	100.0	51	2.94	25.54	-50.0	0.00	100.0
	Cycle 6 Day 22	41	18.29	17.40	0.0	16.67	50.0	41	5.69	18.11	-50.0	0.00	50.0
	Cycle 7 Day 1	46	17.75	19.05	0.0	16.67	83.3	45	4.81	21.50	-66.7	0.00	66.7
	Cycle 7 Day 22	36	22.22	19.92	0.0	33.33	66.7	36	8.80	20.89	-50.0	0.00	50.0
	Cycle 8 Day 1	38	20.61	21.38	0.0	16.67	83.3	37	5.86	24.28	-50.0	0.00	66.7
	Cycle 8 Day 22	29	16.67	17.82	0.0	16.67	66.7	29	2.87	17.29	-33.3	0.00	33.3
	Cycle 9 Day 1	33	13.64	15.84	0.0	0.00	33.3	32	0.52	14.96	-50.0	0.00	33.3
	Cycle 9 Day 22	27	19.14	14.40	0.0	16.67	33.3	27	6.17	20.23	-66.7	0.00	33.3
	Cycle 10 Day 1	29	17.82	16.63	0.0	16.67	50.0	28	4.17	14.79	-33.3	0.00	33.3
	Cycle 10 Day 22	24	16.67	19.03	0.0	0.00	50.0	24	6.25	17.59	-33.3	0.00	33.3
	Cycle 11 Day 1	26	17.95	18.81	0.0	16.67	66.7	25	5.33	17.82	-33.3	0.00	50.0
	Cycle 11 Day 22	22	13.64	16.77	0.0	0.00	50.0	22	3.03	15.97	-16.7	0.00	33.3
	Cycle 12 Day 1	23	15.94	17.03	0.0	16.67	50.0	22	4.55	13.78	-33.3	0.00	33.3
	Cycle 12 Day 22	20	15.83	16.64	0.0	8.33	33.3	20	4.17	15.17	-16.7	0.00	33.3
	Cycle 13 Day 1	23	18.12	15.00	0.0	16.67	50.0	22	6.06	16.70	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	21	17.46	17.06	0.0	16.67	50.0	21	5.56	16.94	-33.3	0.00	33.3
	Cycle 14 Day 1	18	13.89	13.10	0.0	16.67	33.3	18	0.93	16.64	-33.3	0.00	33.3
	Cycle 14 Day 22	16	15.63	16.63	0.0	16.67	50.0	16	3.13	12.50	-16.7	0.00	33.3
	Cycle 15 Day 1	15	16.67	16.67	0.0	16.67	33.3	15	4.44	11.73	-16.7	0.00	33.3
	Cycle 15 Day 22	15	17.78	17.21	0.0	16.67	50.0	15	4.44	18.33	-50.0	0.00	33.3
	Cycle 16 Day 1	16	20.83	18.76	0.0	16.67	66.7	16	7.29	23.55	-50.0	0.00	66.7
	Cycle 16 Day 22	14	16.67	20.67	0.0	8.33	66.7	14	1.19	17.86	-50.0	0.00	33.3
	Cycle 17 Day 1	14	21.43	27.29	0.0	16.67	100.0	14	10.71	31.76	-50.0	0.00	100.0
	Cycle 17 Day 22	11	16.67	22.36	0.0	0.00	66.7	11	7.58	23.99	-16.7	0.00	66.7
	Cycle 18 Day 1	11	12.12	15.08	0.0	0.00	33.3	11	-1.52	24.10	-50.0	0.00	33.3
	Cycle 18 Day 22	10	15.00	14.59	0.0	16.67	33.3	10	1.67	19.95	-50.0	0.00	16.7
	Cycle 19 Day 1	10	11.67	15.81	0.0	0.00	33.3	10	1.67	21.44	-50.0	0.00	33.3
	Cycle 20 Day 1	10	11.67	13.72	0.0	8.33	33.3	10	1.67	18.34	-33.3	0.00	33.3
	Study Disc 1	52	24.68	25.46	0.0	25.00	100.0	51	2.94	28.62	-66.7	0.00	83.3
	30 D SFU Z/P	29	29.31	25.45	0.0	33.33	83.3	28	5.36	32.73	-50.0	0.00	83.3
	90 D SFU Z/P	39	30.34	30.32	0.0	33.33	100.0	38	7.02	32.57	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N= 89)												
	Baseline	87	21.26	19.96	0.0	16.67	83.3						
	Cycle 1 Day 22	77	13.85	16.31	0.0	16.67	66.7	76	-7.24	17.71	-50.0	0.00	33.3
	Cycle 2 Day 1	82	11.99	14.88	0.0	0.00	50.0	81	-9.67	18.04	-50.0	0.00	33.3
	Cycle 2 Day 22	64	11.98	15.84	0.0	0.00	66.7	63	-9.26	22.75	-83.3	0.00	50.0
	Cycle 3 Day 1	70	12.86	17.30	0.0	0.00	66.7	70	-9.05	20.79	-50.0	0.00	50.0
	Cycle 3 Day 22	56	11.61	16.49	0.0	0.00	83.3	56	-11.90	21.49	-66.7	0.00	33.3
	Cycle 4 Day 1	59	11.30	17.63	0.0	0.00	100.0	59	-9.89	19.36	-50.0	0.00	33.3
	Cycle 4 Day 22	41	8.13	11.86	0.0	0.00	33.3	41	-12.60	18.92	-50.0	-16.67	33.3
	Cycle 5 Day 1	46	11.59	14.85	0.0	0.00	50.0	46	-8.33	20.41	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	40	18.33	21.62	0.0	16.67	83.3	40	-1.25	26.79	-50.0	0.00	83.3
	Cycle 6 Day 1	41	14.23	19.21	0.0	0.00	66.7	41	-4.88	22.44	-50.0	0.00	50.0
	Cycle 6 Day 22	31	9.68	13.45	0.0	0.00	33.3	31	-9.14	17.66	-33.3	0.00	33.3
	Cycle 7 Day 1	32	9.90	14.58	0.0	0.00	50.0	32	-6.77	18.87	-33.3	0.00	33.3
	Cycle 7 Day 22	25	12.67	16.16	0.0	0.00	50.0	25	-4.67	21.26	-50.0	0.00	33.3
	Cycle 8 Day 1	26	8.33	12.69	0.0	0.00	33.3	26	-10.26	15.69	-33.3	0.00	16.7
	Cycle 8 Day 22	18	9.26	15.36	0.0	0.00	50.0	18	-6.48	19.92	-33.3	0.00	33.3
	Cycle 9 Day 1	18	8.33	14.29	0.0	0.00	50.0	18	-10.19	19.92	-50.0	0.00	16.7
	Cycle 9 Day 22	14	16.67	16.01	0.0	16.67	50.0	14	-2.38	21.54	-33.3	0.00	33.3
	Cycle 10 Day 1	16	18.75	27.13	0.0	8.33	100.0	16	-2.08	34.36	-33.3	0.00	100.0
	Cycle 10 Day 22	14	19.05	22.51	0.0	16.67	66.7	14	-2.38	31.25	-50.0	-8.33	66.7
	Cycle 11 Day 1	13	16.67	21.52	0.0	16.67	66.7	13	-3.85	24.68	-33.3	0.00	33.3
	Cycle 12 Day 1	10	16.67	17.57	0.0	16.67	50.0	10	-3.33	20.49	-33.3	-8.33	33.3
	Study Disc 1	62	25.81	26.25	0.0	16.67	100.0	62	3.49	30.20	-66.7	0.00	83.3
	30 D SFU Z/P	39	23.93	22.88	0.0	16.67	83.3	38	5.26	29.02	-50.0	0.00	66.7
	90 D SFU Z/P	34	24.02	23.28	0.0	16.67	83.3	33	6.06	30.57	-66.7	0.00	83.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Non-Asia	Zolbetuximab + mFOLFOX6 (N=195)												
	Baseline	173	30.06	25.90	0.0	33.33	100.0						
	Cycle 1 Day 22	122	23.91	21.21	0.0	16.67	100.0	113	-5.75	24.58	-66.7	0.00	66.7
	Cycle 2 Day 1	139	19.30	22.63	0.0	16.67	100.0	131	-8.91	26.25	-83.3	0.00	66.7
	Cycle 2 Day 22	96	17.53	18.79	0.0	16.67	83.3	90	-9.81	26.31	-100.0	0.00	33.3
	Cycle 3 Day 1	123	15.72	20.05	0.0	16.67	100.0	115	-12.03	29.33	-100.0	-16.67	66.7
	Cycle 3 Day 22	100	18.00	19.92	0.0	16.67	83.3	93	-11.47	27.25	-100.0	-16.67	50.0
	Cycle 4 Day 1	110	16.52	19.87	0.0	16.67	66.7	104	-11.06	26.13	-83.3	0.00	50.0
	Cycle 4 Day 22	73	14.84	17.91	0.0	16.67	66.7	68	-10.78	25.56	-66.7	-8.33	50.0
	Cycle 5 Day 1	92	17.03	20.67	0.0	8.33	66.7	85	-9.80	28.09	-83.3	0.00	66.7
	Cycle 5 Day 22	71	16.43	21.91	0.0	0.00	100.0	64	-10.16	29.19	-66.7	0.00	100.0
	Cycle 6 Day 1	80	12.50	16.24	0.0	0.00	66.7	72	-14.35	26.29	-100.0	-16.67	33.3
	Cycle 6 Day 22	67	14.18	20.15	0.0	0.00	83.3	62	-12.63	23.70	-66.7	-16.67	33.3
	Cycle 7 Day 1	74	13.06	17.07	0.0	0.00	66.7	69	-12.32	23.51	-66.7	-16.67	33.3
	Cycle 7 Day 22	51	14.38	18.26	0.0	16.67	83.3	45	-10.00	25.48	-66.7	0.00	83.3
	Cycle 8 Day 1	50	13.33	17.50	0.0	0.00	66.7	43	-10.47	23.58	-66.7	0.00	50.0
	Cycle 8 Day 22	49	11.56	16.03	0.0	0.00	66.7	43	-15.50	24.23	-66.7	0.00	16.7
	Cycle 9 Day 1	50	15.00	18.21	0.0	16.67	66.7	43	-15.89	24.65	-66.7	-16.67	50.0
	Cycle 9 Day 22	38	15.79	20.12	0.0	8.33	83.3	33	-16.16	22.24	-66.7	-16.67	33.3
	Cycle 10 Day 1	43	15.50	17.96	0.0	16.67	66.7	38	-14.47	26.61	-66.7	-16.67	50.0
	Cycle 10 Day 22	37	18.92	17.20	0.0	16.67	66.7	33	-9.60	26.69	-66.7	0.00	50.0
	Cycle 11 Day 1	42	10.71	14.17	0.0	0.00	66.7	38	-18.86	22.65	-83.3	-16.67	33.3
	Cycle 11 Day 22	26	14.10	17.44	0.0	8.33	50.0	22	-17.42	24.39	-66.7	-16.67	50.0
	Cycle 12 Day 1	35	13.81	15.38	0.0	16.67	66.7	31	-16.13	23.76	-83.3	-16.67	33.3
	Cycle 12 Day 22	21	21.43	25.35	0.0	16.67	100.0	18	-6.48	35.76	-66.7	0.00	100.0
	Cycle 13 Day 1	28	12.50	17.35	0.0	0.00	66.7	26	-14.74	28.41	-66.7	-16.67	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	23	13.04	19.43	0.0	0.00	83.3	20	-10.00	31.25	-66.7	0.00	83.3
	Cycle 14 Day 1	23	17.39	23.29	0.0	16.67	83.3	21	-8.73	28.68	-66.7	-16.67	66.7
	Cycle 14 Day 22	17	7.84	10.40	0.0	0.00	33.3	16	-14.58	19.12	-50.0	-8.33	16.7
	Cycle 15 Day 1	21	11.11	17.74	0.0	0.00	66.7	20	-11.67	27.09	-66.7	-16.67	66.7
	Cycle 15 Day 22	15	8.89	17.67	0.0	0.00	66.7	15	-14.44	13.90	-33.3	-16.67	0.0
	Cycle 16 Day 1	19	11.40	12.49	0.0	16.67	33.3	19	-13.16	22.62	-66.7	-16.67	16.7
	Cycle 16 Day 22	15	13.33	16.90	0.0	16.67	50.0	15	-13.33	18.04	-33.3	0.00	16.7
	Cycle 17 Day 1	16	16.67	21.08	0.0	8.33	66.7	16	-8.33	25.82	-33.3	-8.33	66.7
	Cycle 17 Day 22	12	19.44	28.28	0.0	16.67	100.0	12	-2.78	38.16	-50.0	0.00	100.0
	Cycle 18 Day 1	16	17.71	28.20	0.0	0.00	100.0	16	-4.17	31.33	-33.3	-8.33	100.0
	Cycle 18 Day 22	11	12.12	16.82	0.0	0.00	50.0	11	-4.55	15.08	-33.3	0.00	16.7
	Cycle 19 Day 1	13	16.67	24.53	0.0	0.00	66.7	13	-1.28	20.93	-33.3	0.00	50.0
	Cycle 19 Day 22	11	10.61	13.48	0.0	0.00	33.3	11	-7.58	13.67	-33.3	0.00	0.0
	Cycle 20 Day 1	13	12.82	23.72	0.0	0.00	83.3	13	-5.13	31.46	-33.3	0.00	83.3
	Cycle 20 Day 22	10	15.00	18.34	0.0	8.33	50.0	10	-5.00	26.12	-33.3	0.00	50.0
	Cycle 21 Day 1	12	4.17	7.54	0.0	0.00	16.7	12	-15.28	15.01	-33.3	-16.67	0.0
	Study Disc 1	92	27.72	26.76	0.0	16.67	100.0	85	-1.18	24.10	-50.0	0.00	50.0
	30 D SFU Z/P	48	26.39	24.03	0.0	33.33	66.7	44	-2.65	26.88	-66.7	0.00	66.7
	90 D SFU Z/P	50	27.00	27.95	0.0	25.00	100.0	48	0.69	24.54	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=193)												
	Baseline	171	29.34	27.03	0.0	33.33	100.0						
	Cycle 1 Day 22	135	23.95	22.27	0.0	16.67	83.3	134	-4.48	20.04	-66.7	0.00	50.0
	Cycle 2 Day 1	149	18.79	22.70	0.0	16.67	100.0	144	-8.91	23.89	-100.0	0.00	83.3
	Cycle 2 Day 22	121	18.46	25.17	0.0	16.67	100.0	118	-9.18	23.63	-66.7	0.00	100.0
	Cycle 3 Day 1	134	17.04	20.99	0.0	16.67	100.0	128	-9.24	23.55	-66.7	0.00	66.7
	Cycle 3 Day 22	100	20.33	24.91	0.0	16.67	100.0	93	-5.02	22.22	-66.7	0.00	50.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	112	15.03	21.57	0.0	0.00	100.0	104	-9.13	22.98	-66.7	0.00	50.0
	Cycle 4 Day 22	92	18.84	23.73	0.0	16.67	100.0	87	-5.75	24.36	-66.7	0.00	66.7
	Cycle 5 Day 1	103	18.77	22.95	0.0	16.67	100.0	99	-5.72	24.53	-66.7	0.00	100.0
	Cycle 5 Day 22	83	20.48	25.28	0.0	16.67	100.0	76	-7.89	22.69	-66.7	0.00	66.7
	Cycle 6 Day 1	86	19.57	25.59	0.0	0.00	100.0	81	-4.53	25.14	-66.7	0.00	66.7
	Cycle 6 Day 22	67	17.66	23.01	0.0	0.00	83.3	63	-7.67	19.59	-50.0	0.00	33.3
	Cycle 7 Day 1	69	15.46	23.97	0.0	0.00	83.3	66	-6.82	21.48	-66.7	0.00	66.7
	Cycle 7 Day 22	51	13.73	21.53	0.0	0.00	83.3	49	-8.16	20.45	-66.7	0.00	33.3
	Cycle 8 Day 1	58	13.22	22.68	0.0	0.00	100.0	57	-6.73	19.38	-66.7	0.00	33.3
	Cycle 8 Day 22	49	14.97	22.11	0.0	0.00	100.0	47	-5.67	16.03	-50.0	0.00	33.3
	Cycle 9 Day 1	46	14.13	21.65	0.0	0.00	100.0	44	-5.68	18.31	-50.0	0.00	50.0
	Cycle 9 Day 22	43	15.89	20.88	0.0	0.00	83.3	41	-4.47	22.06	-66.7	0.00	33.3
	Cycle 10 Day 1	42	13.49	19.90	0.0	0.00	66.7	40	-2.50	21.86	-66.7	0.00	66.7
	Cycle 10 Day 22	30	14.44	20.40	0.0	0.00	66.7	29	-2.87	21.39	-66.7	0.00	33.3
	Cycle 11 Day 1	35	11.43	19.29	0.0	0.00	66.7	33	-3.54	16.01	-33.3	0.00	33.3
	Cycle 11 Day 22	25	16.67	26.79	0.0	0.00	100.0	23	0.00	12.31	-33.3	0.00	16.7
	Cycle 12 Day 1	33	14.65	19.88	0.0	0.00	66.7	31	-0.54	19.48	-66.7	0.00	50.0
	Cycle 12 Day 22	21	18.25	25.22	0.0	0.00	83.3	19	1.75	15.61	-16.7	0.00	50.0
	Cycle 13 Day 1	28	14.29	24.31	0.0	0.00	100.0	26	-0.64	20.27	-66.7	0.00	50.0
	Cycle 13 Day 22	17	17.65	24.63	0.0	16.67	83.3	16	-3.13	21.27	-66.7	0.00	33.3
	Cycle 14 Day 1	23	18.12	25.08	0.0	0.00	100.0	22	3.79	17.77	-33.3	0.00	33.3
	Cycle 14 Day 22	14	14.29	19.46	0.0	0.00	50.0	13	-6.41	29.30	-66.7	0.00	50.0
	Cycle 15 Day 1	21	10.32	19.35	0.0	0.00	66.7	21	0.00	22.97	-66.7	0.00	50.0
	Cycle 15 Day 22	12	11.11	14.79	0.0	0.00	33.3	12	1.39	27.94	-66.7	0.00	33.3
	Cycle 16 Day 1	16	8.33	17.21	0.0	0.00	66.7	16	-3.13	19.45	-66.7	0.00	16.7
	Cycle 17 Day 1	13	6.41	18.68	0.0	0.00	66.7	13	0.00	9.62	-16.7	0.00	16.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.13.3: EORTC QLQ-C30 - Observed Means and Change from Baseline of Pain by Region - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 18 Day 1	13	5.13	14.25	0.0	0.00	50.0	13	-3.85	7.31	-16.7	0.00	0.0
	Cycle 19 Day 1	13	8.97	19.97	0.0	0.00	66.7	12	0.00	10.05	-16.7	0.00	16.7
	Cycle 20 Day 1	13	6.41	18.68	0.0	0.00	66.7	12	-2.78	13.91	-33.3	0.00	16.7
	Cycle 21 Day 1	12	1.39	4.81	0.0	0.00	16.7	11	-4.55	13.10	-33.3	0.00	16.7
	Cycle 23 Day 1	10	6.67	21.08	0.0	0.00	66.7	10	-3.33	13.15	-33.3	0.00	16.7
	Study Disc 1	91	31.14	26.90	0.0	33.33	100.0	87	1.15	28.05	-66.7	0.00	66.7
	Study Disc 2	10	45.00	28.38	0.0	41.67	100.0	10	16.67	22.22	0.0	8.33	66.7
	30 D SFU Z/P	54	32.41	27.17	0.0	33.33	100.0	53	8.81	26.07	-33.3	0.00	66.7
	90 D SFU Z/P	50	29.33	31.33	0.0	16.67	100.0	50	6.00	29.11	-50.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	13.23	22.97	0.0	0.00	100.0						
Cycle 1 Day 22	187	14.44	21.85	0.0	0.00	100.0	177	1.88	22.67	-66.7	0.00	100.0
Cycle 2 Day 1	217	12.60	20.41	0.0	0.00	66.7	207	0.48	20.90	-100.0	0.00	66.7
Cycle 2 Day 22	157	10.40	17.64	0.0	0.00	100.0	150	-0.67	20.96	-66.7	0.00	66.7
Cycle 3 Day 1	200	11.33	19.89	0.0	0.00	100.0	190	0.35	24.24	-100.0	0.00	66.7
Cycle 3 Day 22	161	13.25	20.17	0.0	0.00	100.0	152	1.32	21.32	-66.7	0.00	33.3
Cycle 4 Day 1	178	11.42	21.27	0.0	0.00	100.0	170	-0.20	23.36	-100.0	0.00	66.7
Cycle 4 Day 22	128	11.46	19.37	0.0	0.00	100.0	123	2.71	20.29	-66.7	0.00	66.7
Cycle 5 Day 1	157	11.89	18.49	0.0	0.00	66.7	149	2.24	20.75	-66.7	0.00	66.7
Cycle 5 Day 22	118	11.02	19.02	0.0	0.00	66.7	111	2.10	22.15	-100.0	0.00	66.7
Cycle 6 Day 1	132	11.11	19.17	0.0	0.00	66.7	123	0.81	22.77	-100.0	0.00	66.7
Cycle 6 Day 22	108	9.88	17.80	0.0	0.00	66.7	103	0.65	20.86	-100.0	0.00	66.7
Cycle 7 Day 1	120	12.78	19.41	0.0	0.00	100.0	114	4.09	21.33	-33.3	0.00	100.0
Cycle 7 Day 22	87	11.11	20.12	0.0	0.00	66.7	81	4.94	19.80	-33.3	0.00	66.7
Cycle 8 Day 1	88	9.85	17.62	0.0	0.00	100.0	80	3.75	20.54	-33.3	0.00	100.0
Cycle 8 Day 22	78	9.83	16.21	0.0	0.00	66.7	72	1.85	18.46	-66.7	0.00	33.3
Cycle 9 Day 1	83	10.44	17.21	0.0	0.00	66.7	75	1.78	18.90	-66.7	0.00	33.3
Cycle 9 Day 22	65	11.28	19.79	0.0	0.00	100.0	60	3.33	27.92	-100.0	0.00	100.0
Cycle 10 Day 1	72	9.72	18.07	0.0	0.00	100.0	66	1.52	25.10	-100.0	0.00	100.0
Cycle 10 Day 22	61	8.74	15.99	0.0	0.00	66.7	57	2.34	18.75	-33.3	0.00	33.3
Cycle 11 Day 1	68	5.88	14.04	0.0	0.00	66.7	63	-0.53	17.45	-33.3	0.00	66.7
Cycle 11 Day 22	48	6.25	14.84	0.0	0.00	66.7	44	2.27	18.18	-33.3	0.00	66.7
Cycle 12 Day 1	58	10.92	19.13	0.0	0.00	66.7	53	4.40	16.06	-33.3	0.00	33.3
Cycle 12 Day 22	41	7.32	13.97	0.0	0.00	33.3	38	2.63	16.22	-33.3	0.00	33.3
Cycle 13 Day 1	51	9.15	16.44	0.0	0.00	66.7	48	2.78	15.12	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	9.09	16.65	0.0	0.00	66.7	41	3.25	16.34	-33.3	0.00	33.3
Cycle 14 Day 1	41	9.76	17.07	0.0	0.00	66.7	39	0.85	16.20	-33.3	0.00	33.3
Cycle 14 Day 22	33	6.06	13.06	0.0	0.00	33.3	32	0.00	16.93	-33.3	0.00	33.3
Cycle 15 Day 1	36	8.33	14.64	0.0	0.00	33.3	35	-0.95	20.59	-66.7	0.00	33.3
Cycle 15 Day 22	30	4.44	11.52	0.0	0.00	33.3	30	-2.22	14.99	-33.3	0.00	33.3
Cycle 16 Day 1	35	9.52	17.29	0.0	0.00	66.7	35	1.90	13.87	-33.3	0.00	33.3
Cycle 16 Day 22	29	10.34	18.05	0.0	0.00	66.7	29	4.60	19.36	-33.3	0.00	66.7
Cycle 17 Day 1	30	11.11	15.98	0.0	0.00	33.3	30	2.22	17.36	-33.3	0.00	33.3
Cycle 17 Day 22	23	8.70	18.03	0.0	0.00	66.7	23	2.90	19.88	-33.3	0.00	66.7
Cycle 18 Day 1	27	7.41	14.12	0.0	0.00	33.3	27	0.00	13.07	-33.3	0.00	33.3
Cycle 18 Day 22	21	9.52	18.69	0.0	0.00	66.7	21	4.76	19.11	-33.3	0.00	66.7
Cycle 19 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	2.90	13.90	-33.3	0.00	33.3
Cycle 19 Day 22	20	8.33	14.81	0.0	0.00	33.3	20	3.33	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	23	7.25	14.06	0.0	0.00	33.3	23	1.45	12.22	-33.3	0.00	33.3
Cycle 20 Day 22	18	5.56	12.78	0.0	0.00	33.3	18	1.85	7.86	0.0	0.00	33.3
Cycle 21 Day 1	20	5.00	12.21	0.0	0.00	33.3	20	0.00	0.00	0.0	0.00	0.0
Cycle 21 Day 22	14	7.14	14.19	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	-2.22	8.61	-33.3	0.00	0.0
Cycle 22 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 23 Day 1	16	14.58	20.97	0.0	0.00	66.7	16	6.25	21.84	-33.3	0.00	66.7
Cycle 23 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 24 Day 1	14	9.52	15.63	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
Cycle 25 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-5.56	12.97	-33.3	0.00	0.0
Cycle 25 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 26 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-2.56	9.25	-33.3	0.00	0.0
Cycle 27 Day 1	11	9.09	21.56	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
Study Disc 1	144	20.37	27.63	0.0	0.00	100.0	136	8.09	29.11	-66.7	0.00	100.0
30 D SFU Z/P	77	19.05	27.80	0.0	0.00	100.0	72	4.63	23.94	-66.7	0.00	66.7
90 D SFU Z/P	89	25.09	28.55	0.0	33.33	100.0	86	13.57	29.98	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	13.70	23.20	0.0	0.00	100.0						
Cycle 1 Day 22	212	12.89	24.10	0.0	0.00	100.0	210	1.43	22.19	-66.7	0.00	100.0
Cycle 2 Day 1	231	11.69	19.98	0.0	0.00	100.0	225	0.59	20.88	-100.0	0.00	100.0
Cycle 2 Day 22	185	11.53	19.94	0.0	0.00	100.0	181	0.18	21.52	-66.7	0.00	66.7
Cycle 3 Day 1	204	12.25	19.49	0.0	0.00	100.0	198	1.01	20.13	-66.7	0.00	66.7
Cycle 3 Day 22	156	12.39	23.10	0.0	0.00	100.0	149	2.24	21.10	-66.7	0.00	66.7
Cycle 4 Day 1	171	12.48	20.46	0.0	0.00	100.0	163	1.43	21.07	-66.7	0.00	66.7
Cycle 4 Day 22	133	11.03	19.56	0.0	0.00	100.0	128	0.26	20.28	-66.7	0.00	66.7
Cycle 5 Day 1	149	10.74	19.86	0.0	0.00	100.0	145	-0.46	24.21	-66.7	0.00	100.0
Cycle 5 Day 22	123	11.92	19.15	0.0	0.00	66.7	116	1.44	22.15	-100.0	0.00	66.7
Cycle 6 Day 1	127	13.65	20.73	0.0	0.00	100.0	122	3.28	22.02	-66.7	0.00	66.7
Cycle 6 Day 22	98	10.88	18.40	0.0	0.00	66.7	94	1.42	20.69	-66.7	0.00	66.7
Cycle 7 Day 1	101	9.24	17.07	0.0	0.00	66.7	98	-1.02	19.42	-100.0	0.00	33.3
Cycle 7 Day 22	76	7.46	16.86	0.0	0.00	100.0	74	-2.25	21.60	-100.0	0.00	33.3
Cycle 8 Day 1	84	9.13	17.43	0.0	0.00	66.7	83	-0.40	21.77	-66.7	0.00	66.7
Cycle 8 Day 22	67	6.97	14.84	0.0	0.00	66.7	65	-3.59	18.75	-66.7	0.00	33.3
Cycle 9 Day 1	64	8.33	16.80	0.0	0.00	66.7	62	-3.23	19.75	-66.7	0.00	33.3
Cycle 9 Day 22	57	6.43	14.69	0.0	0.00	66.7	55	-3.64	21.92	-100.0	0.00	33.3
Cycle 10 Day 1	58	9.77	18.74	0.0	0.00	66.7	56	0.00	22.92	-100.0	0.00	66.7
Cycle 10 Day 22	44	9.85	21.06	0.0	0.00	66.7	43	1.55	24.07	-100.0	0.00	66.7
Cycle 11 Day 1	48	8.33	17.53	0.0	0.00	66.7	46	0.00	17.21	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.14: EORTC QLQ-C30 - Observed Means and Change from Baseline of Dyspnoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	10.10	24.27	0.0	0.00	100.0	31	2.15	28.46	-100.0	0.00	100.0
Cycle 12 Day 1	43	8.53	19.37	0.0	0.00	66.7	41	0.00	21.08	-100.0	0.00	33.3
Cycle 12 Day 22	27	11.11	22.65	0.0	0.00	100.0	25	5.33	15.75	-33.3	0.00	33.3
Cycle 13 Day 1	37	9.91	20.59	0.0	0.00	100.0	35	0.95	22.12	-100.0	0.00	33.3
Cycle 13 Day 22	22	10.61	23.87	0.0	0.00	100.0	21	-1.59	26.82	-100.0	0.00	33.3
Cycle 14 Day 1	31	8.60	17.14	0.0	0.00	66.7	30	0.00	24.76	-100.0	0.00	33.3
Cycle 14 Day 22	20	10.00	19.04	0.0	0.00	66.7	19	-3.51	26.98	-100.0	0.00	33.3
Cycle 15 Day 1	27	7.41	16.88	0.0	0.00	66.7	27	-1.23	26.92	-100.0	0.00	33.3
Cycle 15 Day 22	17	7.84	18.74	0.0	0.00	66.7	17	-3.92	28.58	-100.0	0.00	33.3
Cycle 16 Day 1	22	7.58	17.61	0.0	0.00	66.7	22	-1.52	26.18	-100.0	0.00	33.3
Cycle 16 Day 22	14	9.52	20.37	0.0	0.00	66.7	14	4.76	17.82	-33.3	0.00	33.3
Cycle 17 Day 1	18	3.70	10.78	0.0	0.00	33.3	18	0.00	16.17	-33.3	0.00	33.3
Cycle 18 Day 1	16	8.33	19.25	0.0	0.00	66.7	16	2.08	19.12	-33.3	0.00	33.3
Cycle 18 Day 22	11	6.06	20.10	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 19 Day 1	16	4.17	16.67	0.0	0.00	66.7	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 19 Day 22	12	8.33	28.87	0.0	0.00	100.0	11	0.00	25.82	-33.3	0.00	66.7
Cycle 20 Day 1	16	8.33	25.82	0.0	0.00	100.0	15	2.22	23.46	-33.3	0.00	66.7
Cycle 20 Day 22	11	0.00	0.00	0.0	0.00	0.0	10	-6.67	14.05	-33.3	0.00	0.0
Cycle 21 Day 1	15	11.11	27.22	0.0	0.00	100.0	14	4.76	25.68	-33.3	0.00	66.7
Cycle 22 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	0.00	20.10	-33.3	0.00	33.3
Cycle 23 Day 1	13	7.69	19.97	0.0	0.00	66.7	13	0.00	19.25	-33.3	0.00	33.3
Study Disc 1	153	20.04	26.31	0.0	0.00	100.0	149	7.83	26.67	-66.7	0.00	100.0
Study Disc 2	12	27.78	37.15	0.0	16.67	100.0	12	13.89	33.21	-33.3	0.00	100.0
30 D SFU Z/P	93	14.70	21.68	0.0	0.00	100.0	91	5.49	21.81	-66.7	0.00	100.0
90 D SFU Z/P	84	20.24	25.88	0.0	0.00	100.0	83	12.05	27.83	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	27.50	28.50	0.0	33.33	100.0						
Cycle 1 Day 22	187	24.96	26.91	0.0	33.33	100.0	177	0.00	27.52	-100.0	0.00	66.7
Cycle 2 Day 1	217	22.43	25.44	0.0	33.33	100.0	207	-4.03	29.92	-100.0	0.00	66.7
Cycle 2 Day 22	157	19.53	24.18	0.0	0.00	100.0	150	-5.33	29.18	-100.0	0.00	66.7
Cycle 3 Day 1	200	16.83	24.56	0.0	0.00	100.0	190	-8.42	30.85	-100.0	0.00	100.0
Cycle 3 Day 22	161	20.91	23.52	0.0	33.33	100.0	152	-5.26	27.69	-100.0	0.00	66.7
Cycle 4 Day 1	178	15.17	20.07	0.0	0.00	100.0	170	-10.59	29.55	-100.0	0.00	66.7
Cycle 4 Day 22	128	16.93	21.73	0.0	0.00	100.0	123	-5.42	31.47	-100.0	0.00	100.0
Cycle 5 Day 1	157	19.53	24.47	0.0	0.00	100.0	149	-5.59	32.28	-100.0	0.00	100.0
Cycle 5 Day 22	118	17.80	24.53	0.0	0.00	100.0	111	-6.01	32.47	-100.0	0.00	66.7
Cycle 6 Day 1	132	18.94	26.11	0.0	0.00	100.0	123	-6.50	32.13	-100.0	0.00	100.0
Cycle 6 Day 22	108	18.21	22.04	0.0	0.00	100.0	103	-4.21	29.03	-100.0	0.00	66.7
Cycle 7 Day 1	120	16.11	20.72	0.0	0.00	66.7	114	-7.02	27.86	-100.0	0.00	66.7
Cycle 7 Day 22	87	17.24	20.87	0.0	0.00	100.0	81	-4.94	23.64	-66.7	0.00	66.7
Cycle 8 Day 1	88	15.91	22.02	0.0	0.00	100.0	80	-6.67	26.73	-66.7	0.00	66.7
Cycle 8 Day 22	78	17.52	21.97	0.0	0.00	100.0	72	-6.94	27.37	-100.0	0.00	33.3
Cycle 9 Day 1	83	17.27	24.06	0.0	0.00	100.0	75	-8.44	29.05	-100.0	0.00	66.7
Cycle 9 Day 22	65	14.36	22.02	0.0	0.00	100.0	60	-8.89	32.97	-100.0	0.00	100.0
Cycle 10 Day 1	72	17.13	20.17	0.0	0.00	66.7	66	-8.59	27.62	-100.0	0.00	33.3
Cycle 10 Day 22	61	12.02	17.25	0.0	0.00	66.7	57	-9.94	26.70	-100.0	0.00	33.3
Cycle 11 Day 1	68	15.69	20.34	0.0	0.00	66.7	63	-8.99	27.57	-100.0	0.00	66.7
Cycle 11 Day 22	48	11.81	17.52	0.0	0.00	66.7	44	-11.36	26.84	-100.0	0.00	33.3
Cycle 12 Day 1	58	14.94	19.91	0.0	0.00	66.7	53	-8.18	29.17	-100.0	0.00	66.7
Cycle 12 Day 22	41	14.63	19.79	0.0	0.00	66.7	38	-3.51	26.61	-100.0	0.00	33.3
Cycle 13 Day 1	51	16.99	20.41	0.0	0.00	66.7	48	-6.25	32.73	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	10.61	18.71	0.0	0.00	66.7	41	-9.76	28.13	-66.7	0.00	33.3
Cycle 14 Day 1	41	13.82	21.05	0.0	0.00	100.0	39	-9.40	25.30	-66.7	0.00	33.3
Cycle 14 Day 22	33	10.10	15.56	0.0	0.00	33.3	32	-7.29	29.00	-66.7	0.00	33.3
Cycle 15 Day 1	36	12.96	16.48	0.0	0.00	33.3	35	-7.62	30.34	-100.0	0.00	33.3
Cycle 15 Day 22	30	11.11	15.98	0.0	0.00	33.3	30	-8.89	26.16	-66.7	0.00	33.3
Cycle 16 Day 1	35	11.43	16.05	0.0	0.00	33.3	35	-9.52	28.66	-66.7	0.00	33.3
Cycle 16 Day 22	29	11.49	16.12	0.0	0.00	33.3	29	-9.20	23.40	-66.7	0.00	33.3
Cycle 17 Day 1	30	16.67	25.89	0.0	0.00	100.0	30	-4.44	33.60	-66.7	0.00	100.0
Cycle 17 Day 22	23	13.04	19.43	0.0	0.00	66.7	23	-4.35	30.66	-66.7	0.00	66.7
Cycle 18 Day 1	27	9.88	15.51	0.0	0.00	33.3	27	-9.88	28.96	-66.7	0.00	33.3
Cycle 18 Day 22	21	15.87	17.06	0.0	0.00	33.3	21	-1.59	28.82	-66.7	0.00	33.3
Cycle 19 Day 1	23	10.14	15.68	0.0	0.00	33.3	23	-8.70	28.81	-66.7	0.00	33.3
Cycle 19 Day 22	20	8.33	14.81	0.0	0.00	33.3	20	-8.33	28.36	-66.7	0.00	33.3
Cycle 20 Day 1	23	7.25	14.06	0.0	0.00	33.3	23	-10.14	29.19	-66.7	0.00	33.3
Cycle 20 Day 22	18	9.26	15.36	0.0	0.00	33.3	18	-9.26	31.94	-66.7	0.00	33.3
Cycle 21 Day 1	20	10.00	15.67	0.0	0.00	33.3	20	-6.67	25.59	-66.7	0.00	33.3
Cycle 21 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	-9.52	24.21	-66.7	0.00	33.3
Cycle 22 Day 1	15	11.11	20.57	0.0	0.00	66.7	15	-6.67	25.82	-66.7	0.00	33.3
Cycle 22 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	-3.03	27.71	-33.3	0.00	33.3
Cycle 23 Day 1	16	14.58	20.97	0.0	0.00	66.7	16	-2.08	28.46	-66.7	0.00	33.3
Cycle 23 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-6.06	29.13	-66.7	0.00	33.3
Cycle 24 Day 1	14	11.90	16.57	0.0	0.00	33.3	14	-7.14	26.73	-66.7	0.00	33.3
Cycle 25 Day 1	12	19.44	17.16	0.0	33.33	33.3	12	0.00	24.62	-33.3	0.00	33.3
Cycle 25 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	-3.03	31.46	-66.7	0.00	33.3
Cycle 26 Day 1	13	12.82	16.88	0.0	0.00	33.3	13	-7.69	27.74	-66.7	0.00	33.3
Cycle 27 Day 1	11	12.12	16.82	0.0	0.00	33.3	11	-9.09	30.15	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	13.89	17.16	0.0	0.00	33.3	12	-5.56	27.83	-66.7	0.00	33.3
Study Disc 1	144	24.07	27.15	0.0	33.33	100.0	136	-2.21	31.22	-100.0	0.00	66.7
30 D SFU Z/P	77	24.68	25.59	0.0	33.33	100.0	72	-2.31	28.71	-66.7	0.00	66.7
90 D SFU Z/P	89	28.09	28.38	0.0	33.33	100.0	86	1.94	29.53	-100.0	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	29.59	28.64	0.0	33.33	100.0						
Cycle 1 Day 22	212	23.58	25.54	0.0	33.33	100.0	210	-3.81	29.28	-100.0	0.00	66.7
Cycle 2 Day 1	231	21.07	25.61	0.0	0.00	100.0	225	-6.22	29.73	-100.0	0.00	100.0
Cycle 2 Day 22	185	19.46	22.91	0.0	0.00	100.0	181	-8.84	28.68	-100.0	0.00	66.7
Cycle 3 Day 1	204	16.83	23.74	0.0	0.00	100.0	198	-10.27	30.98	-100.0	0.00	66.7
Cycle 3 Day 22	156	18.38	24.04	0.0	0.00	100.0	149	-10.07	31.17	-100.0	0.00	66.7
Cycle 4 Day 1	171	14.42	21.08	0.0	0.00	100.0	163	-11.86	30.47	-100.0	0.00	66.7
Cycle 4 Day 22	133	16.79	21.95	0.0	0.00	100.0	128	-11.46	29.11	-100.0	0.00	100.0
Cycle 5 Day 1	149	17.67	24.06	0.0	0.00	100.0	145	-8.97	34.30	-100.0	0.00	66.7
Cycle 5 Day 22	123	19.24	22.99	0.0	0.00	100.0	116	-7.47	30.16	-100.0	0.00	66.7
Cycle 6 Day 1	127	19.16	25.03	0.0	0.00	100.0	122	-8.47	31.36	-66.7	0.00	66.7
Cycle 6 Day 22	98	17.01	22.06	0.0	0.00	100.0	94	-12.77	30.57	-100.0	0.00	66.7
Cycle 7 Day 1	101	16.50	22.42	0.0	0.00	66.7	98	-11.90	28.82	-100.0	0.00	66.7
Cycle 7 Day 22	76	15.79	22.09	0.0	0.00	100.0	74	-13.96	25.29	-66.7	0.00	33.3
Cycle 8 Day 1	84	17.86	23.40	0.0	0.00	100.0	83	-8.84	29.49	-66.7	0.00	100.0
Cycle 8 Day 22	67	13.93	21.04	0.0	0.00	66.7	65	-14.36	24.98	-66.7	0.00	33.3
Cycle 9 Day 1	64	16.15	21.41	0.0	0.00	100.0	62	-13.98	25.99	-66.7	0.00	33.3
Cycle 9 Day 22	57	16.37	21.93	0.0	0.00	66.7	55	-11.52	30.24	-100.0	0.00	33.3
Cycle 10 Day 1	58	20.69	27.09	0.0	0.00	100.0	56	-8.33	33.78	-66.7	0.00	100.0
Cycle 10 Day 22	44	21.21	26.01	0.0	0.00	100.0	43	-10.85	29.74	-66.7	0.00	33.3
Cycle 11 Day 1	48	17.36	25.72	0.0	0.00	66.7	46	-10.14	26.17	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.15: EORTC QLQ-C30 - Observed Means and Change from Baseline of Insomnia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	16.16	22.24	0.0	0.00	66.7	31	-10.75	29.04	-66.7	0.00	33.3
Cycle 12 Day 1	43	17.05	21.05	0.0	0.00	66.7	41	-12.20	30.51	-66.7	0.00	33.3
Cycle 12 Day 22	27	27.16	22.72	0.0	33.33	66.7	25	-8.00	25.96	-66.7	0.00	33.3
Cycle 13 Day 1	37	20.72	21.30	0.0	33.33	66.7	35	-10.48	22.54	-66.7	0.00	33.3
Cycle 13 Day 22	22	22.73	26.00	0.0	16.67	66.7	21	-11.11	19.25	-33.3	0.00	33.3
Cycle 14 Day 1	31	22.58	24.93	0.0	33.33	66.7	30	-5.56	27.80	-66.7	0.00	66.7
Cycle 14 Day 22	20	20.00	22.69	0.0	16.67	66.7	19	-8.77	26.86	-66.7	0.00	33.3
Cycle 15 Day 1	27	18.52	25.04	0.0	0.00	66.7	27	-6.17	24.52	-33.3	0.00	66.7
Cycle 15 Day 22	17	19.61	26.51	0.0	0.00	66.7	17	-3.92	26.04	-66.7	0.00	33.3
Cycle 16 Day 1	22	19.70	24.47	0.0	0.00	66.7	22	-1.52	24.07	-66.7	0.00	33.3
Cycle 16 Day 22	14	19.05	28.39	0.0	0.00	66.7	14	-7.14	29.75	-66.7	0.00	33.3
Cycle 17 Day 1	18	12.96	23.26	0.0	0.00	66.7	18	-7.41	29.27	-66.7	0.00	33.3
Cycle 18 Day 1	16	18.75	29.74	0.0	0.00	100.0	16	0.00	21.08	-33.3	0.00	33.3
Cycle 18 Day 22	11	21.21	26.97	0.0	0.00	66.7	10	6.67	21.08	-33.3	0.00	33.3
Cycle 19 Day 1	16	14.58	24.25	0.0	0.00	66.7	15	-2.22	29.46	-66.7	0.00	66.7
Cycle 19 Day 22	12	27.78	27.83	0.0	33.33	66.7	11	12.12	22.47	0.0	0.00	66.7
Cycle 20 Day 1	16	12.50	20.64	0.0	0.00	66.7	15	-4.44	21.33	-66.7	0.00	33.3
Cycle 20 Day 22	11	21.21	22.47	0.0	33.33	66.7	10	10.00	27.44	-33.3	16.67	33.3
Cycle 21 Day 1	15	17.78	24.77	0.0	0.00	66.7	14	2.38	27.62	-66.7	0.00	66.7
Cycle 22 Day 1	12	16.67	22.47	0.0	0.00	66.7	12	2.78	22.29	-33.3	0.00	33.3
Cycle 23 Day 1	13	15.38	25.88	0.0	0.00	66.7	13	-2.56	25.32	-66.7	0.00	33.3
Study Disc 1	153	26.36	26.67	0.0	33.33	100.0	149	-4.25	32.02	-100.0	0.00	100.0
Study Disc 2	12	41.67	40.51	0.0	33.33	100.0	12	-5.56	48.89	-100.0	0.00	66.7
30 D SFU Z/P	93	28.32	28.63	0.0	33.33	100.0	91	-2.93	33.94	-100.0	0.00	66.7
90 D SFU Z/P	84	28.97	33.45	0.0	33.33	100.0	83	-3.21	39.51	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	32.81	32.14	0.0	33.33	100.0						
Cycle 1 Day 22	187	39.22	29.45	0.0	33.33	100.0	177	9.04	33.05	-66.7	0.00	100.0
Cycle 2 Day 1	217	27.19	28.20	0.0	33.33	100.0	207	-4.99	36.01	-100.0	0.00	100.0
Cycle 2 Day 22	157	31.00	27.76	0.0	33.33	100.0	150	-1.33	34.08	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.33	26.46	0.0	33.33	100.0	190	-8.07	34.53	-100.0	0.00	100.0
Cycle 3 Day 22	161	34.78	30.36	0.0	33.33	100.0	152	2.19	35.71	-100.0	0.00	100.0
Cycle 4 Day 1	178	26.78	30.70	0.0	33.33	100.0	170	-6.08	38.49	-100.0	0.00	100.0
Cycle 4 Day 22	128	32.81	28.98	0.0	33.33	100.0	123	1.90	38.01	-100.0	0.00	100.0
Cycle 5 Day 1	157	27.39	29.11	0.0	33.33	100.0	149	-4.03	35.92	-100.0	0.00	100.0
Cycle 5 Day 22	118	26.55	30.68	0.0	33.33	100.0	111	-0.30	37.20	-66.7	0.00	100.0
Cycle 6 Day 1	132	21.97	27.88	0.0	0.00	100.0	123	-6.50	37.37	-100.0	0.00	100.0
Cycle 6 Day 22	108	24.38	29.04	0.0	16.67	100.0	103	-6.15	39.81	-100.0	0.00	100.0
Cycle 7 Day 1	120	19.44	26.14	0.0	0.00	100.0	114	-9.65	36.76	-100.0	0.00	100.0
Cycle 7 Day 22	87	21.84	25.83	0.0	33.33	100.0	81	-4.94	39.48	-100.0	0.00	100.0
Cycle 8 Day 1	88	20.45	28.33	0.0	0.00	100.0	80	-8.75	35.48	-100.0	0.00	100.0
Cycle 8 Day 22	78	22.65	27.12	0.0	16.67	100.0	72	-8.80	38.76	-100.0	0.00	100.0
Cycle 9 Day 1	83	16.87	24.62	0.0	0.00	100.0	75	-15.56	34.37	-100.0	0.00	100.0
Cycle 9 Day 22	65	18.46	27.66	0.0	0.00	100.0	60	-13.33	41.26	-100.0	0.00	66.7
Cycle 10 Day 1	72	18.52	27.91	0.0	0.00	100.0	66	-10.10	38.33	-100.0	0.00	100.0
Cycle 10 Day 22	61	22.40	25.62	0.0	33.33	100.0	57	-5.85	37.86	-100.0	0.00	100.0
Cycle 11 Day 1	68	13.73	22.48	0.0	0.00	100.0	63	-15.34	36.82	-100.0	0.00	100.0
Cycle 11 Day 22	48	15.28	22.76	0.0	0.00	100.0	44	-12.12	33.79	-100.0	0.00	66.7
Cycle 12 Day 1	58	20.11	26.45	0.0	0.00	100.0	53	-10.69	33.83	-100.0	0.00	100.0
Cycle 12 Day 22	41	23.58	23.86	0.0	33.33	100.0	38	1.75	31.90	-66.7	0.00	100.0
Cycle 13 Day 1	51	16.34	24.38	0.0	0.00	100.0	48	-9.72	33.66	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	18.18	26.37	0.0	0.00	100.0	41	-5.69	39.37	-100.0	0.00	100.0
Cycle 14 Day 1	41	21.14	26.62	0.0	0.00	100.0	39	-10.26	35.17	-100.0	0.00	100.0
Cycle 14 Day 22	33	22.22	28.46	0.0	0.00	100.0	32	-6.25	39.20	-100.0	0.00	100.0
Cycle 15 Day 1	36	22.22	28.73	0.0	0.00	100.0	35	-6.67	39.44	-100.0	0.00	100.0
Cycle 15 Day 22	30	21.11	29.66	0.0	0.00	100.0	30	-5.56	42.96	-100.0	0.00	100.0
Cycle 16 Day 1	35	14.29	16.74	0.0	0.00	33.3	35	-14.29	27.16	-100.0	0.00	33.3
Cycle 16 Day 22	29	22.99	30.99	0.0	0.00	100.0	29	-6.90	39.22	-100.0	0.00	66.7
Cycle 17 Day 1	30	16.67	24.37	0.0	0.00	100.0	30	-12.22	33.31	-100.0	0.00	66.7
Cycle 17 Day 22	23	23.19	30.87	0.0	0.00	100.0	23	-4.35	32.26	-66.7	0.00	66.7
Cycle 18 Day 1	27	13.58	21.20	0.0	0.00	66.7	27	-14.81	31.12	-66.7	0.00	66.7
Cycle 18 Day 22	21	14.29	19.92	0.0	0.00	66.7	21	-7.94	27.70	-66.7	0.00	33.3
Cycle 19 Day 1	23	14.49	22.08	0.0	0.00	66.7	23	-11.59	23.80	-66.7	0.00	33.3
Cycle 19 Day 22	20	11.67	19.57	0.0	0.00	66.7	20	-8.33	23.88	-66.7	0.00	33.3
Cycle 20 Day 1	23	11.59	21.58	0.0	0.00	66.7	23	-10.14	27.40	-66.7	0.00	66.7
Cycle 20 Day 22	18	22.22	32.34	0.0	0.00	100.0	18	1.85	33.28	-66.7	0.00	66.7
Cycle 21 Day 1	20	15.00	27.52	0.0	0.00	100.0	20	-6.67	23.20	-66.7	0.00	33.3
Cycle 21 Day 22	14	11.90	28.06	0.0	0.00	100.0	14	-7.14	23.31	-66.7	0.00	33.3
Cycle 22 Day 1	15	11.11	16.27	0.0	0.00	33.3	15	-13.33	21.08	-66.7	0.00	0.0
Cycle 22 Day 22	11	18.18	31.14	0.0	0.00	100.0	11	-6.06	32.72	-66.7	0.00	66.7
Cycle 23 Day 1	16	16.67	17.21	0.0	16.67	33.3	16	-6.25	25.00	-66.7	0.00	33.3
Cycle 23 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	-9.09	26.21	-66.7	0.00	33.3
Cycle 24 Day 1	14	14.29	21.54	0.0	0.00	66.7	14	-11.90	24.83	-66.7	0.00	33.3
Cycle 25 Day 1	12	19.44	22.29	0.0	16.67	66.7	12	-2.78	33.21	-66.7	0.00	66.7
Cycle 25 Day 22	11	18.18	17.41	0.0	33.33	33.3	11	-3.03	27.71	-66.7	0.00	33.3
Cycle 26 Day 1	13	15.38	17.30	0.0	0.00	33.3	13	-10.26	28.50	-66.7	0.00	33.3
Cycle 27 Day 1	11	18.18	22.92	0.0	0.00	66.7	11	-3.03	17.98	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	19.44	22.29	0.0	16.67	66.7	12	0.00	28.43	-33.3	0.00	66.7
Study Disc 1	144	38.43	33.98	0.0	33.33	100.0	136	3.92	37.86	-100.0	0.00	100.0
30 D SFU Z/P	77	37.23	34.19	0.0	33.33	100.0	72	2.31	31.81	-66.7	0.00	66.7
90 D SFU Z/P	89	28.46	30.38	0.0	33.33	100.0	86	-5.04	35.62	-100.0	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	32.17	31.44	0.0	33.33	100.0						
Cycle 1 Day 22	212	33.96	31.79	0.0	33.33	100.0	210	4.13	33.00	-100.0	0.00	100.0
Cycle 2 Day 1	231	22.22	27.39	0.0	0.00	100.0	225	-8.00	31.74	-100.0	0.00	100.0
Cycle 2 Day 22	185	30.27	29.64	0.0	33.33	100.0	181	0.18	35.57	-100.0	0.00	100.0
Cycle 3 Day 1	204	21.41	25.29	0.0	16.67	100.0	198	-8.75	31.18	-100.0	0.00	100.0
Cycle 3 Day 22	156	26.71	26.07	0.0	33.33	100.0	149	-2.68	30.39	-100.0	0.00	66.7
Cycle 4 Day 1	171	20.47	24.59	0.0	0.00	100.0	163	-7.36	34.35	-100.0	0.00	66.7
Cycle 4 Day 22	133	24.31	25.99	0.0	33.33	100.0	128	-4.95	31.05	-100.0	0.00	66.7
Cycle 5 Day 1	149	20.13	24.14	0.0	0.00	100.0	145	-8.28	30.31	-100.0	0.00	33.3
Cycle 5 Day 22	123	20.60	23.58	0.0	33.33	100.0	116	-6.03	30.33	-100.0	0.00	66.7
Cycle 6 Day 1	127	21.26	25.78	0.0	0.00	100.0	122	-5.19	31.50	-100.0	0.00	66.7
Cycle 6 Day 22	98	18.37	22.51	0.0	0.00	100.0	94	-8.51	30.50	-66.7	0.00	66.7
Cycle 7 Day 1	101	13.86	20.15	0.0	0.00	100.0	98	-10.20	28.48	-100.0	0.00	33.3
Cycle 7 Day 22	76	14.91	23.97	0.0	0.00	100.0	74	-11.26	31.35	-66.7	0.00	66.7
Cycle 8 Day 1	84	13.10	20.71	0.0	0.00	100.0	83	-8.43	28.91	-66.7	0.00	100.0
Cycle 8 Day 22	67	18.41	21.15	0.0	0.00	66.7	65	-4.10	28.57	-66.7	0.00	66.7
Cycle 9 Day 1	64	15.62	22.98	0.0	0.00	100.0	62	-5.91	32.24	-66.7	0.00	100.0
Cycle 9 Day 22	57	18.13	21.89	0.0	0.00	100.0	55	-1.82	27.53	-66.7	0.00	100.0
Cycle 10 Day 1	58	14.37	19.86	0.0	0.00	66.7	56	-5.36	27.54	-66.7	0.00	66.7
Cycle 10 Day 22	44	20.45	24.08	0.0	0.00	66.7	43	0.78	33.72	-66.7	0.00	66.7
Cycle 11 Day 1	48	15.97	22.79	0.0	0.00	66.7	46	-2.17	28.46	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.16: EORTC QLQ-C30 - Observed Means and Change from Baseline of Appetite Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	14.14	22.10	0.0	0.00	66.7	31	-6.45	31.53	-66.7	0.00	33.3
Cycle 12 Day 1	43	13.18	21.99	0.0	0.00	66.7	41	-5.69	28.77	-66.7	0.00	66.7
Cycle 12 Day 22	27	17.28	21.42	0.0	0.00	66.7	25	-5.33	28.35	-66.7	0.00	33.3
Cycle 13 Day 1	37	14.41	24.27	0.0	0.00	100.0	35	-4.76	30.40	-66.7	0.00	66.7
Cycle 13 Day 22	22	28.79	23.67	0.0	33.33	66.7	21	7.94	29.64	-33.3	0.00	66.7
Cycle 14 Day 1	31	20.43	22.24	0.0	33.33	66.7	30	0.00	27.68	-33.3	0.00	66.7
Cycle 14 Day 22	20	18.33	25.31	0.0	0.00	66.7	19	-7.02	21.02	-33.3	0.00	33.3
Cycle 15 Day 1	27	11.11	18.49	0.0	0.00	66.7	27	-6.17	27.79	-66.7	0.00	66.7
Cycle 15 Day 22	17	9.80	15.66	0.0	0.00	33.3	17	-7.84	25.08	-66.7	0.00	33.3
Cycle 16 Day 1	22	7.58	14.30	0.0	0.00	33.3	22	-7.58	22.84	-66.7	0.00	33.3
Cycle 16 Day 22	14	11.90	24.83	0.0	0.00	66.7	14	-7.14	23.31	-66.7	0.00	33.3
Cycle 17 Day 1	18	9.26	19.15	0.0	0.00	66.7	18	-5.56	23.57	-66.7	0.00	33.3
Cycle 18 Day 1	16	10.42	20.07	0.0	0.00	66.7	16	-4.17	29.50	-66.7	0.00	66.7
Cycle 18 Day 22	11	9.09	15.57	0.0	0.00	33.3	10	-10.00	27.44	-66.7	0.00	33.3
Cycle 19 Day 1	16	12.50	20.64	0.0	0.00	66.7	15	-2.22	29.46	-66.7	0.00	66.7
Cycle 19 Day 22	12	11.11	16.41	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Cycle 20 Day 1	16	6.25	13.44	0.0	0.00	33.3	15	-8.89	23.46	-66.7	0.00	33.3
Cycle 20 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	27.44	-66.7	0.00	33.3
Cycle 21 Day 1	15	8.89	15.26	0.0	0.00	33.3	14	-7.14	19.30	-66.7	0.00	0.0
Cycle 22 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-11.11	25.95	-66.7	0.00	33.3
Cycle 23 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	-7.69	27.74	-66.7	0.00	33.3
Study Disc 1	153	30.72	34.10	0.0	33.33	100.0	149	0.22	36.86	-100.0	0.00	100.0
Study Disc 2	12	27.78	34.33	0.0	16.67	100.0	12	-8.33	45.23	-66.7	0.00	66.7
30 D SFU Z/P	93	30.82	30.79	0.0	33.33	100.0	91	3.30	32.60	-100.0	0.00	66.7
90 D SFU Z/P	84	35.32	31.62	0.0	33.33	100.0	83	7.63	39.07	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	19.33	28.15	0.0	0.00	100.0						
Cycle 1 Day 22	187	25.13	28.99	0.0	33.33	100.0	177	8.66	32.96	-100.0	0.00	100.0
Cycle 2 Day 1	217	19.51	26.71	0.0	0.00	100.0	207	-0.48	33.25	-100.0	0.00	100.0
Cycle 2 Day 22	157	15.71	23.44	0.0	0.00	100.0	150	-2.89	31.12	-100.0	0.00	66.7
Cycle 3 Day 1	200	14.33	22.79	0.0	0.00	100.0	190	-5.09	31.29	-100.0	0.00	100.0
Cycle 3 Day 22	161	18.01	24.72	0.0	0.00	100.0	152	-2.85	28.18	-100.0	0.00	66.7
Cycle 4 Day 1	178	16.29	25.85	0.0	0.00	100.0	170	-2.75	32.11	-100.0	0.00	100.0
Cycle 4 Day 22	128	16.41	24.39	0.0	0.00	100.0	123	1.08	31.92	-100.0	0.00	100.0
Cycle 5 Day 1	157	16.14	24.64	0.0	0.00	100.0	149	-2.24	31.16	-100.0	0.00	66.7
Cycle 5 Day 22	118	21.19	29.45	0.0	0.00	100.0	111	2.70	31.83	-100.0	0.00	100.0
Cycle 6 Day 1	132	17.68	27.15	0.0	0.00	100.0	123	-2.44	28.04	-66.7	0.00	100.0
Cycle 6 Day 22	108	16.36	25.17	0.0	0.00	100.0	103	-3.24	27.82	-66.7	0.00	100.0
Cycle 7 Day 1	120	16.67	25.93	0.0	0.00	100.0	114	-2.63	29.80	-66.7	0.00	100.0
Cycle 7 Day 22	87	13.79	21.89	0.0	0.00	100.0	81	-2.47	25.70	-100.0	0.00	66.7
Cycle 8 Day 1	88	14.02	22.44	0.0	0.00	100.0	80	-4.17	27.75	-66.7	0.00	66.7
Cycle 8 Day 22	78	14.10	21.16	0.0	0.00	100.0	72	-6.94	29.04	-100.0	0.00	66.7
Cycle 9 Day 1	83	12.85	20.71	0.0	0.00	100.0	75	-8.44	26.90	-66.7	0.00	33.3
Cycle 9 Day 22	65	15.38	22.88	0.0	0.00	100.0	60	-3.33	32.88	-100.0	0.00	100.0
Cycle 10 Day 1	72	14.81	23.66	0.0	0.00	100.0	66	-2.02	29.74	-66.7	0.00	100.0
Cycle 10 Day 22	61	14.75	21.54	0.0	0.00	100.0	57	-1.17	22.68	-66.7	0.00	33.3
Cycle 11 Day 1	68	11.27	18.76	0.0	0.00	66.7	63	-4.23	24.31	-66.7	0.00	66.7
Cycle 11 Day 22	48	9.72	16.78	0.0	0.00	66.7	44	-4.55	26.50	-66.7	0.00	66.7
Cycle 12 Day 1	58	13.79	23.39	0.0	0.00	100.0	53	-6.29	22.70	-66.7	0.00	33.3
Cycle 12 Day 22	41	17.89	21.21	0.0	0.00	66.7	38	1.75	29.96	-66.7	0.00	66.7
Cycle 13 Day 1	51	13.73	22.29	0.0	0.00	66.7	48	-3.47	26.84	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	13.64	19.45	0.0	0.00	66.7	41	-3.25	28.68	-66.7	0.00	66.7
Cycle 14 Day 1	41	9.76	17.07	0.0	0.00	66.7	39	-8.55	25.04	-66.7	0.00	33.3
Cycle 14 Day 22	33	12.12	21.76	0.0	0.00	66.7	32	-3.12	30.95	-66.7	0.00	66.7
Cycle 15 Day 1	36	11.11	17.82	0.0	0.00	66.7	35	-8.57	30.62	-100.0	0.00	33.3
Cycle 15 Day 22	30	8.89	14.99	0.0	0.00	33.3	30	-6.67	25.37	-66.7	0.00	33.3
Cycle 16 Day 1	35	10.48	17.66	0.0	0.00	66.7	35	-5.71	24.90	-66.7	0.00	33.3
Cycle 16 Day 22	29	12.64	20.73	0.0	0.00	66.7	29	-3.45	27.23	-66.7	0.00	33.3
Cycle 17 Day 1	30	12.22	18.54	0.0	0.00	66.7	30	-5.56	27.80	-66.7	0.00	33.3
Cycle 17 Day 22	23	11.59	19.09	0.0	0.00	66.7	23	-7.25	26.51	-66.7	0.00	33.3
Cycle 18 Day 1	27	8.64	14.89	0.0	0.00	33.3	27	-8.64	23.74	-66.7	0.00	33.3
Cycle 18 Day 22	21	11.11	16.10	0.0	0.00	33.3	21	-1.59	24.67	-66.7	0.00	33.3
Cycle 19 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	-2.90	28.27	-66.7	0.00	33.3
Cycle 19 Day 22	20	6.67	13.68	0.0	0.00	33.3	20	-5.00	22.36	-66.7	0.00	33.3
Cycle 20 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	-2.90	24.44	-66.7	0.00	33.3
Cycle 20 Day 22	18	5.56	12.78	0.0	0.00	33.3	18	-7.41	26.95	-66.7	0.00	33.3
Cycle 21 Day 1	20	10.00	15.67	0.0	0.00	33.3	20	-3.33	26.27	-66.7	0.00	33.3
Cycle 21 Day 22	14	11.90	16.57	0.0	0.00	33.3	14	0.00	29.24	-66.7	0.00	33.3
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	-6.67	25.82	-66.7	0.00	33.3
Cycle 22 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-6.06	29.13	-66.7	0.00	33.3
Cycle 23 Day 1	16	8.33	14.91	0.0	0.00	33.3	16	-4.17	26.87	-66.7	0.00	33.3
Cycle 23 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 24 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-9.52	27.51	-66.7	0.00	33.3
Cycle 25 Day 1	12	16.67	17.41	0.0	16.67	33.3	12	2.78	30.01	-66.7	0.00	33.3
Cycle 25 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	-3.03	31.46	-66.7	0.00	33.3
Cycle 26 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	-5.13	32.90	-66.7	0.00	33.3
Cycle 27 Day 1	11	12.12	16.82	0.0	0.00	33.3	11	0.00	33.33	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-5.56	31.25	-66.7	0.00	33.3
Study Disc 1	144	22.92	28.28	0.0	0.00	100.0	136	1.23	36.61	-100.0	0.00	100.0
30 D SFU Z/P	77	22.51	28.33	0.0	0.00	100.0	72	0.00	32.14	-100.0	0.00	66.7
90 D SFU Z/P	89	15.73	23.62	0.0	0.00	100.0	86	-5.43	33.86	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	19.64	28.39	0.0	0.00	100.0						
Cycle 1 Day 22	212	23.27	28.91	0.0	0.00	100.0	210	4.44	29.91	-66.7	0.00	100.0
Cycle 2 Day 1	231	17.32	25.97	0.0	0.00	100.0	225	-2.37	32.80	-100.0	0.00	100.0
Cycle 2 Day 22	185	20.18	25.80	0.0	0.00	100.0	181	0.37	31.23	-66.7	0.00	100.0
Cycle 3 Day 1	204	15.85	23.03	0.0	0.00	100.0	198	-2.53	30.40	-100.0	0.00	100.0
Cycle 3 Day 22	156	19.02	24.28	0.0	0.00	100.0	149	-0.89	31.70	-100.0	0.00	100.0
Cycle 4 Day 1	171	15.79	22.09	0.0	0.00	66.7	163	-1.02	28.79	-100.0	0.00	66.7
Cycle 4 Day 22	133	18.80	22.97	0.0	0.00	100.0	128	2.08	28.91	-100.0	0.00	100.0
Cycle 5 Day 1	149	17.23	23.44	0.0	0.00	100.0	145	-1.15	30.79	-100.0	0.00	100.0
Cycle 5 Day 22	123	15.99	21.91	0.0	0.00	100.0	116	-1.44	26.88	-66.7	0.00	33.3
Cycle 6 Day 1	127	16.01	24.79	0.0	0.00	100.0	122	0.55	28.42	-100.0	0.00	66.7
Cycle 6 Day 22	98	14.97	21.47	0.0	0.00	66.7	94	-1.77	30.67	-100.0	0.00	66.7
Cycle 7 Day 1	101	13.53	22.20	0.0	0.00	100.0	98	-1.36	29.08	-66.7	0.00	100.0
Cycle 7 Day 22	76	12.28	19.51	0.0	0.00	66.7	74	-4.05	32.62	-100.0	0.00	66.7
Cycle 8 Day 1	84	13.89	23.26	0.0	0.00	100.0	83	-0.40	29.67	-66.7	0.00	100.0
Cycle 8 Day 22	67	11.44	18.85	0.0	0.00	66.7	65	-2.56	25.21	-100.0	0.00	33.3
Cycle 9 Day 1	64	14.06	23.61	0.0	0.00	100.0	62	0.00	28.95	-66.7	0.00	100.0
Cycle 9 Day 22	57	16.37	26.07	0.0	0.00	100.0	55	2.42	33.24	-66.7	0.00	100.0
Cycle 10 Day 1	58	14.94	25.87	0.0	0.00	100.0	56	4.17	30.53	-66.7	0.00	100.0
Cycle 10 Day 22	44	18.18	27.33	0.0	0.00	100.0	43	7.75	31.57	-66.7	0.00	100.0
Cycle 11 Day 1	48	15.97	27.50	0.0	0.00	100.0	46	7.25	31.36	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.17: EORTC QLQ-C30 - Observed Means and Change from Baseline of Constipation - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	17.17	25.17	0.0	0.00	100.0	31	6.45	24.97	-33.3	0.00	66.7
Cycle 12 Day 1	43	19.38	27.44	0.0	0.00	100.0	41	10.57	32.86	-66.7	0.00	100.0
Cycle 12 Day 22	27	28.40	31.63	0.0	33.33	100.0	25	18.67	34.80	-33.3	0.00	100.0
Cycle 13 Day 1	37	19.82	29.88	0.0	0.00	100.0	35	10.48	35.95	-66.7	0.00	100.0
Cycle 13 Day 22	22	24.24	31.17	0.0	0.00	100.0	21	11.11	39.91	-66.7	0.00	100.0
Cycle 14 Day 1	31	21.51	31.68	0.0	0.00	100.0	30	11.11	36.44	-33.3	0.00	100.0
Cycle 14 Day 22	20	20.00	25.13	0.0	0.00	66.7	19	3.51	33.14	-66.7	0.00	66.7
Cycle 15 Day 1	27	17.28	25.10	0.0	0.00	66.7	27	6.17	32.08	-66.7	0.00	66.7
Cycle 15 Day 22	17	19.61	23.74	0.0	0.00	66.7	17	3.92	35.12	-66.7	0.00	66.7
Cycle 16 Day 1	22	19.70	33.58	0.0	0.00	100.0	22	7.58	36.99	-66.7	0.00	100.0
Cycle 16 Day 22	14	28.57	38.91	0.0	0.00	100.0	14	14.29	40.75	-33.3	0.00	100.0
Cycle 17 Day 1	18	12.96	20.26	0.0	0.00	66.7	18	1.85	29.09	-66.7	0.00	66.7
Cycle 18 Day 1	16	16.67	29.81	0.0	0.00	100.0	16	10.42	33.82	-33.3	0.00	100.0
Cycle 18 Day 22	11	15.15	27.34	0.0	0.00	66.7	10	6.67	37.84	-33.3	0.00	66.7
Cycle 19 Day 1	16	20.83	31.91	0.0	0.00	100.0	15	15.56	37.52	-33.3	0.00	100.0
Cycle 19 Day 22	12	25.00	32.18	0.0	16.67	100.0	11	18.18	37.61	-33.3	0.00	100.0
Cycle 20 Day 1	16	16.67	29.81	0.0	0.00	100.0	15	11.11	34.88	-33.3	0.00	100.0
Cycle 20 Day 22	11	12.12	22.47	0.0	0.00	66.7	10	3.33	29.19	-33.3	0.00	66.7
Cycle 21 Day 1	15	22.22	29.99	0.0	0.00	100.0	14	14.29	33.88	-33.3	0.00	100.0
Cycle 22 Day 1	12	11.11	21.71	0.0	0.00	66.7	12	2.78	30.01	-33.3	0.00	66.7
Cycle 23 Day 1	13	25.64	30.89	0.0	33.33	100.0	13	17.95	35.00	-33.3	0.00	100.0
Study Disc 1	153	18.30	24.16	0.0	0.00	100.0	149	0.00	31.00	-100.0	0.00	100.0
Study Disc 2	12	22.22	32.82	0.0	0.00	100.0	12	-5.56	34.33	-66.7	0.00	66.7
30 D SFU Z/P	93	22.22	27.51	0.0	0.00	100.0	91	2.56	34.15	-66.7	0.00	100.0
90 D SFU Z/P	84	18.65	28.03	0.0	0.00	100.0	83	1.20	30.11	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.91	17.25	0.0	0.00	100.0						
Cycle 1 Day 22	187	12.83	21.06	0.0	0.00	100.0	177	4.90	23.05	-100.0	0.00	100.0
Cycle 2 Day 1	217	13.67	22.74	0.0	0.00	100.0	207	6.28	26.03	-66.7	0.00	100.0
Cycle 2 Day 22	157	11.04	19.39	0.0	0.00	100.0	150	4.67	24.74	-100.0	0.00	100.0
Cycle 3 Day 1	200	9.83	16.30	0.0	0.00	66.7	190	2.11	22.39	-100.0	0.00	66.7
Cycle 3 Day 22	161	10.56	18.04	0.0	0.00	66.7	152	2.19	24.16	-66.7	0.00	66.7
Cycle 4 Day 1	178	8.99	15.66	0.0	0.00	66.7	170	-0.20	22.20	-100.0	0.00	66.7
Cycle 4 Day 22	128	10.42	17.62	0.0	0.00	66.7	123	1.90	23.49	-66.7	0.00	66.7
Cycle 5 Day 1	157	11.89	20.33	0.0	0.00	100.0	149	3.58	24.55	-66.7	0.00	66.7
Cycle 5 Day 22	118	8.19	15.68	0.0	0.00	66.7	111	0.30	20.84	-66.7	0.00	66.7
Cycle 6 Day 1	132	7.07	15.43	0.0	0.00	66.7	123	-2.17	22.48	-100.0	0.00	66.7
Cycle 6 Day 22	108	5.25	12.20	0.0	0.00	33.3	103	-3.24	17.16	-66.7	0.00	33.3
Cycle 7 Day 1	120	6.11	13.65	0.0	0.00	66.7	114	-3.51	20.50	-100.0	0.00	33.3
Cycle 7 Day 22	87	9.58	17.54	0.0	0.00	100.0	81	0.41	22.04	-66.7	0.00	100.0
Cycle 8 Day 1	88	8.33	15.37	0.0	0.00	66.7	80	-2.08	20.78	-100.0	0.00	33.3
Cycle 8 Day 22	78	5.56	12.50	0.0	0.00	33.3	72	-5.09	22.14	-66.7	0.00	33.3
Cycle 9 Day 1	83	8.84	15.69	0.0	0.00	66.7	75	-2.22	26.47	-100.0	0.00	66.7
Cycle 9 Day 22	65	6.15	14.30	0.0	0.00	66.7	60	-5.00	20.19	-66.7	0.00	33.3
Cycle 10 Day 1	72	6.94	14.74	0.0	0.00	66.7	66	-5.05	24.97	-100.0	0.00	33.3
Cycle 10 Day 22	61	7.65	15.39	0.0	0.00	66.7	57	-2.92	24.62	-66.7	0.00	66.7
Cycle 11 Day 1	68	7.84	16.41	0.0	0.00	66.7	63	-4.76	26.00	-100.0	0.00	66.7
Cycle 11 Day 22	48	5.56	14.31	0.0	0.00	66.7	44	-4.55	18.46	-66.7	0.00	33.3
Cycle 12 Day 1	58	10.34	16.76	0.0	0.00	66.7	53	0.00	23.57	-66.7	0.00	66.7
Cycle 12 Day 22	41	8.94	14.95	0.0	0.00	33.3	38	-1.75	20.43	-66.7	0.00	33.3
Cycle 13 Day 1	51	7.84	19.54	0.0	0.00	100.0	48	-3.47	30.93	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	6.82	13.60	0.0	0.00	33.3	41	-4.07	23.80	-66.7	0.00	33.3
Cycle 14 Day 1	41	10.57	15.70	0.0	0.00	33.3	39	-1.71	22.88	-66.7	0.00	33.3
Cycle 14 Day 22	33	6.06	13.06	0.0	0.00	33.3	32	-3.13	21.35	-66.7	0.00	33.3
Cycle 15 Day 1	36	7.41	14.05	0.0	0.00	33.3	35	-4.76	23.07	-66.7	0.00	33.3
Cycle 15 Day 22	30	6.67	13.56	0.0	0.00	33.3	30	-3.33	20.25	-66.7	0.00	33.3
Cycle 16 Day 1	35	5.71	12.75	0.0	0.00	33.3	35	-6.67	27.77	-100.0	0.00	33.3
Cycle 16 Day 22	29	8.05	21.19	0.0	0.00	100.0	29	0.00	25.20	-33.3	0.00	100.0
Cycle 17 Day 1	30	6.67	16.14	0.0	0.00	66.7	30	-6.67	26.84	-66.7	0.00	33.3
Cycle 17 Day 22	23	7.25	14.06	0.0	0.00	33.3	23	-1.45	23.52	-66.7	0.00	33.3
Cycle 18 Day 1	27	7.41	14.12	0.0	0.00	33.3	27	-4.94	23.94	-66.7	0.00	33.3
Cycle 18 Day 22	21	12.70	26.82	0.0	0.00	100.0	21	4.76	33.81	-66.7	0.00	100.0
Cycle 19 Day 1	23	10.14	23.43	0.0	0.00	100.0	23	-1.45	32.53	-66.7	0.00	100.0
Cycle 19 Day 22	20	5.00	12.21	0.0	0.00	33.3	20	-3.33	21.36	-66.7	0.00	33.3
Cycle 20 Day 1	23	7.25	14.06	0.0	0.00	33.3	23	-4.35	25.23	-66.7	0.00	33.3
Cycle 20 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	-5.56	20.61	-66.7	0.00	33.3
Cycle 21 Day 1	20	6.67	13.68	0.0	0.00	33.3	20	-5.00	24.84	-66.7	0.00	33.3
Cycle 21 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	22.10	-66.7	0.00	33.3
Cycle 22 Day 1	15	6.67	18.69	0.0	0.00	66.7	15	-8.89	23.46	-66.7	0.00	33.3
Cycle 22 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-12.12	22.47	-66.7	0.00	0.0
Cycle 23 Day 1	16	8.33	19.25	0.0	0.00	66.7	16	-8.33	22.77	-66.7	0.00	33.3
Cycle 23 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Cycle 24 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-11.90	24.83	-66.7	0.00	0.0
Cycle 25 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-16.67	26.59	-66.7	0.00	0.0
Cycle 25 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-12.12	22.47	-66.7	0.00	0.0
Cycle 26 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-15.38	25.88	-66.7	0.00	0.0
Cycle 27 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	-9.09	21.56	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-11.11	21.71	-66.7	0.00	0.0
Study Disc 1	144	11.57	21.71	0.0	0.00	100.0	136	2.94	25.81	-66.7	0.00	100.0
30 D SFU Z/P	77	12.12	19.43	0.0	0.00	66.7	72	3.24	24.49	-66.7	0.00	66.7
90 D SFU Z/P	89	12.73	21.03	0.0	0.00	100.0	86	3.88	26.77	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	10.59	19.94	0.0	0.00	100.0						
Cycle 1 Day 22	212	13.21	21.12	0.0	0.00	100.0	210	2.86	24.01	-66.7	0.00	100.0
Cycle 2 Day 1	231	12.99	21.64	0.0	0.00	100.0	225	2.96	22.52	-66.7	0.00	100.0
Cycle 2 Day 22	185	12.25	20.71	0.0	0.00	100.0	181	0.92	22.06	-66.7	0.00	66.7
Cycle 3 Day 1	204	12.42	21.91	0.0	0.00	100.0	198	1.18	24.99	-100.0	0.00	100.0
Cycle 3 Day 22	156	11.97	21.06	0.0	0.00	100.0	149	1.57	24.91	-66.7	0.00	66.7
Cycle 4 Day 1	171	11.50	21.49	0.0	0.00	100.0	163	1.02	24.12	-66.7	0.00	66.7
Cycle 4 Day 22	133	10.53	21.07	0.0	0.00	100.0	128	-0.78	24.91	-66.7	0.00	66.7
Cycle 5 Day 1	149	9.62	16.57	0.0	0.00	66.7	145	-0.92	25.44	-100.0	0.00	66.7
Cycle 5 Day 22	123	6.23	13.73	0.0	0.00	66.7	116	-4.31	22.64	-100.0	0.00	66.7
Cycle 6 Day 1	127	8.92	16.51	0.0	0.00	66.7	122	-1.37	24.01	-100.0	0.00	66.7
Cycle 6 Day 22	98	8.50	15.37	0.0	0.00	66.7	94	-1.77	23.63	-100.0	0.00	66.7
Cycle 7 Day 1	101	9.57	17.85	0.0	0.00	66.7	98	-2.04	24.32	-100.0	0.00	66.7
Cycle 7 Day 22	76	6.14	14.10	0.0	0.00	66.7	74	-7.66	23.11	-100.0	0.00	33.3
Cycle 8 Day 1	84	8.73	14.74	0.0	0.00	33.3	83	-2.81	22.81	-100.0	0.00	33.3
Cycle 8 Day 22	67	10.45	17.61	0.0	0.00	66.7	65	-2.05	22.73	-66.7	0.00	66.7
Cycle 9 Day 1	64	9.37	16.23	0.0	0.00	66.7	62	-2.69	18.40	-66.7	0.00	33.3
Cycle 9 Day 22	57	9.36	20.66	0.0	0.00	100.0	55	-3.03	22.47	-66.7	0.00	66.7
Cycle 10 Day 1	58	9.20	17.43	0.0	0.00	66.7	56	-1.79	19.51	-66.7	0.00	66.7
Cycle 10 Day 22	44	10.61	22.47	0.0	0.00	100.0	43	-1.55	21.77	-33.3	0.00	66.7
Cycle 11 Day 1	48	10.42	21.91	0.0	0.00	100.0	46	0.72	22.76	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	9.09	20.87	0.0	0.00	100.0	31	-2.15	24.24	-66.7	0.00	66.7
Cycle 12 Day 1	43	7.75	17.57	0.0	0.00	66.7	41	-3.25	19.44	-66.7	0.00	33.3
Cycle 12 Day 22	27	11.11	20.67	0.0	0.00	66.7	25	-4.00	20.00	-66.7	0.00	33.3
Cycle 13 Day 1	37	14.41	22.96	0.0	0.00	100.0	35	2.86	27.26	-66.7	0.00	66.7
Cycle 13 Day 22	22	13.64	22.20	0.0	0.00	66.7	21	4.76	19.11	-33.3	0.00	33.3
Cycle 14 Day 1	31	15.05	27.00	0.0	0.00	100.0	30	4.44	29.99	-66.7	0.00	100.0
Cycle 14 Day 22	20	11.67	19.57	0.0	0.00	66.7	19	1.75	26.00	-66.7	0.00	33.3
Cycle 15 Day 1	27	6.17	16.11	0.0	0.00	66.7	27	-3.70	21.35	-66.7	0.00	33.3
Cycle 15 Day 22	17	9.80	15.66	0.0	0.00	33.3	17	0.00	16.67	-33.3	0.00	33.3
Cycle 16 Day 1	22	13.64	26.55	0.0	0.00	100.0	22	3.03	32.38	-66.7	0.00	100.0
Cycle 16 Day 22	14	7.14	14.19	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
Cycle 17 Day 1	18	5.56	12.78	0.0	0.00	33.3	18	-3.70	19.43	-66.7	0.00	33.3
Cycle 18 Day 1	16	12.50	20.64	0.0	0.00	66.7	16	-2.08	25.73	-66.7	0.00	33.3
Cycle 18 Day 22	11	9.09	15.57	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 19 Day 1	16	12.50	20.64	0.0	0.00	66.7	15	0.00	25.20	-66.7	0.00	33.3
Cycle 19 Day 22	12	11.11	21.71	0.0	0.00	66.7	11	0.00	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	16	10.42	15.96	0.0	0.00	33.3	15	-2.22	23.46	-66.7	0.00	33.3
Cycle 20 Day 22	11	9.09	21.56	0.0	0.00	66.7	10	3.33	10.54	0.0	0.00	33.3
Cycle 21 Day 1	15	15.56	21.33	0.0	0.00	66.7	14	7.14	19.30	-33.3	0.00	33.3
Cycle 22 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-5.56	23.92	-66.7	0.00	33.3
Cycle 23 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-5.13	22.96	-66.7	0.00	33.3
Study Disc 1	153	13.94	23.76	0.0	0.00	100.0	149	2.01	25.77	-66.7	0.00	66.7
Study Disc 2	12	11.11	21.71	0.0	0.00	66.7	12	-2.78	26.43	-66.7	0.00	33.3
30 D SFU Z/P	93	13.62	19.18	0.0	0.00	66.7	91	3.66	20.76	-66.7	0.00	33.3
90 D SFU Z/P	84	19.05	28.48	0.0	0.00	100.0	83	9.24	30.49	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	8.63	17.57	0.0	0.00	100.0						
	Cycle 1 Day 22	123	11.65	18.10	0.0	0.00	66.7	117	3.99	22.39	-100.0	0.00	66.7
	Cycle 2 Day 1	137	14.36	23.15	0.0	0.00	100.0	132	6.31	26.09	-66.7	0.00	100.0
	Cycle 2 Day 22	104	11.22	20.04	0.0	0.00	100.0	100	5.00	25.68	-100.0	0.00	100.0
	Cycle 3 Day 1	133	9.27	16.59	0.0	0.00	66.7	127	1.05	22.98	-100.0	0.00	66.7
	Cycle 3 Day 22	107	10.28	17.38	0.0	0.00	66.7	102	1.63	22.68	-66.7	0.00	66.7
	Cycle 4 Day 1	112	8.33	14.50	0.0	0.00	33.3	108	-2.16	21.99	-100.0	0.00	33.3
	Cycle 4 Day 22	85	10.59	18.70	0.0	0.00	66.7	81	2.06	23.18	-66.7	0.00	66.7
	Cycle 5 Day 1	105	13.65	22.02	0.0	0.00	100.0	100	5.33	25.39	-66.7	0.00	66.7
	Cycle 5 Day 22	79	8.44	14.59	0.0	0.00	33.3	74	0.00	19.89	-66.7	0.00	33.3
	Cycle 6 Day 1	88	7.58	15.76	0.0	0.00	66.7	83	-2.01	21.05	-66.7	0.00	66.7
	Cycle 6 Day 22	67	5.47	12.44	0.0	0.00	33.3	64	-3.65	16.92	-66.7	0.00	33.3
	Cycle 7 Day 1	77	6.93	14.65	0.0	0.00	66.7	74	-3.60	18.77	-66.7	0.00	33.3
	Cycle 7 Day 22	62	9.68	15.25	0.0	0.00	33.3	57	0.58	19.41	-66.7	0.00	33.3
	Cycle 8 Day 1	57	9.36	16.37	0.0	0.00	66.7	52	-0.64	18.07	-66.7	0.00	33.3
	Cycle 8 Day 22	48	4.17	11.14	0.0	0.00	33.3	44	-7.58	20.16	-66.7	0.00	33.3
	Cycle 9 Day 1	49	8.84	14.87	0.0	0.00	33.3	44	-2.27	23.18	-66.7	0.00	33.3
	Cycle 9 Day 22	43	7.75	16.00	0.0	0.00	66.7	39	-3.42	19.93	-66.7	0.00	33.3
	Cycle 10 Day 1	47	8.51	16.25	0.0	0.00	66.7	43	-2.33	22.30	-66.7	0.00	33.3
	Cycle 10 Day 22	42	8.73	16.56	0.0	0.00	66.7	39	-2.56	25.80	-66.7	0.00	66.7
	Cycle 11 Day 1	44	8.33	17.79	0.0	0.00	66.7	41	-4.07	24.94	-66.7	0.00	66.7
	Cycle 11 Day 22	31	6.45	15.91	0.0	0.00	66.7	28	-3.57	16.58	-33.3	0.00	33.3
	Cycle 12 Day 1	35	7.62	16.34	0.0	0.00	66.7	32	-1.04	19.83	-33.3	0.00	66.7
	Cycle 12 Day 22	29	9.20	15.16	0.0	0.00	33.3	26	0.00	16.33	-33.3	0.00	33.3
	Cycle 13 Day 1	32	6.25	15.70	0.0	0.00	66.7	31	-3.23	23.34	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	28	5.95	13.00	0.0	0.00	33.3	26	-5.13	22.49	-66.7	0.00	33.3
	Cycle 14 Day 1	24	9.72	15.48	0.0	0.00	33.3	23	0.00	17.41	-33.3	0.00	33.3
	Cycle 14 Day 22	17	5.88	13.10	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
	Cycle 15 Day 1	21	6.35	13.41	0.0	0.00	33.3	21	-1.59	19.65	-66.7	0.00	33.3
	Cycle 15 Day 22	18	7.41	14.26	0.0	0.00	33.3	18	0.00	16.17	-33.3	0.00	33.3
	Cycle 16 Day 1	21	6.35	13.41	0.0	0.00	33.3	21	-1.59	22.30	-66.7	0.00	33.3
	Cycle 16 Day 22	18	9.26	25.06	0.0	0.00	100.0	18	3.70	30.01	-33.3	0.00	100.0
	Cycle 17 Day 1	17	3.92	11.07	0.0	0.00	33.3	17	-3.92	23.22	-66.7	0.00	33.3
	Cycle 17 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
	Cycle 18 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
	Cycle 18 Day 22	12	16.67	33.33	0.0	0.00	100.0	12	13.89	36.12	-33.3	0.00	100.0
	Cycle 19 Day 1	13	7.69	27.74	0.0	0.00	100.0	13	5.13	29.96	-33.3	0.00	100.0
	Cycle 19 Day 22	12	2.78	9.62	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
	Cycle 20 Day 22	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 21 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Study Disc 1	97	11.34	20.91	0.0	0.00	100.0	93	2.15	24.97	-66.7	0.00	100.0
	30 D SFU Z/P	50	12.67	20.08	0.0	0.00	66.7	47	3.55	24.31	-33.3	0.00	66.7
	90 D SFU Z/P	56	9.52	17.65	0.0	0.00	66.7	55	0.61	25.25	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	8.54	17.95	0.0	0.00	100.0						
	Cycle 1 Day 22	134	13.18	20.85	0.0	0.00	100.0	132	5.05	23.83	-66.7	0.00	100.0
	Cycle 2 Day 1	148	14.86	23.74	0.0	0.00	100.0	144	6.25	23.97	-66.7	0.00	100.0
	Cycle 2 Day 22	117	12.25	20.81	0.0	0.00	100.0	113	3.54	19.60	-66.7	0.00	66.7
	Cycle 3 Day 1	129	11.89	21.57	0.0	0.00	100.0	126	3.17	24.01	-100.0	0.00	100.0
	Cycle 3 Day 22	102	12.09	19.22	0.0	0.00	66.7	98	2.38	24.05	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	108	10.19	19.04	0.0	0.00	100.0	103	2.91	21.44	-66.7	0.00	66.7
	Cycle 4 Day 22	87	9.20	17.38	0.0	0.00	66.7	84	0.40	22.25	-66.7	0.00	66.7
	Cycle 5 Day 1	97	9.62	17.32	0.0	0.00	66.7	95	1.40	25.69	-100.0	0.00	66.7
	Cycle 5 Day 22	81	5.35	12.31	0.0	0.00	33.3	77	-3.03	19.63	-100.0	0.00	33.3
	Cycle 6 Day 1	84	8.73	16.46	0.0	0.00	66.7	82	1.63	22.77	-100.0	0.00	66.7
	Cycle 6 Day 22	64	7.29	13.89	0.0	0.00	33.3	62	-1.08	21.74	-100.0	0.00	33.3
	Cycle 7 Day 1	68	7.84	16.41	0.0	0.00	66.7	65	-1.03	22.02	-100.0	0.00	66.7
	Cycle 7 Day 22	49	5.44	12.45	0.0	0.00	33.3	47	-6.38	21.58	-100.0	0.00	33.3
	Cycle 8 Day 1	57	6.43	13.27	0.0	0.00	33.3	56	-2.38	20.94	-100.0	0.00	33.3
	Cycle 8 Day 22	43	8.53	16.42	0.0	0.00	66.7	41	-3.25	24.50	-66.7	0.00	66.7
	Cycle 9 Day 1	40	6.67	13.50	0.0	0.00	33.3	38	-3.51	16.96	-66.7	0.00	33.3
	Cycle 9 Day 22	35	6.67	15.76	0.0	0.00	66.7	33	-4.04	16.15	-33.3	0.00	33.3
	Cycle 10 Day 1	37	8.11	14.50	0.0	0.00	33.3	35	-1.90	17.97	-66.7	0.00	33.3
	Cycle 10 Day 22	28	7.14	16.62	0.0	0.00	66.7	27	-2.47	18.32	-33.3	0.00	33.3
	Cycle 11 Day 1	29	6.90	16.38	0.0	0.00	66.7	27	0.00	18.49	-66.7	0.00	33.3
	Cycle 11 Day 22	21	6.35	13.41	0.0	0.00	33.3	19	-1.75	17.48	-66.7	0.00	33.3
	Cycle 12 Day 1	27	6.17	13.19	0.0	0.00	33.3	25	-2.67	16.44	-66.7	0.00	33.3
	Cycle 12 Day 22	17	7.84	14.57	0.0	0.00	33.3	15	-4.44	11.73	-33.3	0.00	0.0
	Cycle 13 Day 1	22	10.61	15.89	0.0	0.00	33.3	20	1.67	17.01	-33.3	0.00	33.3
	Cycle 13 Day 22	13	5.13	12.52	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 14 Day 1	18	14.81	26.13	0.0	0.00	100.0	17	5.88	29.43	-33.3	0.00	100.0
	Cycle 14 Day 22	15	8.89	15.26	0.0	0.00	33.3	14	2.38	20.52	-33.3	0.00	33.3
	Cycle 15 Day 1	16	10.42	20.07	0.0	0.00	66.7	16	2.08	14.75	-33.3	0.00	33.3
	Cycle 15 Day 22	12	11.11	16.41	0.0	0.00	33.3	12	2.78	17.16	-33.3	0.00	33.3
	Cycle 16 Day 1	12	13.89	22.29	0.0	0.00	66.7	12	5.56	23.92	-33.3	0.00	66.7
	Study Disc 1	100	13.00	22.17	0.0	0.00	100.0	97	2.41	23.69	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	30 D SFU Z/P	55	14.55	18.99	0.0	0.00	66.7	53	6.92	18.90	-33.3	0.00	33.3
	90 D SFU Z/P	51	18.95	30.00	0.0	0.00	100.0	50	12.67	31.51	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	6.59	16.64	0.0	0.00	100.0						
	Cycle 1 Day 22	64	15.10	25.84	0.0	0.00	100.0	60	6.67	24.39	-33.3	0.00	100.0
	Cycle 2 Day 1	80	12.50	22.11	0.0	0.00	100.0	75	6.22	26.11	-66.7	0.00	100.0
	Cycle 2 Day 22	53	10.69	18.23	0.0	0.00	66.7	50	4.00	22.98	-66.7	0.00	66.7
	Cycle 3 Day 1	67	10.95	15.77	0.0	0.00	33.3	63	4.23	21.16	-66.7	0.00	33.3
	Cycle 3 Day 22	54	11.11	19.43	0.0	0.00	66.7	50	3.33	27.15	-66.7	0.00	66.7
	Cycle 4 Day 1	66	10.10	17.51	0.0	0.00	66.7	62	3.23	22.35	-66.7	0.00	66.7
	Cycle 4 Day 22	43	10.08	15.49	0.0	0.00	33.3	42	1.59	24.36	-66.7	0.00	33.3
	Cycle 5 Day 1	52	8.33	16.00	0.0	0.00	66.7	49	0.00	22.57	-66.7	0.00	66.7
	Cycle 5 Day 22	39	7.69	17.87	0.0	0.00	66.7	37	0.90	22.89	-66.7	0.00	66.7
	Cycle 6 Day 1	44	6.06	14.86	0.0	0.00	66.7	40	-2.50	25.47	-100.0	0.00	33.3
	Cycle 6 Day 22	41	4.88	11.93	0.0	0.00	33.3	39	-2.56	17.75	-66.7	0.00	33.3
	Cycle 7 Day 1	43	4.65	11.69	0.0	0.00	33.3	40	-3.33	23.63	-100.0	0.00	33.3
	Cycle 7 Day 22	25	9.33	22.61	0.0	0.00	100.0	24	0.00	27.80	-66.7	0.00	100.0
	Cycle 8 Day 1	31	6.45	13.39	0.0	0.00	33.3	28	-4.76	25.20	-100.0	0.00	33.3
	Cycle 8 Day 22	30	7.78	14.34	0.0	0.00	33.3	28	-1.19	24.82	-66.7	0.00	33.3
	Cycle 9 Day 1	34	8.82	17.03	0.0	0.00	66.7	31	-2.15	30.95	-100.0	0.00	66.7
	Cycle 9 Day 22	22	3.03	9.81	0.0	0.00	33.3	21	-7.94	20.83	-66.7	0.00	33.3
	Cycle 10 Day 1	25	4.00	11.06	0.0	0.00	33.3	23	-10.14	29.19	-100.0	0.00	33.3
	Cycle 10 Day 22	19	5.26	12.49	0.0	0.00	33.3	18	-3.70	22.55	-66.7	0.00	33.3
	Cycle 11 Day 1	24	6.94	13.83	0.0	0.00	33.3	22	-6.06	28.43	-100.0	0.00	33.3
	Cycle 11 Day 22	17	3.92	11.07	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
	Cycle 12 Day 1	23	14.49	16.90	0.0	0.00	33.3	21	1.59	28.82	-66.7	0.00	33.3
	Cycle 12 Day 22	12	8.33	15.08	0.0	0.00	33.3	12	-5.56	27.83	-66.7	0.00	33.3
	Cycle 13 Day 1	19	10.53	24.98	0.0	0.00	100.0	17	-3.92	42.30	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	16	8.33	14.91	0.0	0.00	33.3	15	-2.22	26.63	-66.7	0.00	33.3
	Cycle 14 Day 1	17	11.76	16.42	0.0	0.00	33.3	16	-4.17	29.50	-66.7	0.00	33.3
	Cycle 14 Day 22	16	6.25	13.44	0.0	0.00	33.3	15	-4.44	24.77	-66.7	0.00	33.3
	Cycle 15 Day 1	15	8.89	15.26	0.0	0.00	33.3	14	-9.52	27.51	-66.7	0.00	33.3
	Cycle 15 Day 22	12	5.56	12.97	0.0	0.00	33.3	12	-8.33	25.13	-66.7	0.00	33.3
	Cycle 16 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-14.29	33.88	-100.0	0.00	33.3
	Cycle 16 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Cycle 17 Day 1	13	10.26	21.01	0.0	0.00	66.7	13	-10.26	31.58	-66.7	0.00	33.3
	Cycle 17 Day 22	13	7.69	14.62	0.0	0.00	33.3	13	-5.13	26.69	-66.7	0.00	33.3
	Cycle 18 Day 1	13	12.82	16.88	0.0	0.00	33.3	13	-7.69	30.89	-66.7	0.00	33.3
	Cycle 19 Day 1	10	13.33	17.21	0.0	0.00	33.3	10	-10.00	35.31	-66.7	0.00	33.3
	Cycle 20 Day 1	10	10.00	16.10	0.0	0.00	33.3	10	-13.33	32.20	-66.7	0.00	33.3
	Cycle 21 Day 1	10	10.00	16.10	0.0	0.00	33.3	10	-13.33	32.20	-66.7	0.00	33.3
	Study Disc 1	47	12.06	23.49	0.0	0.00	100.0	43	4.65	27.78	-66.7	0.00	66.7
	30 D SFU Z/P	27	11.11	18.49	0.0	0.00	66.7	25	2.67	25.31	-66.7	0.00	66.7
	90 D SFU Z/P	33	18.18	25.13	0.0	0.00	100.0	31	9.68	28.79	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	94	14.18	22.66	0.0	0.00	100.0						
	Cycle 1 Day 22	78	13.25	21.72	0.0	0.00	100.0	78	-0.85	24.01	-66.7	0.00	66.7
	Cycle 2 Day 1	83	9.64	16.89	0.0	0.00	66.7	81	-2.88	18.41	-66.7	0.00	33.3
	Cycle 2 Day 22	68	12.25	20.69	0.0	0.00	66.7	68	-3.43	25.20	-66.7	0.00	66.7
	Cycle 3 Day 1	75	13.33	22.59	0.0	0.00	100.0	72	-2.31	26.43	-66.7	0.00	100.0
	Cycle 3 Day 22	54	11.73	24.36	0.0	0.00	100.0	51	0.00	26.67	-66.7	0.00	66.7
	Cycle 4 Day 1	63	13.76	25.14	0.0	0.00	100.0	60	-2.22	28.03	-66.7	0.00	66.7
	Cycle 4 Day 22	46	13.04	26.74	0.0	0.00	100.0	44	-3.03	29.48	-66.7	0.00	66.7
	Cycle 5 Day 1	52	9.62	15.25	0.0	0.00	33.3	50	-5.33	24.61	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.18.1: EORTC QLQ-C30 - Observed Means and Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	42	7.94	16.15	0.0	0.00	66.7	39	-6.84	27.76	-66.7	0.00	66.7
	Cycle 6 Day 1	43	9.30	16.79	0.0	0.00	66.7	40	-7.50	25.58	-66.7	0.00	33.3
	Cycle 6 Day 22	34	10.78	17.83	0.0	0.00	66.7	32	-3.13	27.25	-66.7	0.00	66.7
	Cycle 7 Day 1	33	13.13	20.31	0.0	0.00	66.7	33	-4.04	28.57	-66.7	0.00	66.7
	Cycle 7 Day 22	27	7.41	16.88	0.0	0.00	66.7	27	-9.88	25.84	-66.7	0.00	33.3
	Cycle 8 Day 1	27	13.58	16.69	0.0	0.00	33.3	27	-3.70	26.69	-66.7	0.00	33.3
	Cycle 8 Day 22	24	13.89	19.45	0.0	0.00	66.7	24	0.00	19.66	-66.7	0.00	33.3
	Cycle 9 Day 1	24	13.89	19.45	0.0	0.00	66.7	24	-1.39	20.80	-66.7	0.00	33.3
	Cycle 9 Day 22	22	13.64	26.55	0.0	0.00	100.0	22	-1.52	29.95	-66.7	0.00	66.7
	Cycle 10 Day 1	21	11.11	21.94	0.0	0.00	66.7	21	-1.59	22.30	-33.3	0.00	66.7
	Cycle 10 Day 22	16	16.67	29.81	0.0	0.00	100.0	16	0.00	27.22	-33.3	0.00	66.7
	Cycle 11 Day 1	19	15.79	28.04	0.0	0.00	100.0	19	1.75	28.27	-66.7	0.00	66.7
	Cycle 11 Day 22	12	13.89	30.01	0.0	0.00	100.0	12	-2.78	33.21	-66.7	0.00	66.7
	Cycle 12 Day 1	16	10.42	23.47	0.0	0.00	66.7	16	-4.17	23.96	-66.7	0.00	33.3
	Cycle 12 Day 22	10	16.67	28.33	0.0	0.00	66.7	10	-3.33	29.19	-66.7	0.00	33.3
	Cycle 13 Day 1	15	20.00	30.34	0.0	0.00	100.0	15	4.44	37.52	-66.7	0.00	66.7
	Cycle 14 Day 1	13	15.38	29.24	0.0	0.00	100.0	13	2.56	31.80	-66.7	0.00	66.7
	Cycle 15 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-12.12	26.97	-66.7	0.00	0.0
	Cycle 16 Day 1	10	13.33	32.20	0.0	0.00	100.0	10	0.00	41.57	-66.7	0.00	100.0
	Study Disc 1	53	15.72	26.64	0.0	0.00	100.0	52	1.28	29.49	-66.7	0.00	66.7
	30 D SFU Z/P	38	12.28	19.64	0.0	0.00	66.7	38	-0.88	22.58	-66.7	0.00	33.3
	90 D SFU Z/P	33	19.19	26.39	0.0	0.00	100.0	33	4.04	28.57	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	19.58	28.89	0.0	0.00	100.0						
Cycle 1 Day 22	187	17.83	28.35	0.0	0.00	100.0	177	0.38	24.62	-100.0	0.00	100.0
Cycle 2 Day 1	217	16.90	27.24	0.0	0.00	100.0	207	-1.45	21.86	-66.7	0.00	100.0
Cycle 2 Day 22	157	17.62	26.57	0.0	0.00	100.0	150	-0.67	20.96	-66.7	0.00	100.0
Cycle 3 Day 1	200	17.50	26.09	0.0	0.00	100.0	190	-0.88	22.86	-100.0	0.00	100.0
Cycle 3 Day 22	161	18.84	25.76	0.0	0.00	100.0	152	0.00	21.36	-66.7	0.00	66.7
Cycle 4 Day 1	178	14.23	23.44	0.0	0.00	100.0	170	-2.55	20.51	-66.7	0.00	100.0
Cycle 4 Day 22	128	17.97	25.41	0.0	0.00	100.0	123	-1.90	26.41	-100.0	0.00	66.7
Cycle 5 Day 1	157	18.90	26.22	0.0	0.00	100.0	149	0.67	27.25	-100.0	0.00	100.0
Cycle 5 Day 22	118	23.16	29.72	0.0	0.00	100.0	111	2.10	23.04	-66.7	0.00	66.7
Cycle 6 Day 1	132	19.44	27.02	0.0	0.00	100.0	123	-1.63	22.93	-100.0	0.00	66.7
Cycle 6 Day 22	108	16.67	25.17	0.0	0.00	100.0	103	-2.27	21.52	-66.7	0.00	66.7
Cycle 7 Day 1	120	17.78	24.42	0.0	0.00	100.0	114	-1.46	24.04	-100.0	0.00	66.7
Cycle 7 Day 22	87	18.77	24.75	0.0	0.00	100.0	81	-1.65	22.91	-100.0	0.00	66.7
Cycle 8 Day 1	88	17.80	24.21	0.0	0.00	100.0	80	0.42	24.59	-100.0	0.00	66.7
Cycle 8 Day 22	78	14.96	23.20	0.0	0.00	100.0	72	-1.39	24.67	-100.0	0.00	33.3
Cycle 9 Day 1	83	17.27	24.06	0.0	0.00	100.0	75	-1.33	23.53	-100.0	0.00	66.7
Cycle 9 Day 22	65	16.92	25.09	0.0	0.00	100.0	60	-1.11	28.10	-100.0	0.00	66.7
Cycle 10 Day 1	72	16.67	25.64	0.0	0.00	100.0	66	-1.01	26.13	-100.0	0.00	66.7
Cycle 10 Day 22	61	16.94	25.55	0.0	0.00	100.0	57	-2.92	26.19	-100.0	0.00	33.3
Cycle 11 Day 1	68	15.20	26.03	0.0	0.00	100.0	63	-3.17	28.53	-100.0	0.00	66.7
Cycle 11 Day 22	48	15.97	24.78	0.0	0.00	100.0	44	-2.27	31.66	-100.0	0.00	66.7
Cycle 12 Day 1	58	16.09	27.39	0.0	0.00	100.0	53	-1.26	30.64	-100.0	0.00	100.0
Cycle 12 Day 22	41	17.89	27.99	0.0	0.00	100.0	38	-2.63	30.39	-100.0	0.00	33.3
Cycle 13 Day 1	51	16.99	27.79	0.0	0.00	100.0	48	-2.78	27.36	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	44	19.70	27.20	0.0	0.00	100.0	41	0.81	30.27	-100.0	0.00	33.3
Cycle 14 Day 1	41	17.89	26.97	0.0	0.00	100.0	39	0.85	22.28	-100.0	0.00	33.3
Cycle 14 Day 22	33	15.15	23.70	0.0	0.00	100.0	32	0.00	23.95	-100.0	0.00	33.3
Cycle 15 Day 1	36	12.04	22.75	0.0	0.00	100.0	35	-5.71	28.57	-100.0	0.00	33.3
Cycle 15 Day 22	30	12.22	23.95	0.0	0.00	100.0	30	-5.56	26.38	-100.0	0.00	33.3
Cycle 16 Day 1	35	14.29	23.27	0.0	0.00	100.0	35	-1.90	24.18	-100.0	0.00	33.3
Cycle 16 Day 22	29	13.79	20.93	0.0	0.00	66.7	29	-1.15	28.84	-100.0	0.00	33.3
Cycle 17 Day 1	30	15.56	22.71	0.0	0.00	100.0	30	-1.11	25.50	-100.0	0.00	33.3
Cycle 17 Day 22	23	15.94	17.03	0.0	0.00	33.3	23	5.80	16.37	-33.3	0.00	33.3
Cycle 18 Day 1	27	11.11	16.01	0.0	0.00	33.3	27	1.23	17.25	-33.3	0.00	33.3
Cycle 18 Day 22	21	9.52	15.43	0.0	0.00	33.3	21	0.00	14.91	-33.3	0.00	33.3
Cycle 19 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	0.00	17.41	-33.3	0.00	33.3
Cycle 19 Day 22	20	13.33	16.75	0.0	0.00	33.3	20	5.00	16.31	-33.3	0.00	33.3
Cycle 20 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	0.00	17.41	-33.3	0.00	33.3
Cycle 20 Day 22	18	12.96	16.72	0.0	0.00	33.3	18	3.70	19.43	-33.3	0.00	33.3
Cycle 21 Day 1	20	10.00	19.04	0.0	0.00	66.7	20	1.67	22.88	-33.3	0.00	66.7
Cycle 21 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	-7.14	19.30	-33.3	0.00	33.3
Cycle 22 Day 1	15	8.89	19.79	0.0	0.00	66.7	15	-2.22	19.79	-33.3	0.00	33.3
Cycle 22 Day 22	11	12.12	22.47	0.0	0.00	66.7	11	0.00	25.82	-33.3	0.00	33.3
Cycle 23 Day 1	16	10.42	20.07	0.0	0.00	66.7	16	-2.08	19.12	-33.3	0.00	33.3
Cycle 23 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	-6.06	20.10	-33.3	0.00	33.3
Cycle 24 Day 1	14	7.14	19.30	0.0	0.00	66.7	14	-4.76	22.10	-33.3	0.00	33.3
Cycle 25 Day 1	12	11.11	21.71	0.0	0.00	66.7	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 25 Day 22	11	12.12	22.47	0.0	0.00	66.7	11	-6.06	25.03	-33.3	0.00	33.3
Cycle 26 Day 1	13	10.26	21.01	0.0	0.00	66.7	13	-5.13	22.96	-33.3	0.00	33.3
Cycle 27 Day 1	11	12.12	22.47	0.0	0.00	66.7	11	-3.03	23.35	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	11.11	21.71	0.0	0.00	66.7	12	-2.78	22.29	-33.3	0.00	33.3
Study Disc 1	144	22.92	29.36	0.0	0.00	100.0	136	2.94	25.81	-100.0	0.00	66.7
30 D SFU Z/P	77	24.24	32.28	0.0	0.00	100.0	72	4.17	26.79	-33.3	0.00	100.0
90 D SFU Z/P	89	23.97	26.59	0.0	33.33	100.0	86	7.75	24.35	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	258	18.86	27.38	0.0	0.00	100.0						
Cycle 1 Day 22	212	18.55	26.79	0.0	0.00	100.0	210	-0.48	21.75	-100.0	0.00	66.7
Cycle 2 Day 1	231	17.46	25.02	0.0	0.00	100.0	225	-1.93	24.01	-100.0	0.00	66.7
Cycle 2 Day 22	185	16.22	24.35	0.0	0.00	100.0	181	-1.84	23.76	-66.7	0.00	100.0
Cycle 3 Day 1	204	17.65	24.85	0.0	0.00	100.0	198	-1.85	24.26	-100.0	0.00	100.0
Cycle 3 Day 22	156	19.02	27.59	0.0	0.00	100.0	149	-1.12	22.06	-100.0	0.00	33.3
Cycle 4 Day 1	171	16.37	24.35	0.0	0.00	100.0	163	-3.07	22.77	-100.0	0.00	66.7
Cycle 4 Day 22	133	18.30	24.44	0.0	0.00	100.0	128	-0.78	20.26	-66.7	0.00	33.3
Cycle 5 Day 1	149	19.91	28.98	0.0	0.00	100.0	145	-0.23	26.79	-100.0	0.00	100.0
Cycle 5 Day 22	123	17.62	24.64	0.0	0.00	100.0	116	-1.72	26.32	-100.0	0.00	100.0
Cycle 6 Day 1	127	19.16	27.06	0.0	0.00	100.0	122	2.73	25.92	-100.0	0.00	66.7
Cycle 6 Day 22	98	17.35	24.98	0.0	0.00	100.0	94	0.00	26.32	-100.0	0.00	66.7
Cycle 7 Day 1	101	17.49	26.07	0.0	0.00	100.0	98	0.68	23.92	-100.0	0.00	66.7
Cycle 7 Day 22	76	15.35	25.20	0.0	0.00	100.0	74	-2.70	28.00	-100.0	0.00	66.7
Cycle 8 Day 1	84	17.46	26.62	0.0	0.00	100.0	83	0.80	26.02	-66.7	0.00	100.0
Cycle 8 Day 22	67	17.41	24.86	0.0	0.00	100.0	65	1.54	27.28	-66.7	0.00	66.7
Cycle 9 Day 1	64	16.15	27.85	0.0	0.00	100.0	62	-1.08	27.64	-100.0	0.00	66.7
Cycle 9 Day 22	57	16.96	25.29	0.0	0.00	100.0	55	1.82	32.34	-100.0	0.00	100.0
Cycle 10 Day 1	58	20.69	29.83	0.0	0.00	100.0	56	4.76	31.42	-100.0	0.00	100.0
Cycle 10 Day 22	44	19.70	29.92	0.0	0.00	100.0	43	3.88	33.50	-100.0	0.00	66.7
Cycle 11 Day 1	48	15.28	24.75	0.0	0.00	100.0	46	0.72	31.02	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.19: EORTC QLQ-C30 - Observed Means and Change from Baseline of Financial Difficulties - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	20.20	28.79	0.0	0.00	100.0	31	6.45	23.44	-66.7	0.00	33.3
Cycle 12 Day 1	43	17.05	28.52	0.0	0.00	100.0	41	5.69	23.45	-33.3	0.00	66.7
Cycle 12 Day 22	27	16.05	29.77	0.0	0.00	100.0	25	2.67	25.31	-33.3	0.00	66.7
Cycle 13 Day 1	37	17.12	30.04	0.0	0.00	100.0	35	3.81	22.54	-33.3	0.00	66.7
Cycle 13 Day 22	22	9.09	18.35	0.0	0.00	66.7	21	-4.76	26.43	-66.7	0.00	33.3
Cycle 14 Day 1	31	17.20	29.65	0.0	0.00	100.0	30	5.56	26.38	-66.7	0.00	66.7
Cycle 14 Day 22	20	10.00	19.04	0.0	0.00	66.7	19	-5.26	27.81	-66.7	0.00	33.3
Cycle 15 Day 1	27	18.52	31.12	0.0	0.00	100.0	27	6.17	30.71	-66.7	0.00	66.7
Cycle 15 Day 22	17	13.73	26.51	0.0	0.00	100.0	17	-1.96	27.56	-66.7	0.00	33.3
Cycle 16 Day 1	22	13.64	24.47	0.0	0.00	100.0	22	1.52	26.18	-66.7	0.00	33.3
Cycle 16 Day 22	14	16.67	28.50	0.0	0.00	100.0	14	2.38	27.62	-33.3	0.00	33.3
Cycle 17 Day 1	18	12.96	25.92	0.0	0.00	100.0	18	1.85	24.18	-33.3	0.00	33.3
Cycle 18 Day 1	16	14.58	27.13	0.0	0.00	100.0	16	2.08	25.73	-33.3	0.00	33.3
Cycle 18 Day 22	11	12.12	16.82	0.0	0.00	33.3	10	3.33	24.60	-33.3	0.00	33.3
Cycle 19 Day 1	16	18.75	29.74	0.0	0.00	100.0	15	8.89	26.63	-33.3	0.00	66.7
Cycle 19 Day 22	12	19.44	33.21	0.0	0.00	100.0	11	6.06	32.72	-33.3	0.00	66.7
Cycle 20 Day 1	16	14.58	27.13	0.0	0.00	100.0	15	4.44	24.77	-33.3	0.00	33.3
Cycle 20 Day 22	11	21.21	34.23	0.0	0.00	100.0	10	6.67	34.43	-33.3	0.00	66.7
Cycle 21 Day 1	15	26.67	31.37	0.0	33.33	100.0	14	11.90	28.06	-33.3	0.00	66.7
Cycle 22 Day 1	12	11.11	16.41	0.0	0.00	33.3	12	2.78	26.43	-33.3	0.00	33.3
Cycle 23 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	0.00	23.57	-33.3	0.00	33.3
Study Disc 1	153	20.92	26.73	0.0	0.00	100.0	149	2.46	25.44	-66.7	0.00	100.0
Study Disc 2	12	27.78	34.33	0.0	16.67	100.0	12	8.33	45.23	-66.7	0.00	100.0
30 D SFU Z/P	93	22.22	25.22	0.0	33.33	100.0	91	5.13	26.26	-66.7	0.00	66.7
90 D SFU Z/P	84	23.02	29.71	0.0	0.00	100.0	83	4.02	31.41	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

Table 301.3.3004.5.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	168 (59.4%)	151 (53.5%)	
Number of patients censored	115 (40.6%)	131 (46.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.4 [2.3, 4.4]	5.2 [4.2, 6.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.218 [0.975, 1.522]
Log-rank test			
Two-sided stratified log-rank p-value			0.0824

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; 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: 08SEP23

Table 301.3.3004.5.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Global Health Status by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	110 (60.8)	3.6 [2.4, 5.5]	181	99 (54.7)	4.7 [3.0, 7.7]	1.138 [0.867, 1.494]	0.3539	0.3548
>65 years	102	58 (56.9)	2.8 [1.6, 3.9]	101	52 (51.5)	5.6 [4.4, 10.9]	1.526 [1.047, 2.224]	0.0267	
Sex									
Male	176	96 (54.5)	3.7 [2.2, 5.5]	175	94 (53.7)	5.6 [3.9, 8.0]	1.154 [0.868, 1.535]	0.3206	0.4072
Female	107	72 (67.3)	3.0 [1.4, 3.7]	107	57 (53.3)	4.6 [3.5, 6.8]	1.400 [0.988, 1.985]	0.0591	
Region									
Asia	88	61 (69.3)	3.7 [1.9, 5.8]	89	54 (60.7)	5.6 [2.3, 8.1]	1.123 [0.774, 1.629]	0.5417	0.6526
Non-Asia	195	107 (54.9)	3.0 [2.2, 4.2]	193	97 (50.3)	5.1 [4.1, 6.8]	1.301 [0.988, 1.713]	0.0605	
Number of Organs with Metastatic Sites									
0-2	219	132 (60.3)	3.0 [2.2, 4.6]	219	121 (55.3)	5.3 [4.2, 7.5]	1.255 [0.980, 1.608]	0.0721	0.8792
>=3	64	36 (56.3)	3.7 [1.6, 4.8]	63	30 (47.6)	4.8 [2.3, 10.7]	1.211 [0.743, 1.973]	0.4382	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.6.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	156 (55.1%)	148 (52.5%)	
Number of patients censored	127 (44.9%)	134 (47.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.5 [2.6, 4.8]	6.4 [4.9, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.168 [0.930, 1.466]
Log-rank test			
Two-sided stratified log-rank p-value			0.1792

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; 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: 08SEP23

Table 301.3.3004.6.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Physical Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	96 (53.0)	3.8 [2.4, 9.7]	181	84 (46.4)	8.3 [6.2, 12.7]	1.232 [0.918, 1.655]	0.1668	0.3975
>65 years	102	60 (58.8)	3.0 [2.1, 3.7]	101	64 (63.4)	4.6 [2.8, 6.5]	1.066 [0.748, 1.518]	0.7169	
Sex									
Male	176	95 (54.0)	3.3 [2.1, 5.1]	175	92 (52.6)	6.5 [4.9, 9.3]	1.200 [0.899, 1.602]	0.2152	0.7767
Female	107	61 (57.0)	3.8 [2.4, 6.9]	107	56 (52.3)	6.2 [2.6, 9.5]	1.083 [0.753, 1.559]	0.6650	
Region									
Asia	88	49 (55.7)	6.0 [3.2, 10.9]	89	45 (50.6)	8.6 [6.9, 12.3]	1.150 [0.765, 1.729]	0.4976	0.8615
Non-Asia	195	107 (54.9)	2.8 [1.6, 3.6]	193	103 (53.4)	4.9 [3.3, 6.6]	1.164 [0.887, 1.527]	0.2726	
Number of Organs with Metastatic Sites									
0-2	219	117 (53.4)	3.6 [2.6, 6.0]	219	113 (51.6)	6.4 [4.4, 8.6]	1.113 [0.858, 1.443]	0.4167	0.5186
>=3	64	39 (60.9)	3.0 [1.6, 3.8]	63	35 (55.6)	6.5 [4.9, 9.4]	1.327 [0.838, 2.101]	0.2310	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.7.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	171 (60.4%)	171 (60.6%)	
Number of patients censored	112 (39.6%)	111 (39.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.3 [1.6, 3.0]	2.8 [2.1, 4.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.072 [0.866, 1.328]
Log-rank test			
Two-sided stratified log-rank p-value			0.5177

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; 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: 08SEP23

Table 301.3.3004.7.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Role Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	112 (61.9)	1.7 [1.4, 3.1]	181	108 (59.7)	2.4 [1.9, 4.9]	1.118 [0.858, 1.457]	0.4122	0.6526
>65 years	102	59 (57.8)	2.7 [1.6, 4.3]	101	63 (62.4)	2.8 [1.6, 4.6]	1.002 [0.702, 1.430]	0.9844	
Sex									
Male	176	104 (59.1)	2.3 [1.6, 3.9]	175	110 (62.9)	2.8 [1.8, 4.8]	0.973 [0.744, 1.272]	0.8436	0.2373
Female	107	67 (62.6)	1.6 [1.2, 3.0]	107	61 (57.0)	3.0 [1.9, 5.6]	1.283 [0.906, 1.815]	0.1616	
Region									
Asia	88	59 (67.0)	3.5 [1.4, 5.5]	89	58 (65.2)	3.9 [1.6, 6.7]	1.079 [0.750, 1.552]	0.6842	0.9279
Non-Asia	195	112 (57.4)	1.9 [1.5, 2.8]	193	113 (58.5)	2.8 [1.9, 4.2]	1.079 [0.831, 1.402]	0.5618	
Number of Organs with Metastatic Sites									
0-2	219	128 (58.4)	2.3 [1.5, 4.3]	219	134 (61.2)	3.0 [2.1, 4.8]	1.027 [0.806, 1.309]	0.8315	0.4266
>=3	64	43 (67.2)	1.7 [1.4, 3.0]	63	37 (58.7)	2.6 [1.0, 5.1]	1.277 [0.820, 1.987]	0.2748	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.8.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	125 (44.2%)	119 (42.2%)	
Number of patients censored	158 (55.8%)	163 (57.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.4 [5.1, 13.1]	11.1 [8.5, 14.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.145 [0.888, 1.476]
Log-rank test			
Two-sided stratified log-rank p-value			0.3015

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; 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: 08SEP23

Table 301.3.3004.8.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Emotional Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	77 (42.5)	8.5 [5.3, 19.6]	181	73 (40.3)	11.9 [8.6, 15.1]	1.066 [0.773, 1.470]	0.6993	0.5358
>65 years	102	48 (47.1)	5.3 [2.8, 11.0]	101	46 (45.5)	9.3 [5.8, 15.8]	1.269 [0.846, 1.904]	0.2475	
Sex									
Male	176	75 (42.6)	7.4 [5.1, 13.8]	175	77 (44.0)	11.0 [8.0, 15.4]	1.050 [0.764, 1.444]	0.7633	0.4682
Female	107	50 (46.7)	5.8 [3.3, 18.4]	107	42 (39.3)	11.9 [7.1, 15.9]	1.283 [0.849, 1.938]	0.2364	
Region									
Asia	88	40 (45.5)	10.7 [5.5, NC]	89	41 (46.1)	12.3 [8.0, 15.7]	0.860 [0.552, 1.342]	0.5083	0.1992
Non-Asia	195	85 (43.6)	5.5 [3.6, 11.0]	193	78 (40.4)	10.6 [7.1, 15.4]	1.277 [0.939, 1.737]	0.1194	
Number of Organs with Metastatic Sites									
0-2	219	98 (44.7)	7.4 [5.0, 13.8]	219	95 (43.4)	11.9 [8.1, 15.1]	1.111 [0.837, 1.475]	0.4673	0.7995
>=3	64	27 (42.2)	6.2 [3.3, NC]	63	24 (38.1)	10.4 [6.2, 15.4]	1.212 [0.698, 2.106]	0.4913	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.9.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	161 (56.9%)	154 (54.6%)	
Number of patients censored	122 (43.1%)	128 (45.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.3 [2.9, 5.2]	5.1 [3.7, 7.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.124 [0.900, 1.404]
Log-rank test			
Two-sided stratified log-rank p-value			0.3055

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; 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: 08SEP23

Table 301.3.3004.9.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Cognitive Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	105 (58.0)	4.6 [2.9, 5.7]	181	93 (51.4)	6.2 [3.9, 8.7]	1.191 [0.901, 1.575]	0.2201	0.5520
>65 years	102	56 (54.9)	3.9 [1.6, 5.2]	101	61 (60.4)	3.9 [2.8, 6.7]	1.044 [0.726, 1.501]	0.8143	
Sex									
Male	176	96 (54.5)	4.9 [3.2, 5.8]	175	94 (53.7)	5.1 [3.1, 7.5]	1.055 [0.793, 1.402]	0.7096	0.3985
Female	107	65 (60.7)	2.9 [1.7, 4.6]	107	60 (56.1)	5.3 [2.8, 7.2]	1.291 [0.908, 1.835]	0.1546	
Region									
Asia	88	60 (68.2)	4.1 [2.8, 5.3]	89	53 (59.6)	6.2 [2.4, 8.1]	1.141 [0.788, 1.653]	0.4840	0.9515
Non-Asia	195	101 (51.8)	4.3 [2.3, 5.8]	193	101 (52.3)	4.9 [3.6, 7.2]	1.121 [0.851, 1.477]	0.4204	
Number of Organs with Metastatic Sites									
0-2	219	127 (58.0)	4.3 [2.8, 5.2]	219	124 (56.6)	5.1 [3.3, 7.2]	1.119 [0.873, 1.433]	0.3774	0.8290
>=3	64	34 (53.1)	3.7 [1.6, 11.1]	63	30 (47.6)	5.7 [2.8, 15.1]	1.180 [0.721, 1.931]	0.5104	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.10.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	173 (61.1%)	148 (52.5%)	
Number of patients censored	110 (38.9%)	134 (47.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.6 [2.1, 3.5]	4.6 [2.5, 6.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.311 [1.050, 1.636]
Log-rank test			
Two-sided stratified log-rank p-value			0.0148

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; 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: 08SEP23

Table 301.3.3004.10.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Social Functioning by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	113 (62.4)	3.0 [2.1, 4.0]	181	90 (49.7)	5.6 [3.1, 8.8]	1.456 [1.103, 1.922]	0.0075	0.2071
>65 years	102	60 (58.8)	2.3 [1.6, 3.7]	101	58 (57.4)	2.6 [1.4, 5.1]	1.086 [0.756, 1.558]	0.6332	
Sex									
Male	176	102 (58.0)	3.0 [2.1, 4.1]	175	93 (53.1)	5.1 [2.8, 7.2]	1.235 [0.932, 1.637]	0.1357	0.4961
Female	107	71 (66.4)	2.4 [1.4, 3.7]	107	55 (51.4)	2.8 [1.5, 7.2]	1.428 [1.003, 2.033]	0.0452	
Region									
Asia	88	53 (60.2)	4.1 [2.4, 5.9]	89	44 (49.4)	6.5 [4.8, 26.3]	1.350 [0.905, 2.014]	0.1427	0.9256
Non-Asia	195	120 (61.5)	2.3 [1.6, 3.0]	193	104 (53.9)	2.8 [1.9, 5.1]	1.296 [0.996, 1.686]	0.0486	
Number of Organs with Metastatic Sites									
0-2	219	134 (61.2)	2.8 [2.1, 3.5]	219	114 (52.1)	4.9 [2.8, 6.3]	1.359 [1.058, 1.745]	0.0153	0.5984
>=3	64	39 (60.9)	2.4 [1.0, 5.1]	63	34 (54.0)	3.2 [1.4, 11.1]	1.135 [0.716, 1.801]	0.5752	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.11.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	192 (67.8%)	179 (63.5%)	
Number of patients censored	91 (32.2%)	103 (36.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.5 [1.2, 1.7]	2.2 [1.5, 3.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.228 [0.999, 1.509]
Log-rank test			
Two-sided stratified log-rank p-value			0.0473

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; 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: 08SEP23

Table 301.3.3004.11.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Fatigue by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	124 (68.5)	1.5 [1.0, 2.1]	181	110 (60.8)	2.3 [1.5, 4.2]	1.257 [0.971, 1.627]	0.0812	0.7248
>65 years	102	68 (66.7)	1.5 [1.4, 2.1]	101	69 (68.3)	1.5 [1.0, 3.0]	1.183 [0.844, 1.660]	0.3018	
Sex									
Male	176	118 (67.0)	1.5 [1.4, 2.1]	175	122 (69.7)	1.5 [1.0, 2.3]	1.037 [0.805, 1.338]	0.7358	0.0362
Female	107	74 (69.2)	1.4 [1.0, 2.1]	107	57 (53.3)	3.9 [2.3, 6.1]	1.655 [1.170, 2.341]	0.0040	
Region									
Asia	88	65 (73.9)	1.5 [1.1, 2.4]	89	57 (64.0)	3.9 [1.4, 6.2]	1.366 [0.954, 1.956]	0.0849	0.4368
Non-Asia	195	127 (65.1)	1.5 [1.1, 1.7]	193	122 (63.2)	1.9 [1.2, 2.6]	1.159 [0.904, 1.487]	0.2304	
Number of Organs with Metastatic Sites									
0-2	219	152 (69.4)	1.5 [1.2, 1.7]	219	140 (63.9)	2.1 [1.4, 3.5]	1.268 [1.007, 1.596]	0.0404	0.6358
>=3	64	40 (62.5)	1.6 [0.9, 3.0]	63	39 (61.9)	2.3 [1.0, 6.3]	1.123 [0.719, 1.756]	0.5922	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.12.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	168 (59.4%)	157 (55.7%)	
Number of patients censored	115 (40.6%)	125 (44.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.5 [1.4, 2.3]	3.0 [2.1, 4.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.243 [0.996, 1.550]
Log-rank test			
Two-sided stratified log-rank p-value			0.0515

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; 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: 08SEP23

Table 301.3.3004.12.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Nausea and Vomiting by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	109 (60.2)	1.4 [1.0, 2.4]	181	108 (59.7)	2.2 [1.5, 3.7]	1.106 [0.847, 1.444]	0.4726	0.1316
>65 years	102	59 (57.8)	1.8 [1.5, 3.6]	101	49 (48.5)	7.2 [3.0, 15.4]	1.605 [1.096, 2.349]	0.0131	
Sex									
Male	176	105 (59.7)	1.6 [1.4, 2.8]	175	104 (59.4)	2.8 [2.1, 6.1]	1.186 [0.904, 1.556]	0.2211	0.4455
Female	107	63 (58.9)	1.4 [1.0, 2.6]	107	53 (49.5)	3.5 [1.9, 15.1]	1.399 [0.970, 2.018]	0.0676	
Region									
Asia	88	60 (68.2)	1.6 [1.0, 3.3]	89	58 (65.2)	1.8 [1.0, 6.1]	1.116 [0.776, 1.605]	0.5423	0.3848
Non-Asia	195	108 (55.4)	1.5 [1.4, 2.6]	193	99 (51.3)	3.5 [2.3, 9.0]	1.343 [1.022, 1.765]	0.0346	
Number of Organs with Metastatic Sites									
0-2	219	134 (61.2)	1.5 [1.1, 2.3]	219	122 (55.7)	3.5 [2.2, 7.1]	1.379 [1.078, 1.763]	0.0104	0.1518
>=3	64	34 (53.1)	1.6 [1.4, 13.2]	63	35 (55.6)	2.3 [1.0, 3.7]	0.900 [0.561, 1.443]	0.6685	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.13.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	148 (52.3%)	146 (51.8%)	
Number of patients censored	135 (47.7%)	136 (48.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.5 [3.4, 6.0]	5.6 [4.0, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.137 [0.902, 1.434]
Log-rank test			
Two-sided stratified log-rank p-value			0.2782

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; 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: 08SEP23

Table 301.3.3004.13.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Pain by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	94 (51.9)	5.1 [3.3, 7.4]	181	87 (48.1)	5.8 [3.7, 10.6]	1.168 [0.873, 1.564]	0.2955	0.6200
>65 years	102	54 (52.9)	3.5 [2.1, 5.7]	101	59 (58.4)	5.1 [3.8, 8.8]	1.068 [0.738, 1.547]	0.7249	
Sex									
Male	176	87 (49.4)	4.5 [3.0, 8.0]	175	95 (54.3)	5.6 [4.4, 8.8]	1.001 [0.748, 1.340]	0.9892	0.2302
Female	107	61 (57.0)	4.2 [2.4, 6.5]	107	51 (47.7)	6.7 [3.1, 14.3]	1.337 [0.921, 1.941]	0.1248	
Region									
Asia	88	54 (61.4)	3.4 [2.1, 5.5]	89	45 (50.6)	9.1 [5.5, 12.3]	1.726 [1.157, 2.573]	0.0067	0.0173
Non-Asia	195	94 (48.2)	5.7 [3.5, 7.4]	193	101 (52.3)	4.6 [3.6, 5.8]	0.912 [0.688, 1.209]	0.5239	
Number of Organs with Metastatic Sites									
0-2	219	114 (52.1)	5.4 [3.5, 6.7]	219	112 (51.1)	5.6 [4.0, 9.3]	1.126 [0.867, 1.461]	0.3747	0.9019
>=3	64	34 (53.1)	3.3 [1.7, 5.6]	63	34 (54.0)	5.5 [2.6, 8.8]	1.105 [0.687, 1.780]	0.6756	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.14.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	134 (47.3%)	130 (46.1%)	
Number of patients censored	149 (52.7%)	152 (53.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.4 [4.0, 8.6]	7.6 [6.2, 11.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.115 [0.874, 1.421]
Log-rank test			
Two-sided stratified log-rank p-value			0.3809

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; 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: 08SEP23

Table 301.3.3004.14.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Dyspnoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	87 (48.1)	6.4 [3.3, 10.0]	181	79 (43.6)	10.4 [6.5, 12.7]	1.240 [0.914, 1.682]	0.1665	0.3646
>65 years	102	47 (46.1)	6.5 [3.7, 9.0]	101	51 (50.5)	6.2 [3.1, 8.1]	0.991 [0.666, 1.473]	0.9645	
Sex									
Male	176	80 (45.5)	7.5 [4.4, 10.0]	175	87 (49.7)	7.2 [4.9, 8.8]	0.982 [0.724, 1.330]	0.9019	0.0971
Female	107	54 (50.5)	5.3 [3.1, 9.2]	107	43 (40.2)	10.4 [6.0, NC]	1.502 [1.005, 2.244]	0.0456	
Region									
Asia	88	48 (54.5)	5.6 [3.4, 10.9]	89	48 (53.9)	7.2 [6.0, 12.3]	1.074 [0.719, 1.603]	0.7290	0.7086
Non-Asia	195	86 (44.1)	6.5 [3.7, 9.2]	193	82 (42.5)	8.4 [4.9, 12.7]	1.178 [0.871, 1.595]	0.2884	
Number of Organs with Metastatic Sites									
0-2	219	108 (49.3)	6.0 [4.0, 8.5]	219	105 (47.9)	7.4 [4.9, 11.5]	1.131 [0.865, 1.480]	0.3683	0.8223
>=3	64	26 (40.6)	7.5 [3.0, NC]	63	25 (39.7)	10.4 [5.5, NC]	1.184 [0.682, 2.053]	0.5514	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.15.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	130 (45.9%)	132 (46.8%)	
Number of patients censored	153 (54.1%)	150 (53.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.8 [4.5, 8.5]	7.1 [5.0, 10.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.012 [0.793, 1.291]
Log-rank test			
Two-sided stratified log-rank p-value			0.9233

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; 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: 08SEP23

Table 301.3.3004.15.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Insomnia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	89 (49.2)	5.1 [3.4, 8.1]	181	82 (45.3)	7.6 [4.9, 11.1]	1.130 [0.837, 1.526]	0.4240	0.2446
>65 years	102	41 (40.2)	6.0 [4.5, NC]	101	50 (49.5)	6.6 [3.9, 12.2]	0.844 [0.558, 1.277]	0.4242	
Sex									
Male	176	80 (45.5)	5.8 [4.4, 11.8]	175	82 (46.9)	8.1 [4.6, 11.1]	1.039 [0.763, 1.414]	0.8102	0.8595
Female	107	50 (46.7)	5.5 [2.4, 13.7]	107	50 (46.7)	5.3 [4.2, 12.2]	0.986 [0.665, 1.460]	0.9513	
Region									
Asia	88	47 (53.4)	5.8 [3.1, 12.0]	89	44 (49.4)	9.0 [5.2, 12.3]	1.134 [0.751, 1.713]	0.5531	0.5721
Non-Asia	195	83 (42.6)	5.6 [4.2, 11.8]	193	88 (45.6)	6.2 [4.4, 9.4]	0.969 [0.718, 1.309]	0.8457	
Number of Organs with Metastatic Sites									
0-2	219	107 (48.9)	5.6 [4.1, 6.7]	219	104 (47.5)	7.1 [4.9, 11.8]	1.065 [0.813, 1.396]	0.6470	0.4715
>=3	64	23 (35.9)	8.1 [3.3, NC]	63	28 (44.4)	6.6 [3.0, 11.1]	0.820 [0.467, 1.439]	0.4932	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.16.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	144 (50.9%)	143 (50.7%)	
Number of patients censored	139 (49.1%)	139 (49.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.2 [2.0, 4.4]	4.5 [2.3, 7.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.112 [0.880, 1.405]
Log-rank test			
Two-sided stratified log-rank p-value			0.3676

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; 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: 08SEP23

Table 301.3.3004.16.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Appetite Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	91 (50.3)	3.4 [1.6, 7.5]	181	89 (49.2)	4.4 [2.3, 10.6]	1.029 [0.768, 1.379]	0.8514	0.6258
>65 years	102	53 (52.0)	2.3 [1.5, 4.4]	101	54 (53.5)	4.6 [1.7, 7.8]	1.225 [0.837, 1.792]	0.2859	
Sex									
Male	176	94 (53.4)	2.8 [1.5, 3.7]	175	96 (54.9)	4.5 [2.3, 7.2]	1.132 [0.851, 1.506]	0.3921	0.7342
Female	107	50 (46.7)	5.4 [1.6, 10.9]	107	47 (43.9)	6.2 [1.8, 17.3]	1.029 [0.690, 1.534]	0.8824	
Region									
Asia	88	55 (62.5)	1.5 [1.0, 3.5]	89	53 (59.6)	3.9 [2.1, 8.1]	1.248 [0.855, 1.823]	0.2524	0.3653
Non-Asia	195	89 (45.6)	4.2 [2.3, 5.7]	193	90 (46.6)	4.9 [2.3, 8.0]	1.004 [0.749, 1.347]	0.9680	
Number of Organs with Metastatic Sites									
0-2	219	119 (54.3)	2.8 [1.5, 4.3]	219	111 (50.7)	4.5 [2.2, 7.8]	1.205 [0.930, 1.561]	0.1563	0.0839
>=3	64	25 (39.1)	4.8 [2.1, NC]	63	32 (50.8)	4.2 [1.5, 8.0]	0.728 [0.431, 1.231]	0.2348	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.17.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	137 (48.4%)	139 (49.3%)	
Number of patients censored	146 (51.6%)	143 (50.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.9 [2.9, 5.3]	4.3 [2.8, 6.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.006 [0.793, 1.277]
Log-rank test			
Two-sided stratified log-rank p-value			0.9633

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; 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: 08SEP23

Table 301.3.3004.17.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Constipation by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	90 (49.7)	3.9 [2.9, 5.3]	181	87 (48.1)	5.2 [2.8, 7.7]	1.067 [0.794, 1.433]	0.6772	0.6416
>65 years	102	47 (46.1)	3.4 [2.1, 10.8]	101	52 (51.5)	3.6 [2.1, 6.2]	0.962 [0.648, 1.428]	0.8572	
Sex									
Male	176	83 (47.2)	4.1 [2.8, 7.1]	175	89 (50.9)	4.9 [2.8, 7.7]	0.990 [0.734, 1.336]	0.9513	0.7518
Female	107	54 (50.5)	3.4 [2.1, 6.5]	107	50 (46.7)	3.8 [2.1, 6.5]	1.082 [0.736, 1.590]	0.6931	
Region									
Asia	88	51 (58.0)	4.4 [2.9, 7.1]	89	49 (55.1)	5.2 [2.3, 7.9]	1.057 [0.712, 1.568]	0.7897	0.8216
Non-Asia	195	86 (44.1)	3.4 [2.5, 6.5]	193	90 (46.6)	3.9 [2.5, 6.2]	1.001 [0.745, 1.346]	0.9929	
Number of Organs with Metastatic Sites									
0-2	219	109 (49.8)	3.9 [2.8, 5.3]	219	114 (52.1)	3.9 [2.4, 6.2]	0.981 [0.754, 1.276]	0.8796	0.4698
>=3	64	28 (43.8)	3.5 [1.6, 10.8]	63	25 (39.7)	6.2 [2.3, NC]	1.185 [0.690, 2.036]	0.5280	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.18.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	134 (47.3%)	139 (49.3%)	
Number of patients censored	149 (52.7%)	143 (50.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.9, 6.9]	5.6 [3.9, 8.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.996 [0.783, 1.267]
Log-rank test			
Two-sided stratified log-rank p-value			0.9925

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; 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: 08SEP23

Table 301.3.3004.18.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Diarrhoea by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	83 (45.9)	5.5 [3.9, 9.7]	181	97 (53.6)	4.7 [2.5, 6.2]	0.792 [0.590, 1.063]	0.1209	0.0151
>65 years	102	51 (50.0)	4.3 [2.2, 7.6]	101	42 (41.6)	10.4 [4.6, NC]	1.498 [0.995, 2.257]	0.0501	
Sex									
Male	176	82 (46.6)	5.2 [4.2, 9.4]	175	88 (50.3)	5.6 [3.7, 8.1]	0.907 [0.670, 1.227]	0.5393	0.3184
Female	107	52 (48.6)	3.9 [2.1, 6.5]	107	51 (47.7)	6.0 [3.6, 11.1]	1.157 [0.786, 1.703]	0.4606	
Region									
Asia	88	46 (52.3)	6.5 [4.4, 15.5]	89	43 (48.3)	7.2 [3.9, NC]	1.035 [0.681, 1.574]	0.8620	0.8475
Non-Asia	195	88 (45.1)	4.2 [3.1, 6.0]	193	96 (49.7)	4.9 [3.6, 7.5]	0.981 [0.734, 1.311]	0.9080	
Number of Organs with Metastatic Sites									
0-2	219	99 (45.2)	6.0 [4.1, 9.6]	219	112 (51.1)	5.2 [3.7, 7.5]	0.889 [0.678, 1.167]	0.4033	0.0873
>=3	64	35 (54.7)	3.9 [1.9, 5.3]	63	27 (42.9)	10.4 [2.4, NC]	1.460 [0.882, 2.416]	0.1341	

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; 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Table 301.3.3004.19.1: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	107 (37.8%)	100 (35.5%)	
Number of patients censored	176 (62.2%)	182 (64.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	9.2 [6.9, 16.4]	12.3 [8.2, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.093 [0.831, 1.438]
Log-rank test			
Two-sided stratified log-rank p-value			0.5224

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; 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: 08SEP23

Table 301.3.3004.19.2: EORTC QLQ-C30 - Summary of Time to First Deterioration of Financial Difficulties by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	72 (39.8)	8.0 [5.8, 13.7]	181	62 (34.3)	12.3 [7.5, NC]	1.197 [0.853, 1.682]	0.2957	0.4247
>65 years	102	35 (34.3)	13.8 [6.9, NC]	101	38 (37.6)	10.9 [7.3, NC]	0.929 [0.586, 1.473]	0.7538	
Sex									
Male	176	64 (36.4)	10.0 [6.7, NC]	175	63 (36.0)	12.3 [8.1, NC]	1.076 [0.760, 1.524]	0.6745	0.8840
Female	107	43 (40.2)	8.6 [5.8, 19.1]	107	37 (34.6)	11.1 [7.0, NC]	1.114 [0.717, 1.732]	0.6300	
Region									
Asia	88	45 (51.1)	7.5 [5.1, 13.7]	89	34 (38.2)	12.3 [7.0, NC]	1.250 [0.799, 1.955]	0.3272	0.4426
Non-Asia	195	62 (31.8)	10.4 [6.9, NC]	193	66 (34.2)	11.1 [8.2, NC]	1.008 [0.712, 1.426]	0.9599	
Number of Organs with Metastatic Sites									
0-2	219	86 (39.3)	10.0 [6.9, 16.4]	219	78 (35.6)	12.3 [7.9, NC]	1.129 [0.831, 1.535]	0.4378	0.6747
>=3	64	21 (32.8)	6.9 [5.1, NC]	63	22 (34.9)	10.9 [4.9, NC]	0.990 [0.544, 1.803]	0.9852	

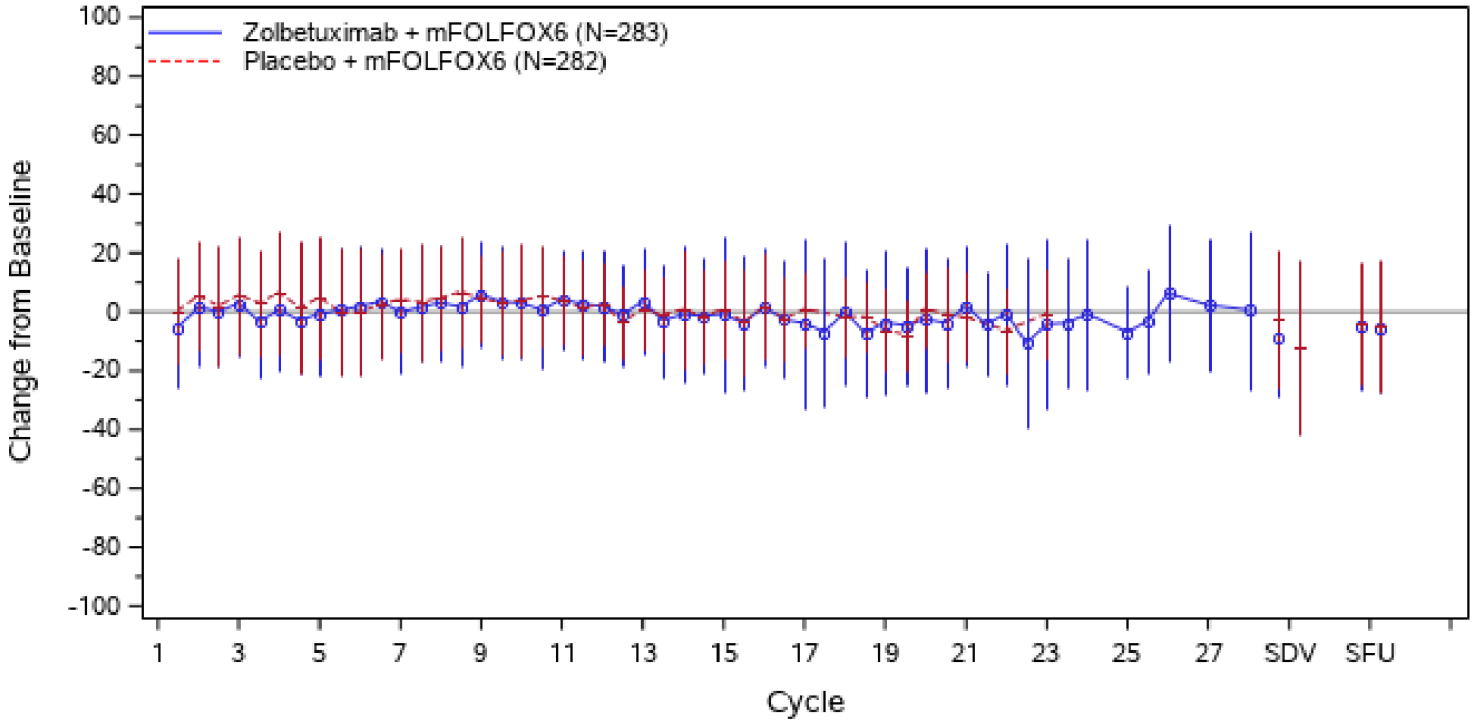
Abbreviations: CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; NC=not calculated.
Note: 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 [b] Calculated from unstratified Cox proportional hazards model [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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

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

The SAS System

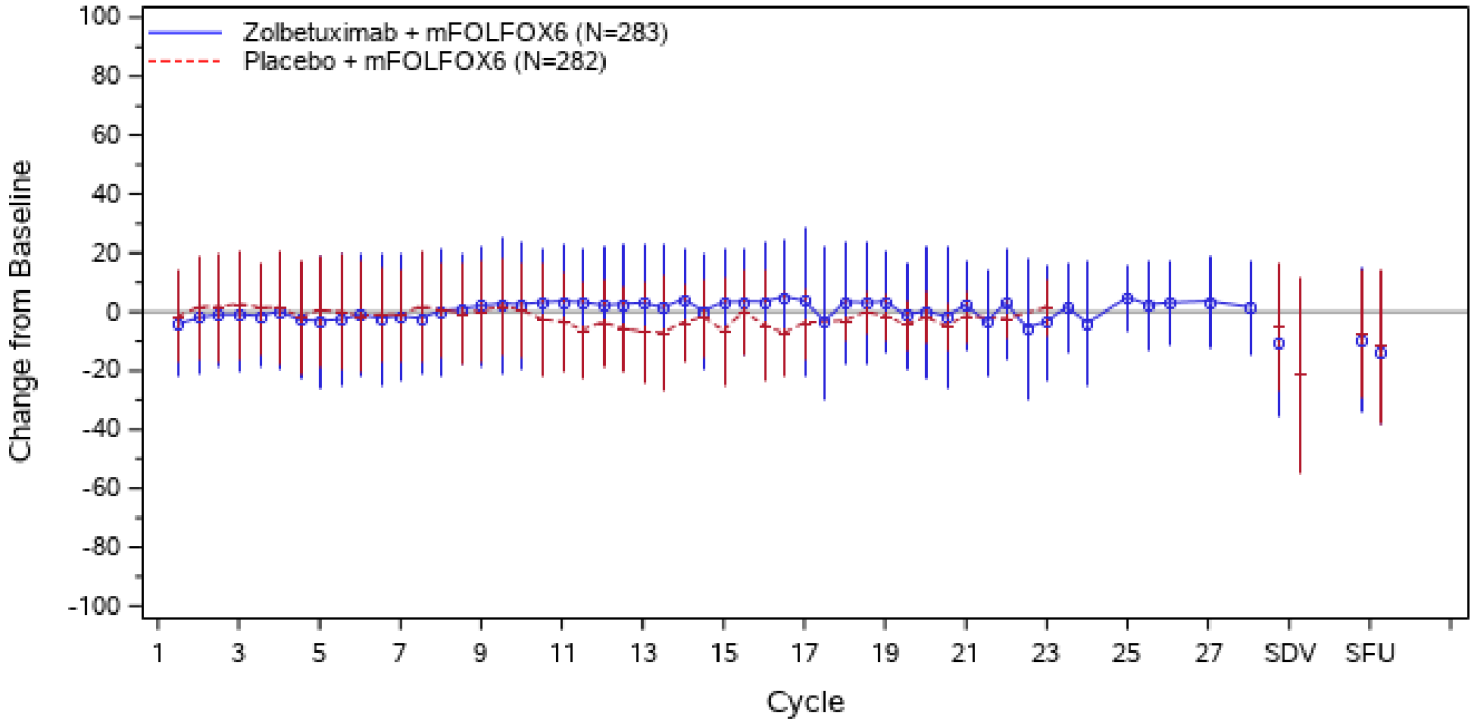
Figure 301.3.3002.5: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Global Health Status - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

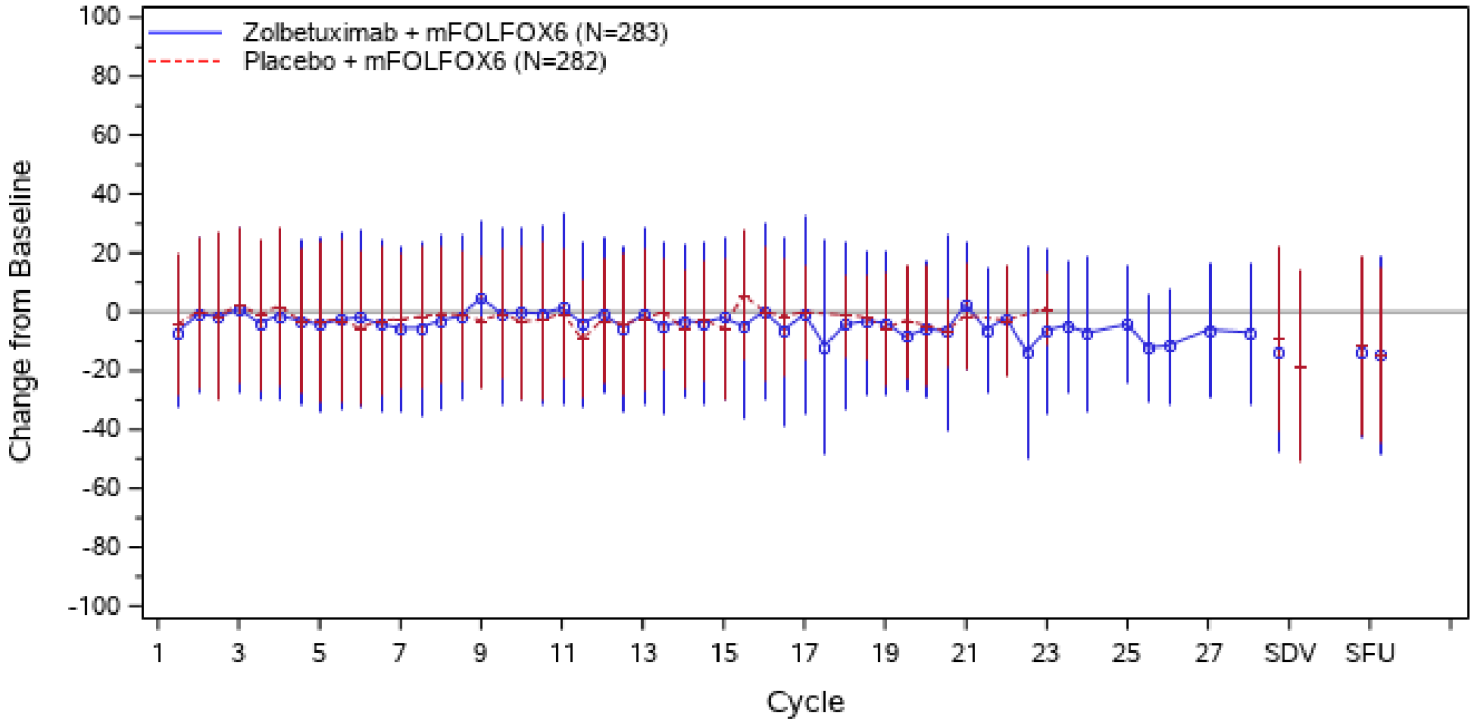
Figure 301.3.3002.6: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Physical Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

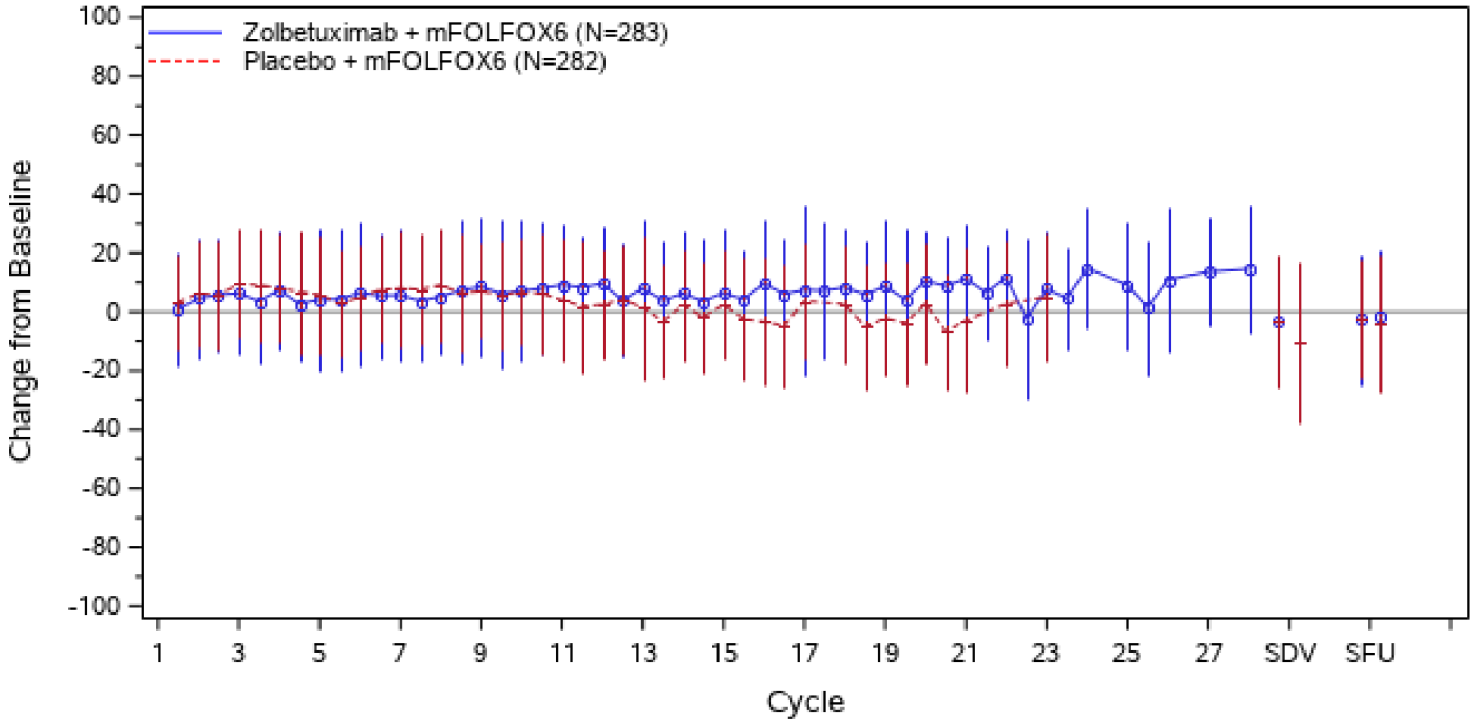
Figure 301.3.3002.7: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Role Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

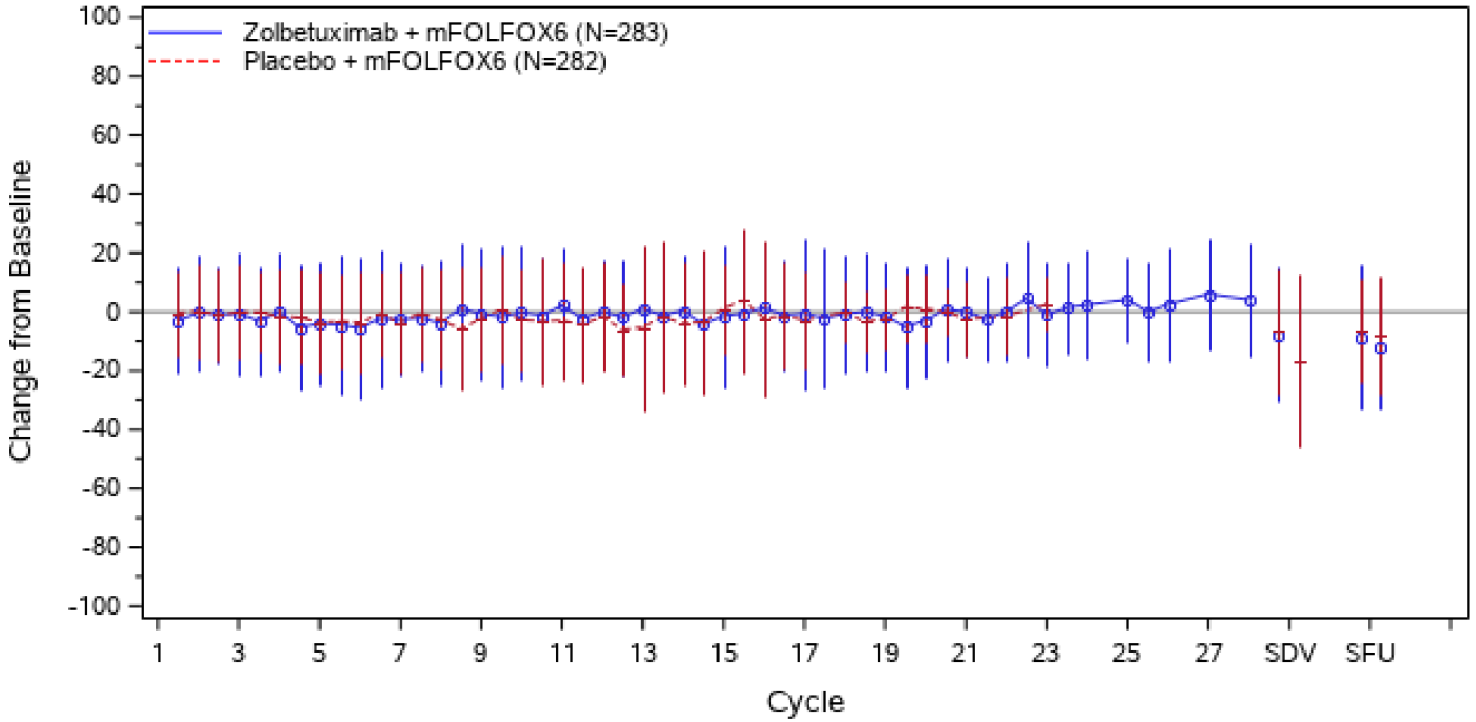
Figure 301.3.3002.8: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Emotional Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

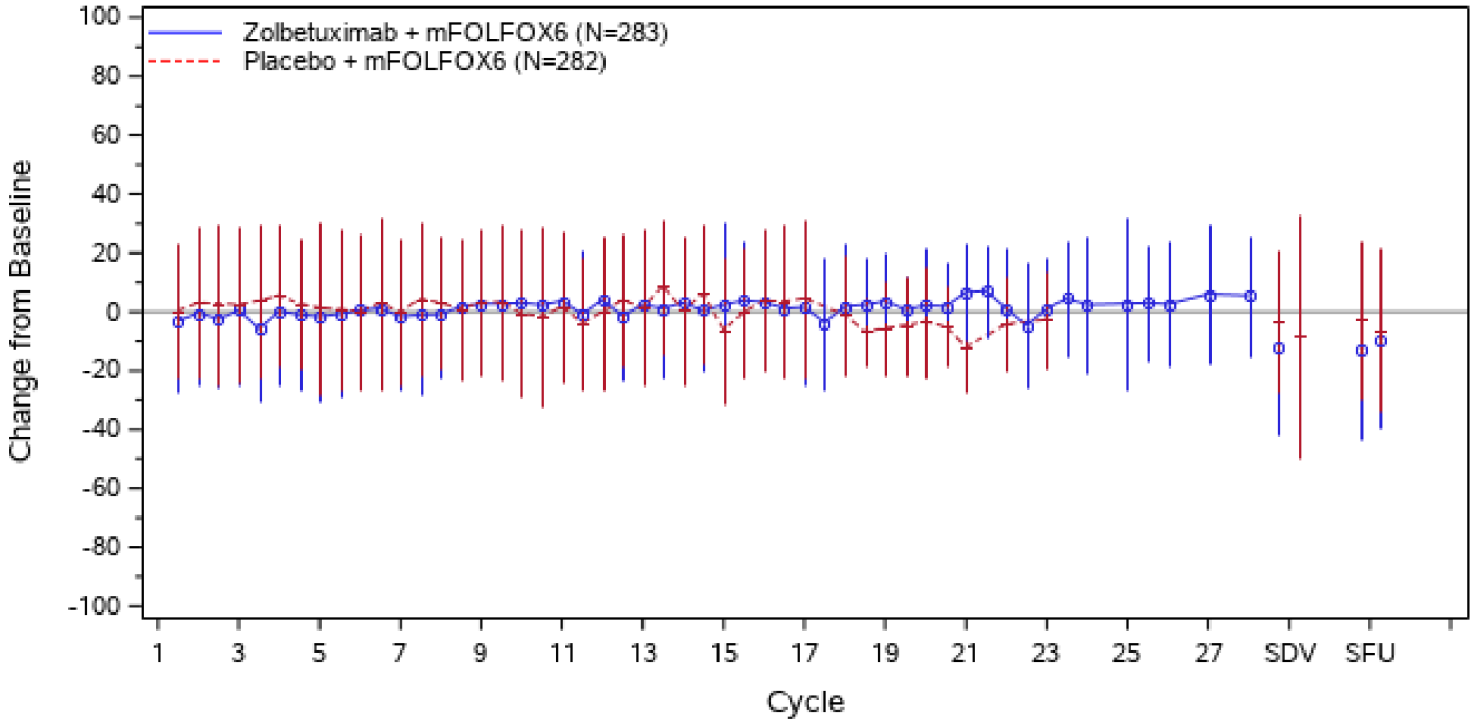
Figure 301.3.3002.9: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Cognitive Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

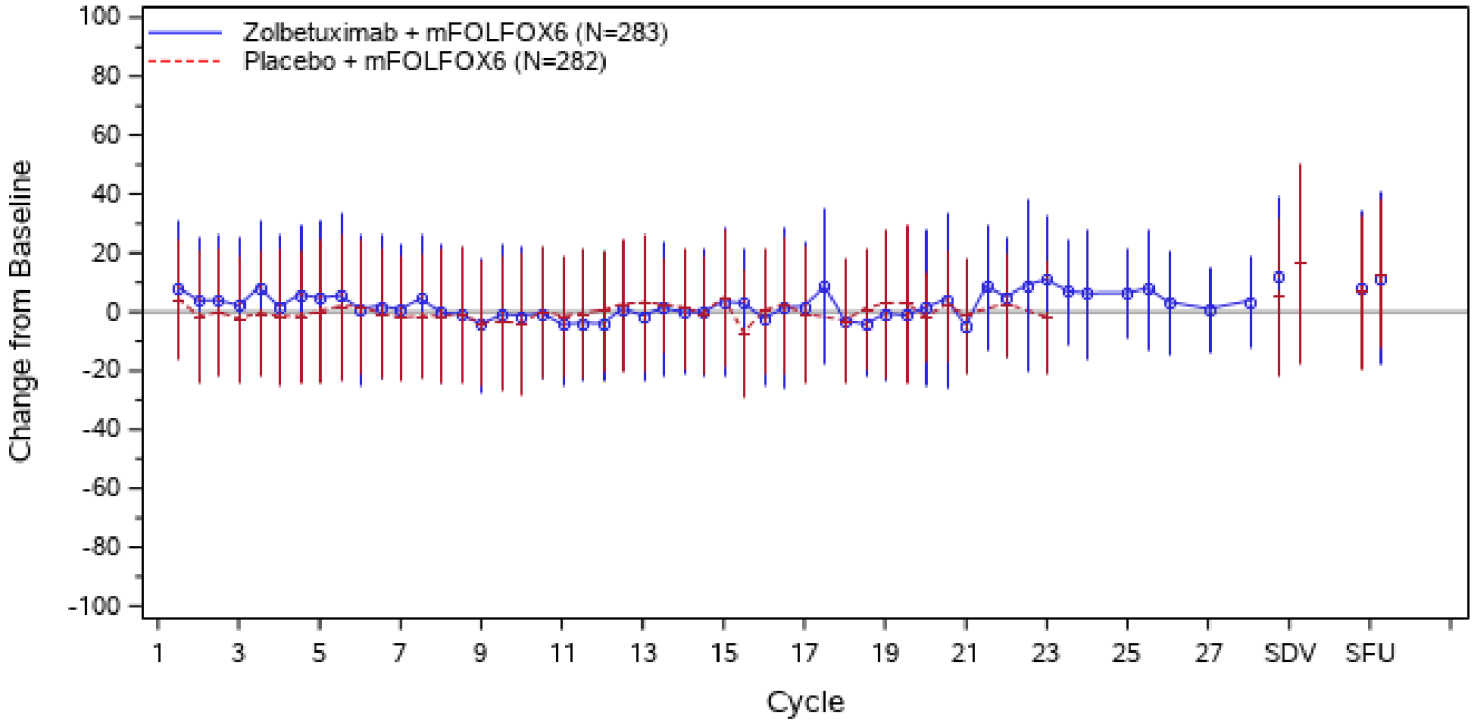
Figure 301.3.3002.10: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Social Functioning - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.11: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue - Full Analysis Set

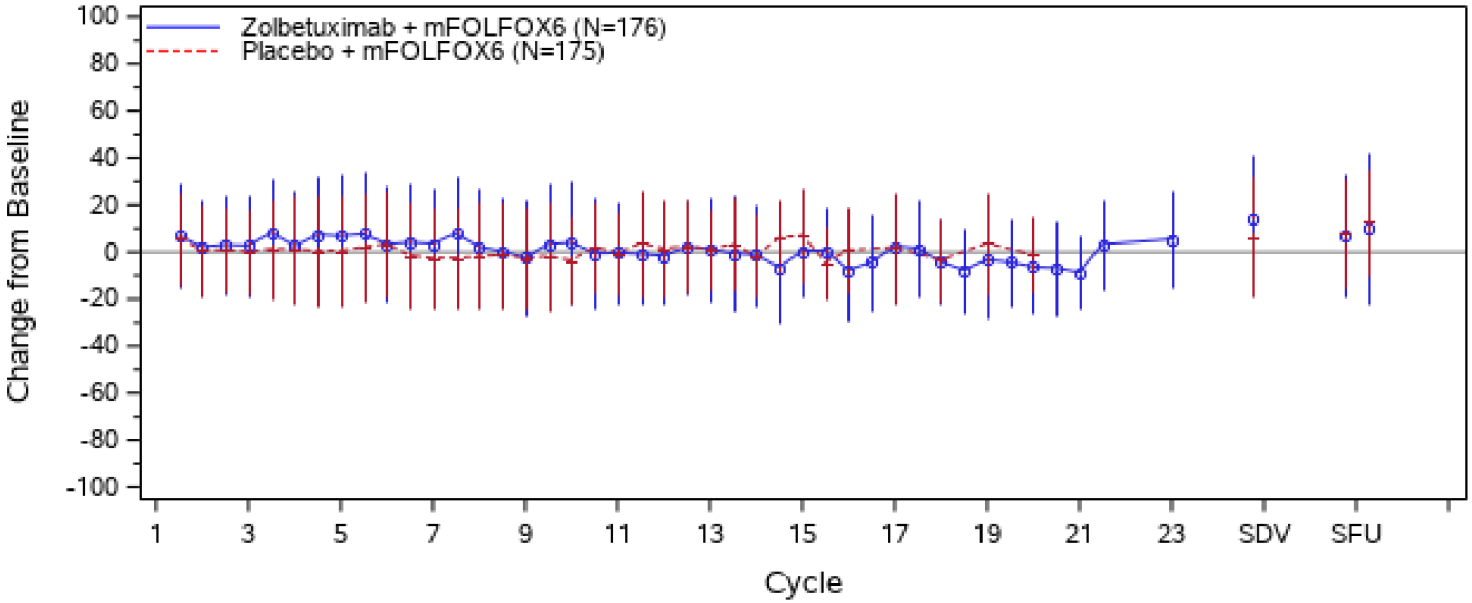


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.11.2: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue by Sex - Full Analysis Set

Sex: Male

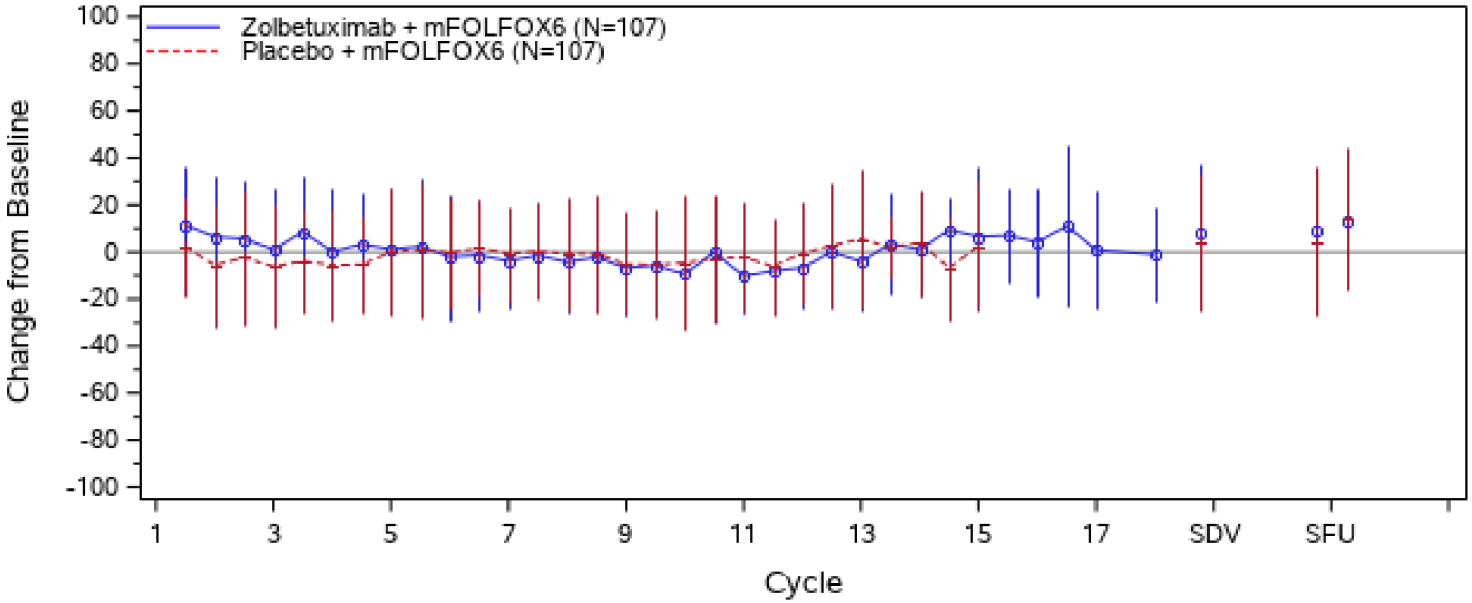


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.11.2: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Fatigue by Sex - Full Analysis Set

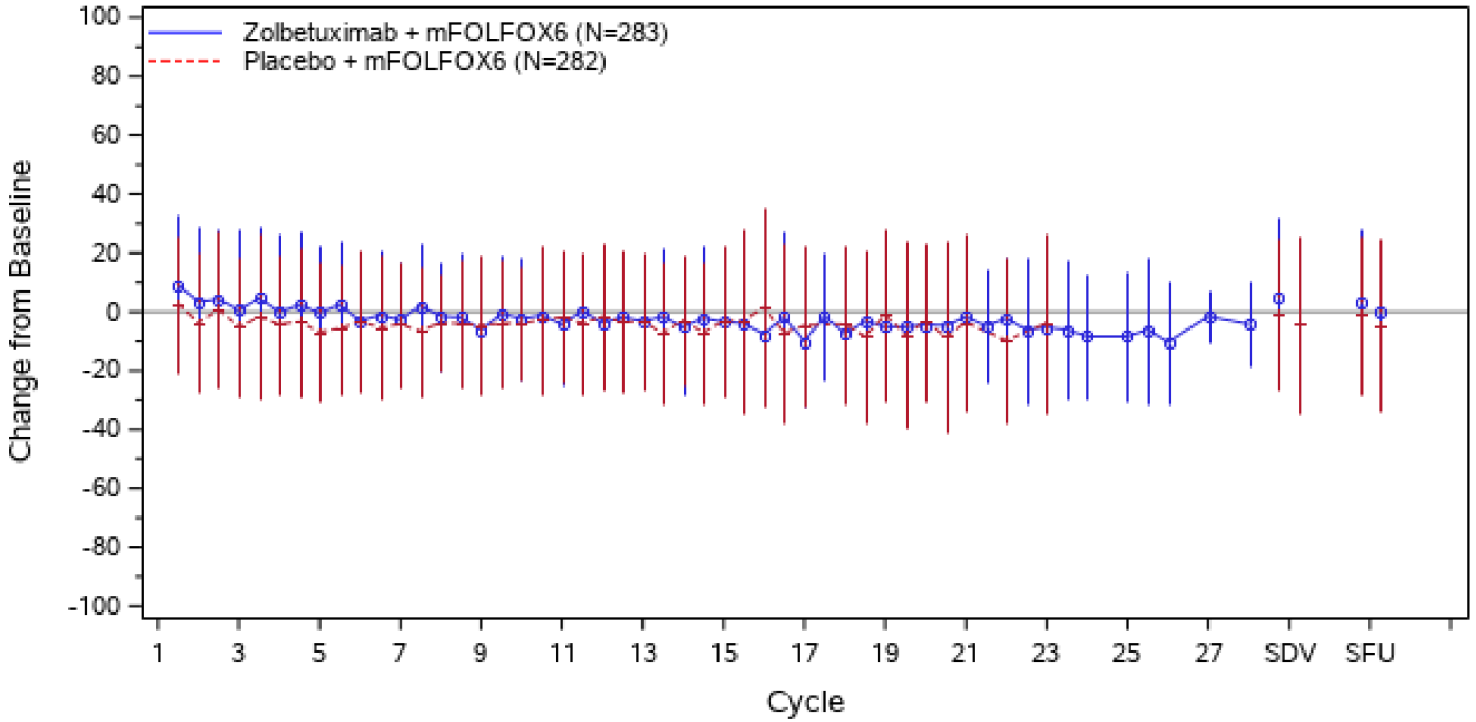
Sex: Female



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

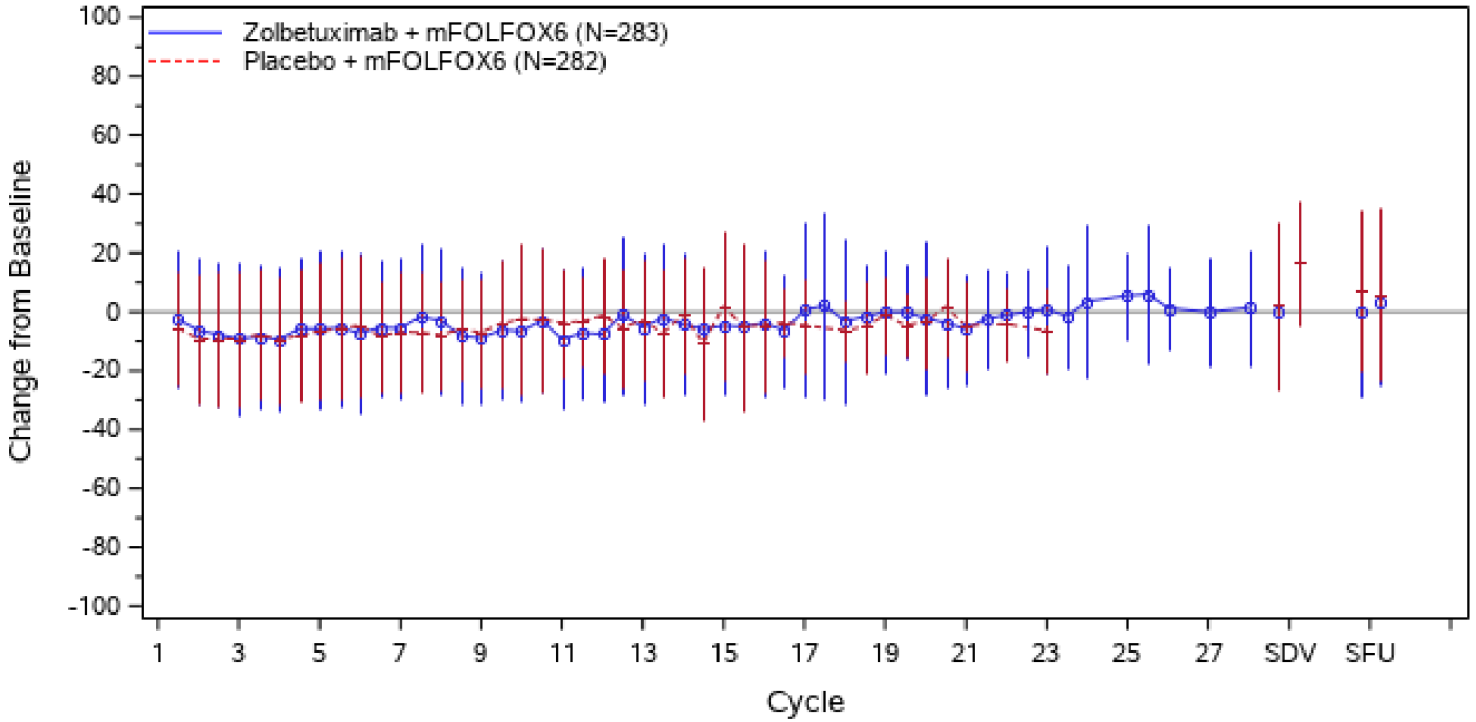
Figure 301.3.3002.12: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Nausea and Vomiting - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.13: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain - Full Analysis Set

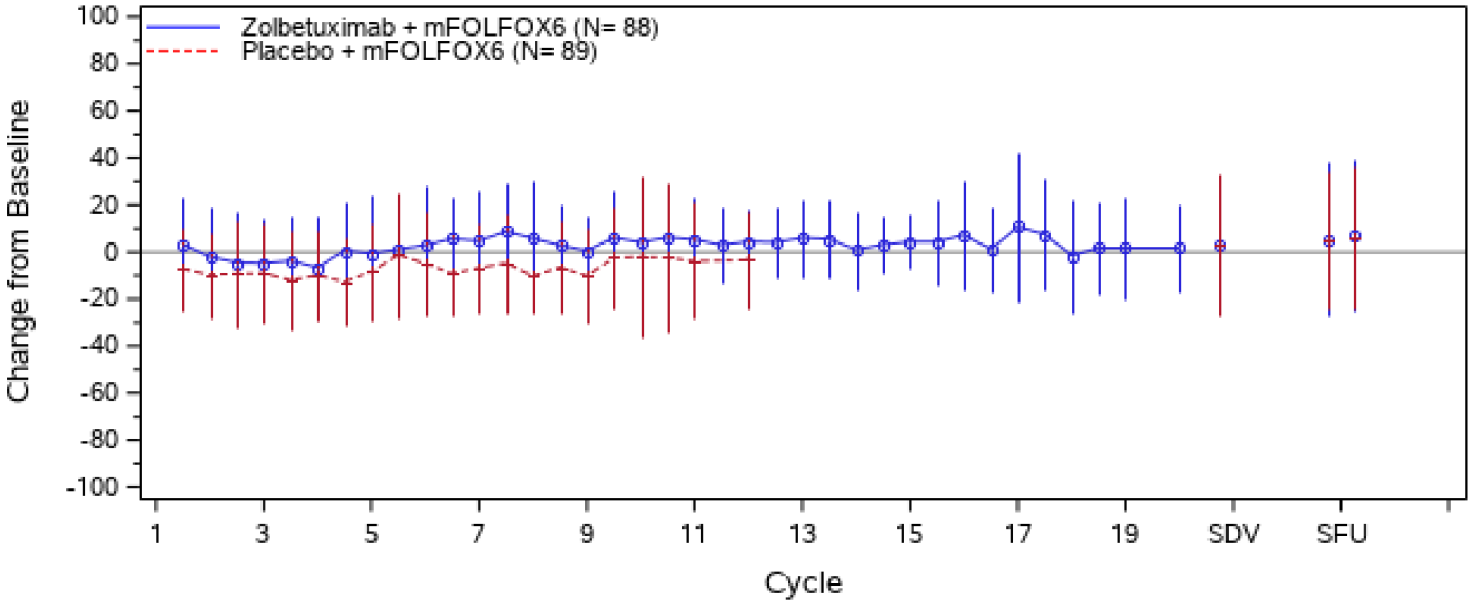


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.13.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain by Region - Full Analysis Set

Region: Asia

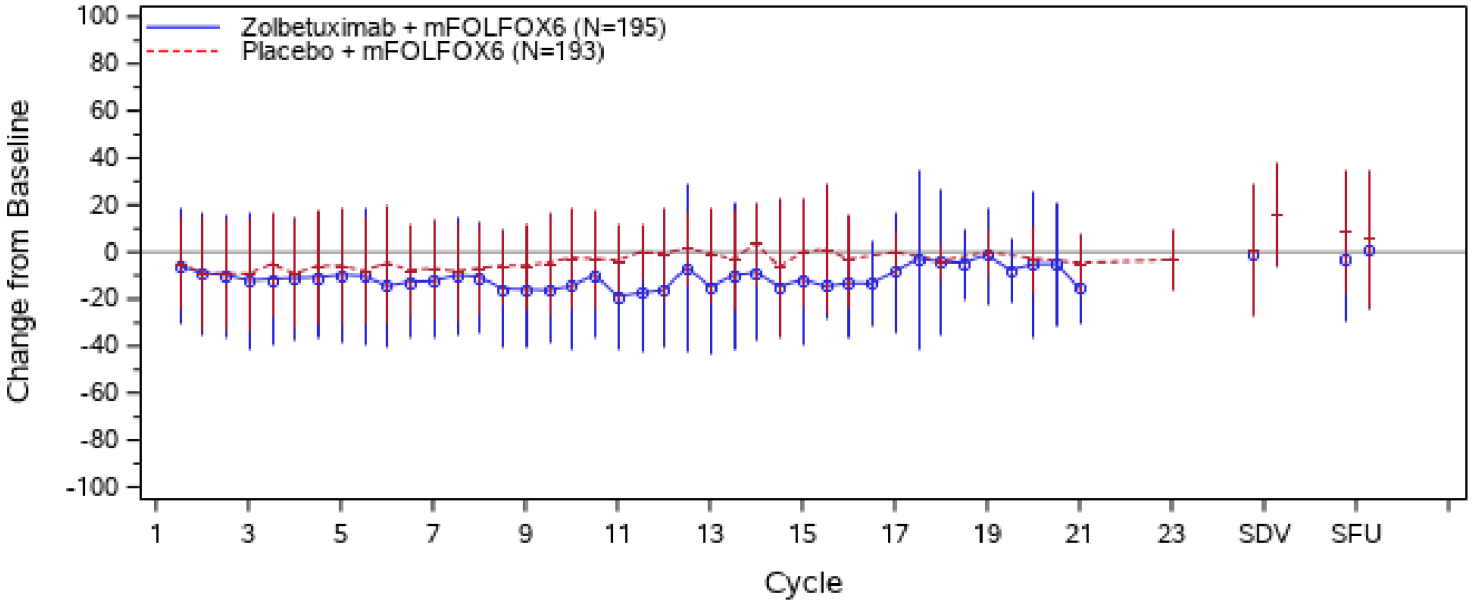


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.13.3: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Pain by Region - Full Analysis Set

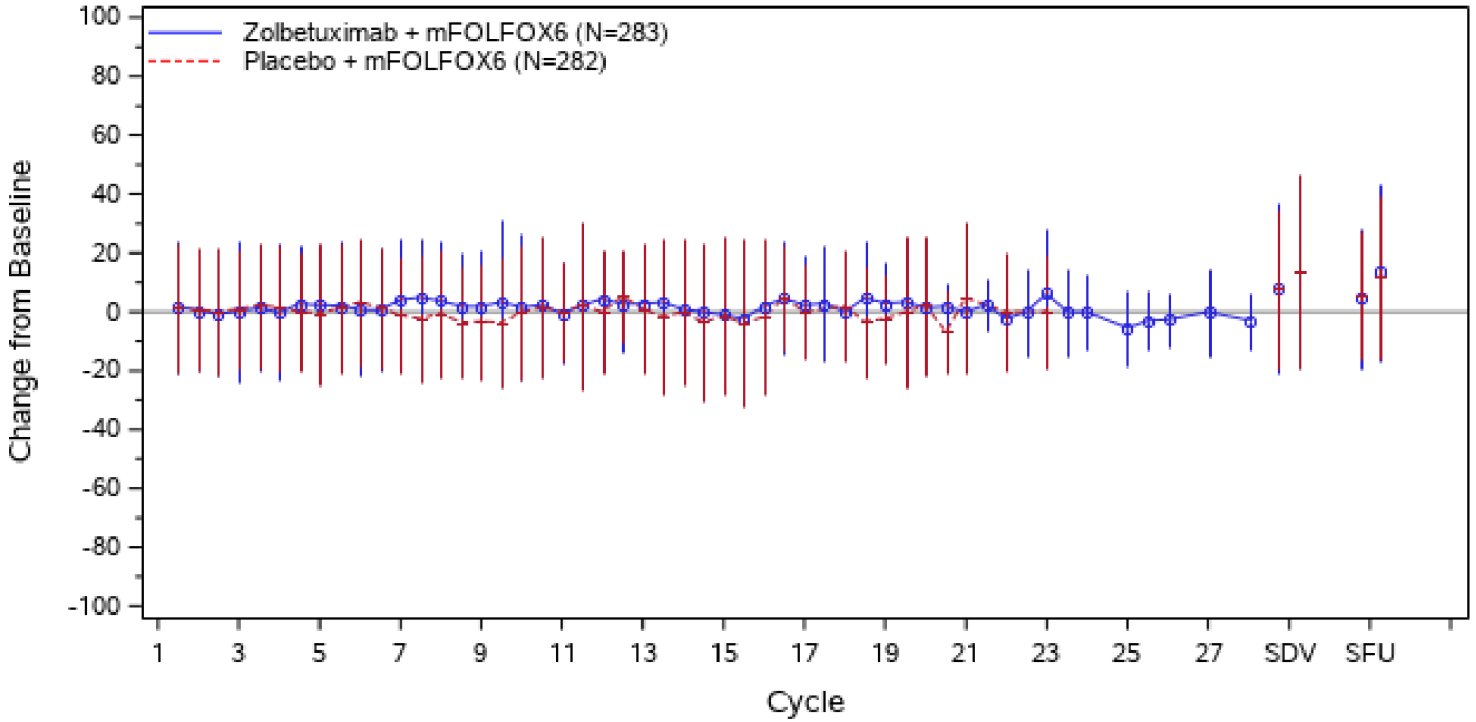
Region: Non-Asia



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

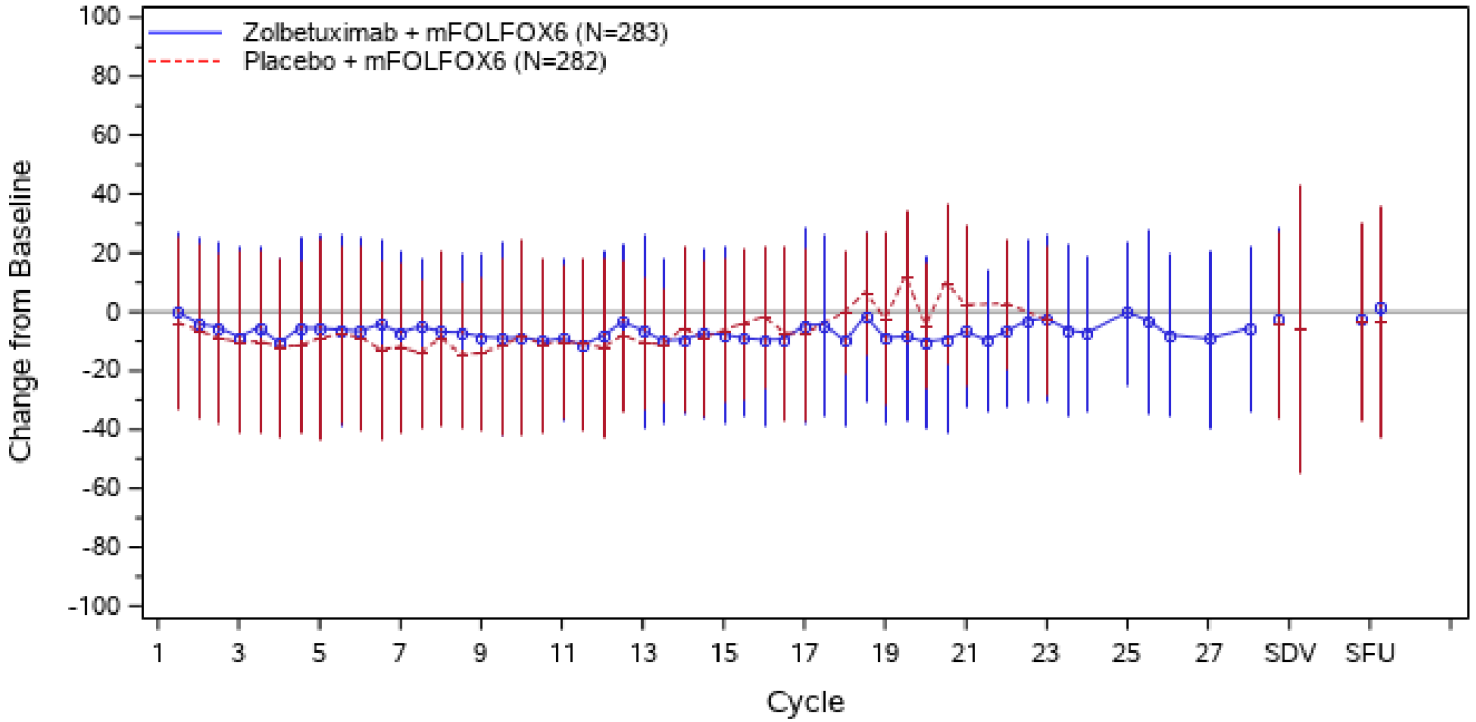
Figure 301.3.3002.14: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Dyspnoea - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

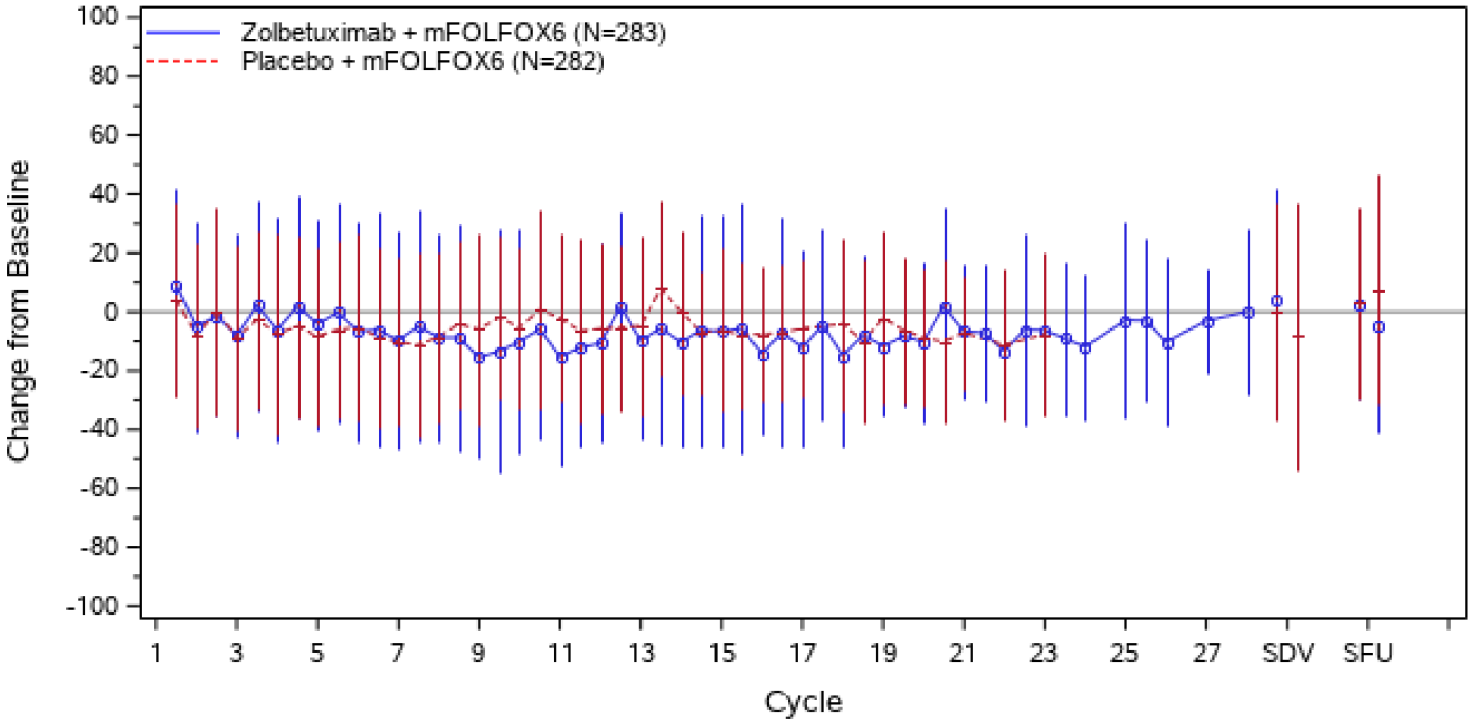
Figure 301.3.3002.15: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Insomnia - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

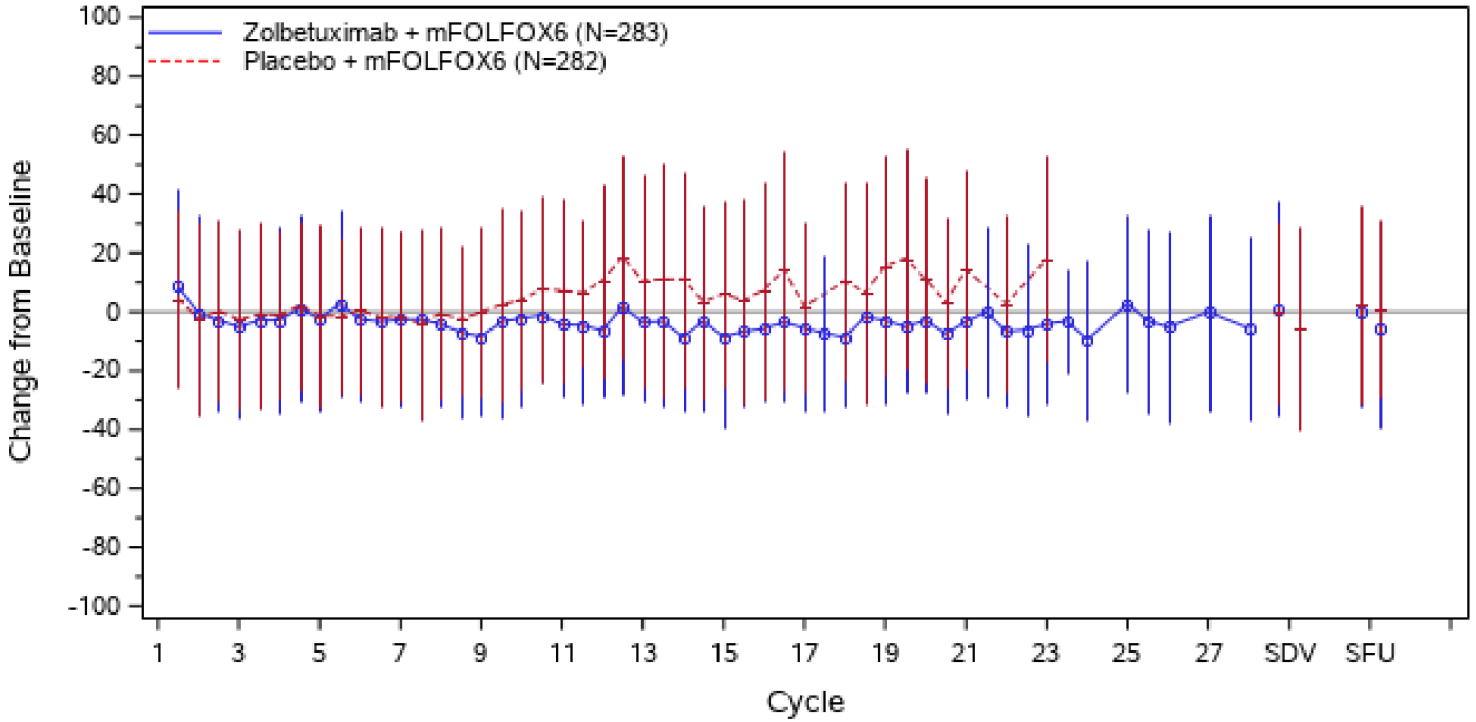
Figure 301.3.3002.16: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Appetite Loss - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

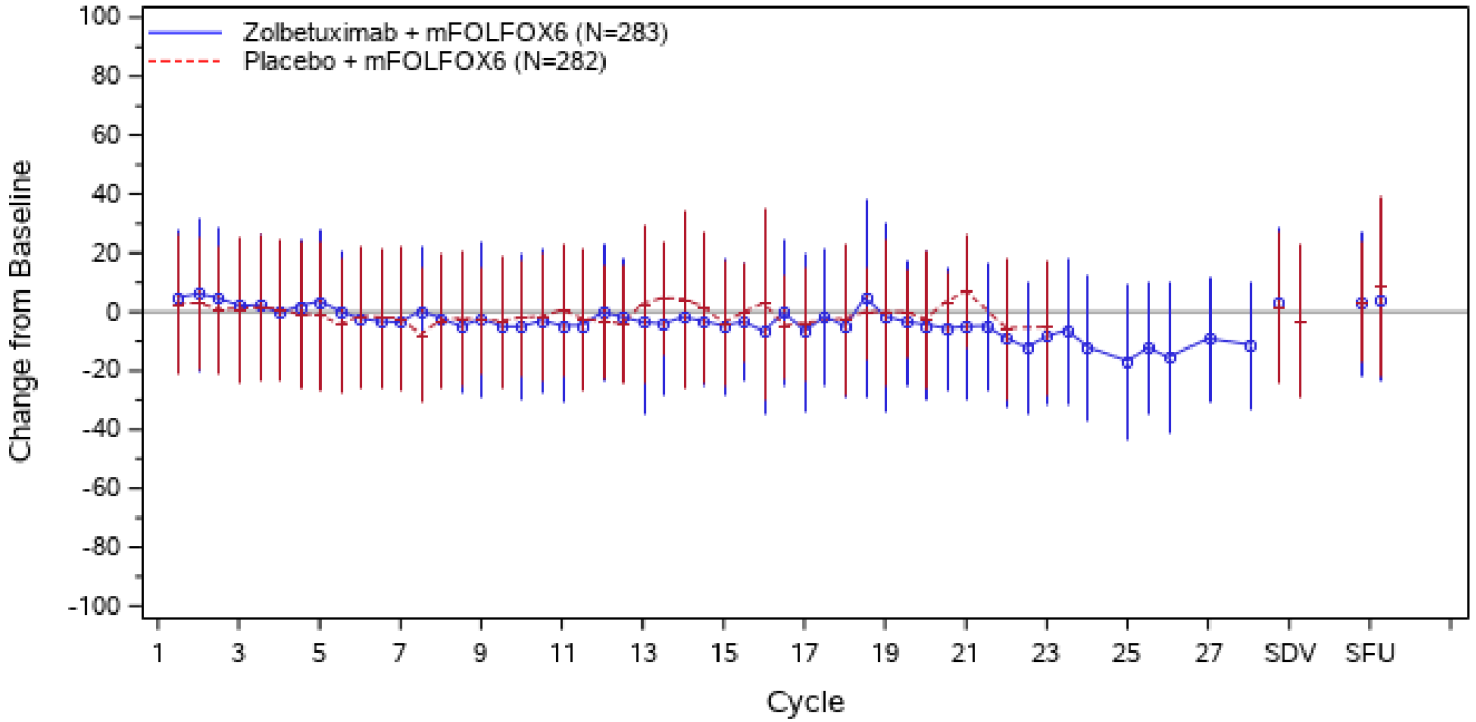
Figure 301.3.3002.17: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Constipation - Full Analysis Set



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.18: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea - Full Analysis Set

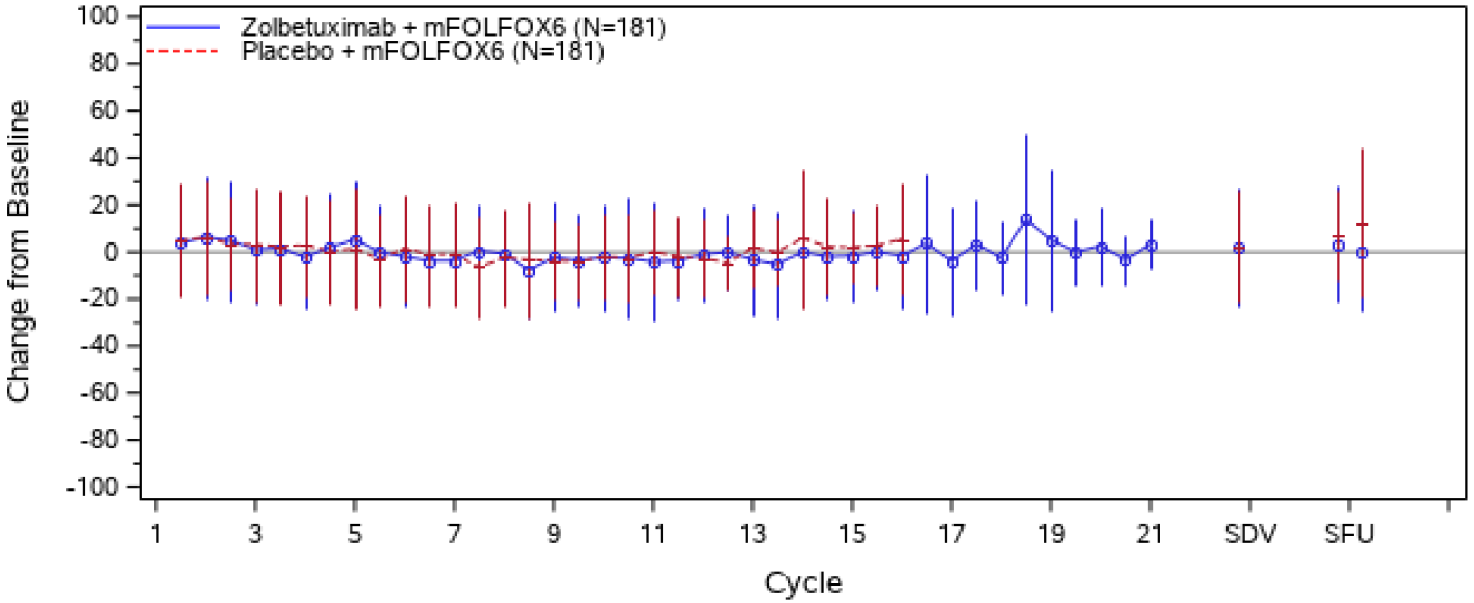


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.18.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

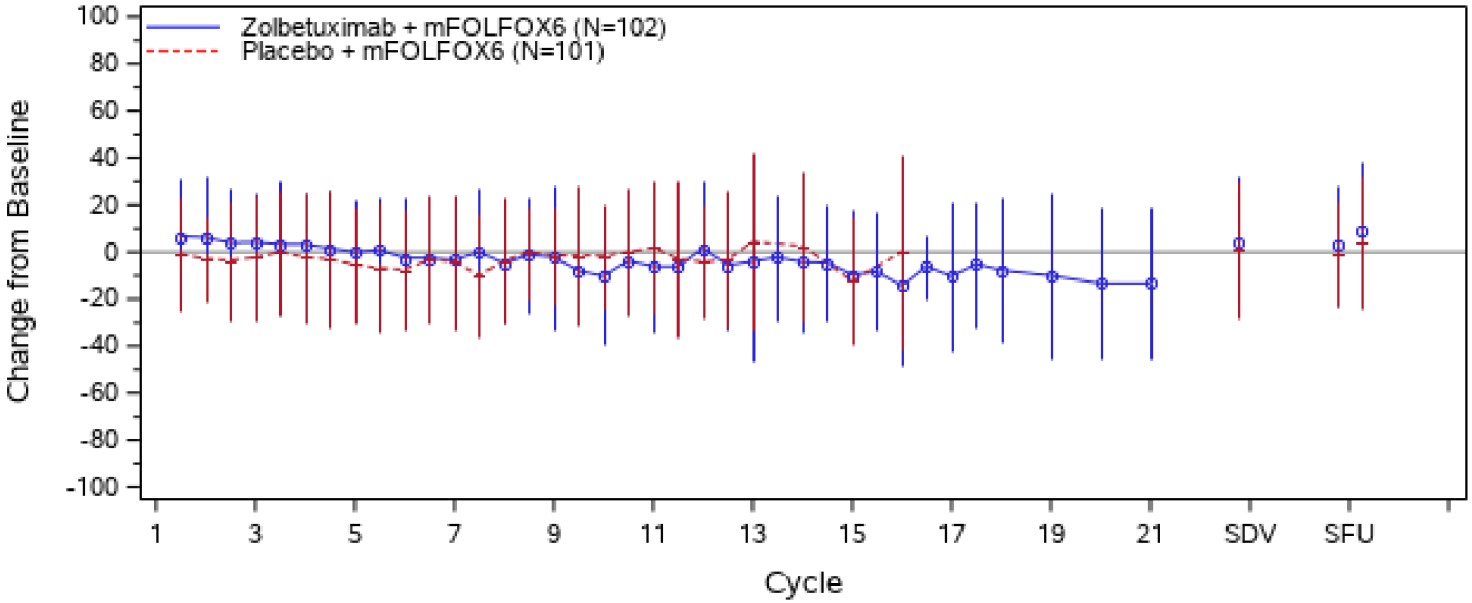


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.18.1: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Diarrhoea by Age Group 1 - Full Analysis Set

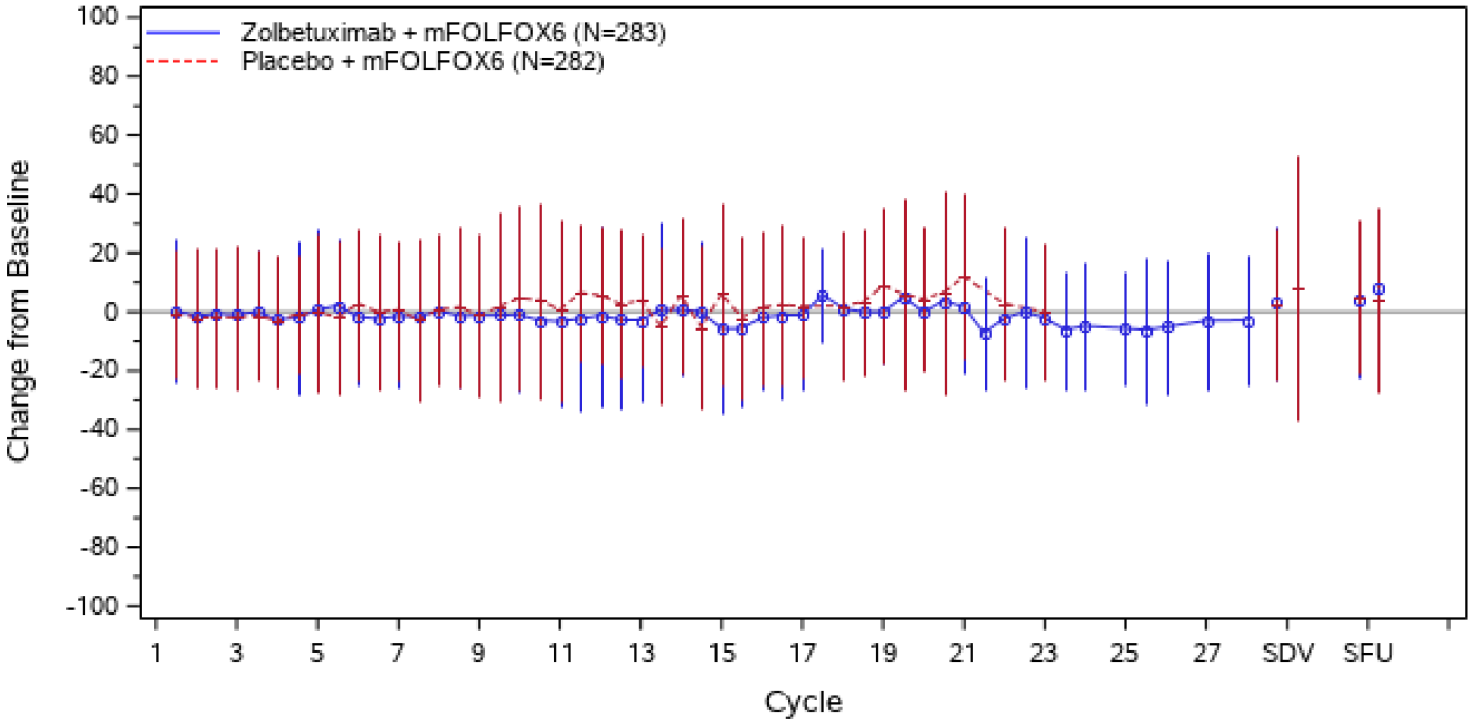
Age Group 1: >65 years



Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.19: EORTC QLQ-C30 v3.0 - Plot of Mean Change from Baseline of Financial Difficulties - Full Analysis Set

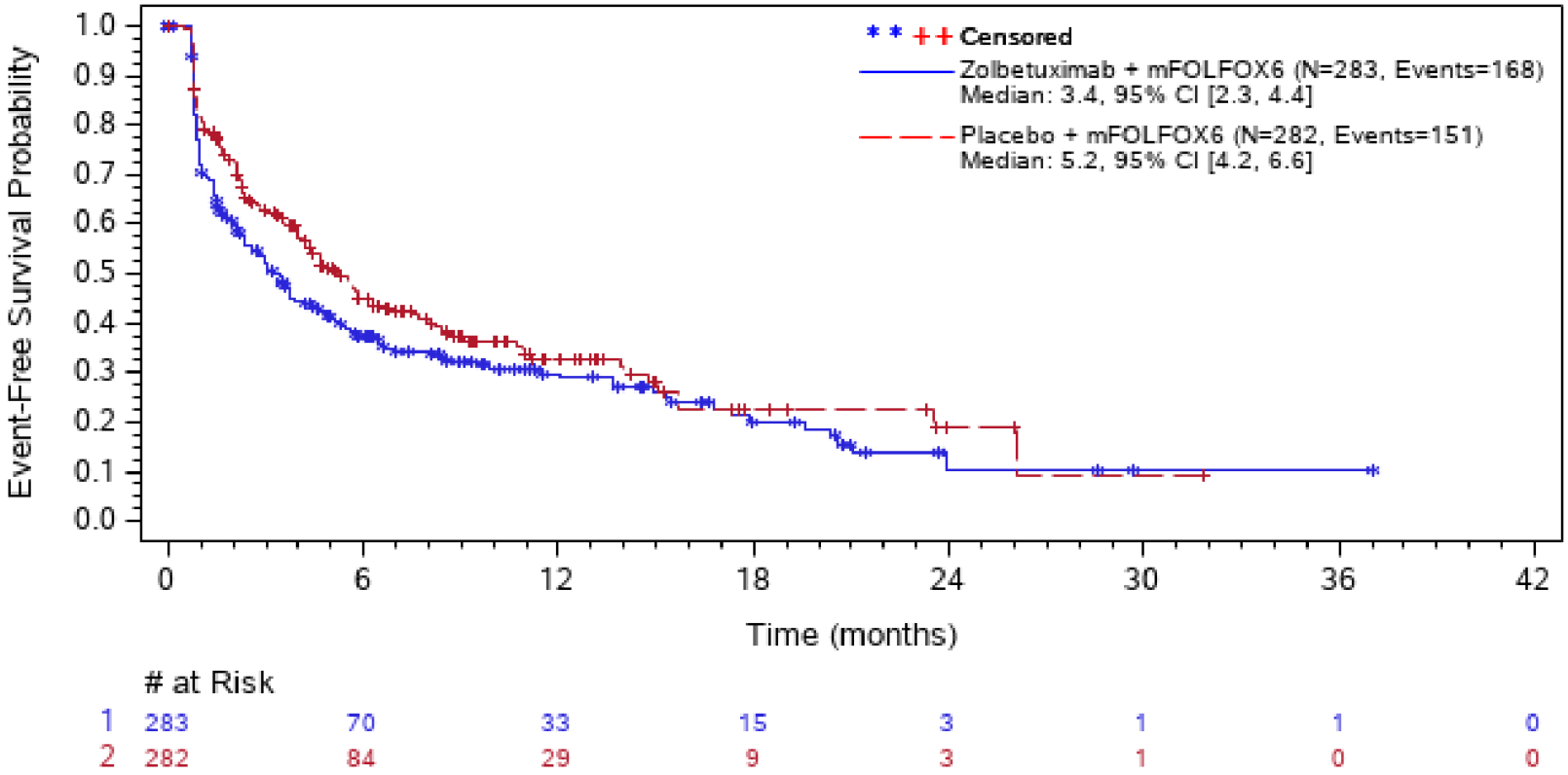


Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment 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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik und Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

5. Kaplan-Meier-Plots

Figure 301.3.3004.5: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Global Health Status (MID=10) - Full 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; MID=minimally important difference; 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.

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

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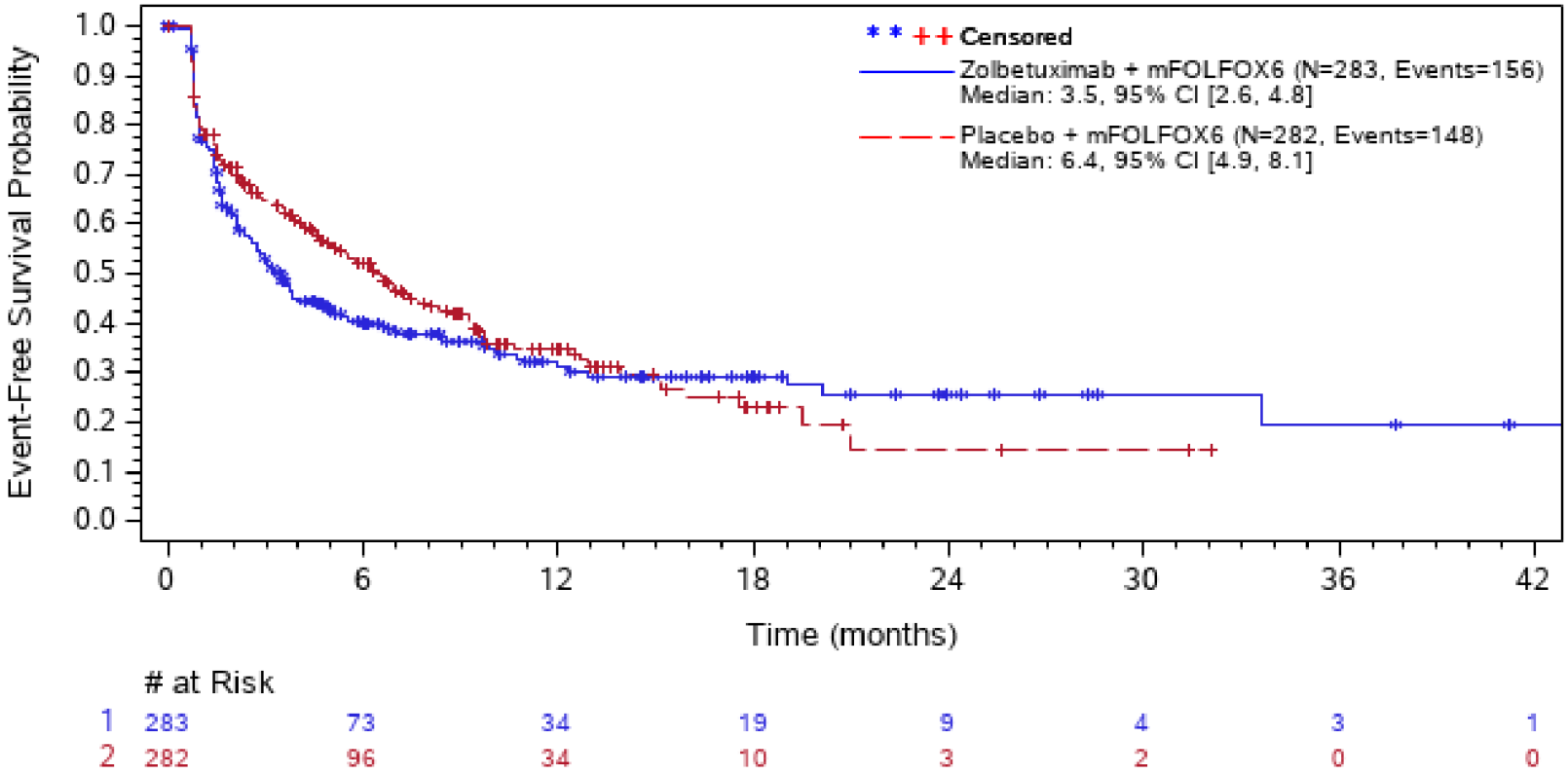
Figure 301.3.3004.6: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Physical Functioning (MID=10) - Full Analysis Set



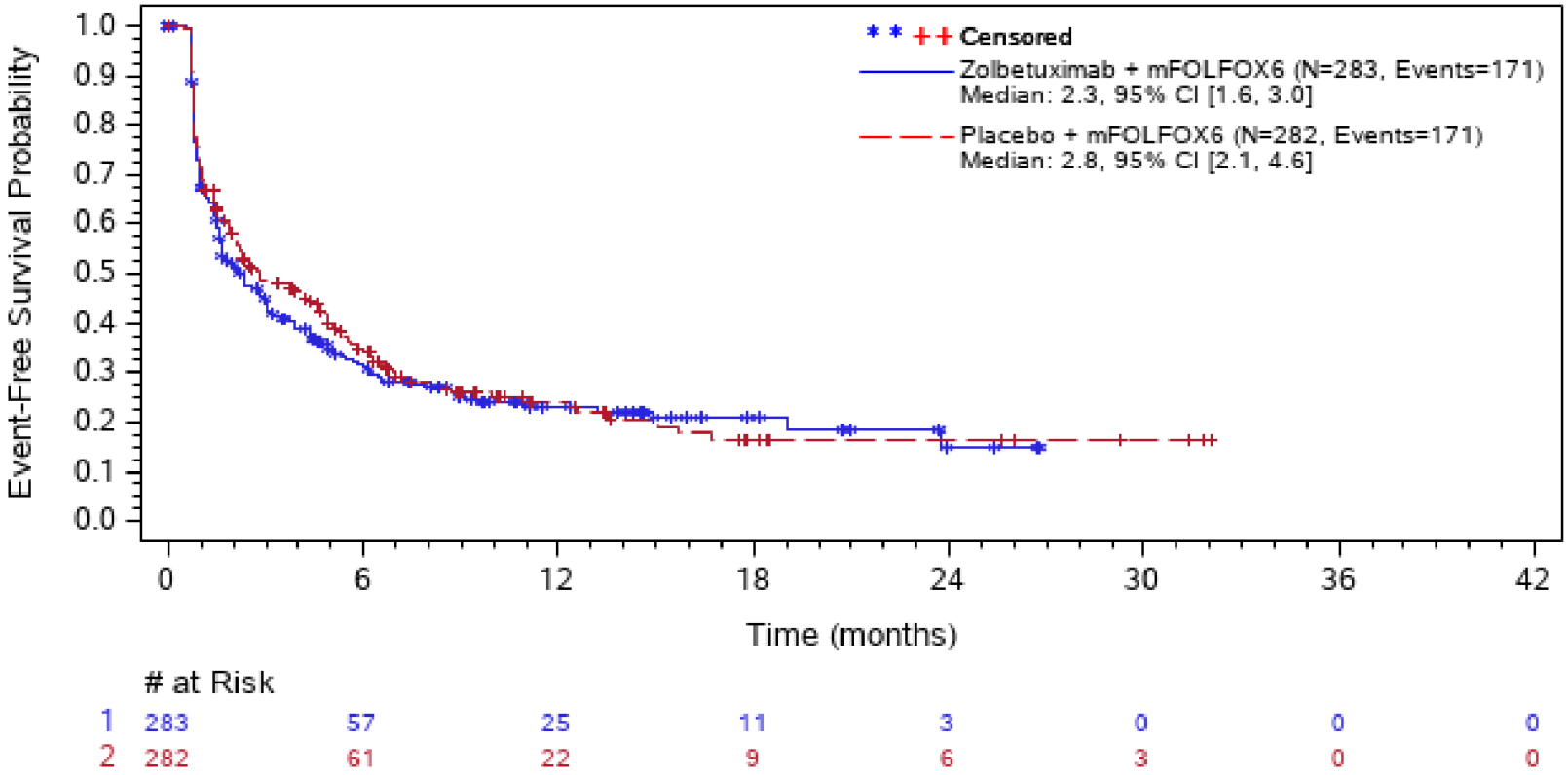
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.7: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Role Functioning (MID=10) - Full Analysis Set



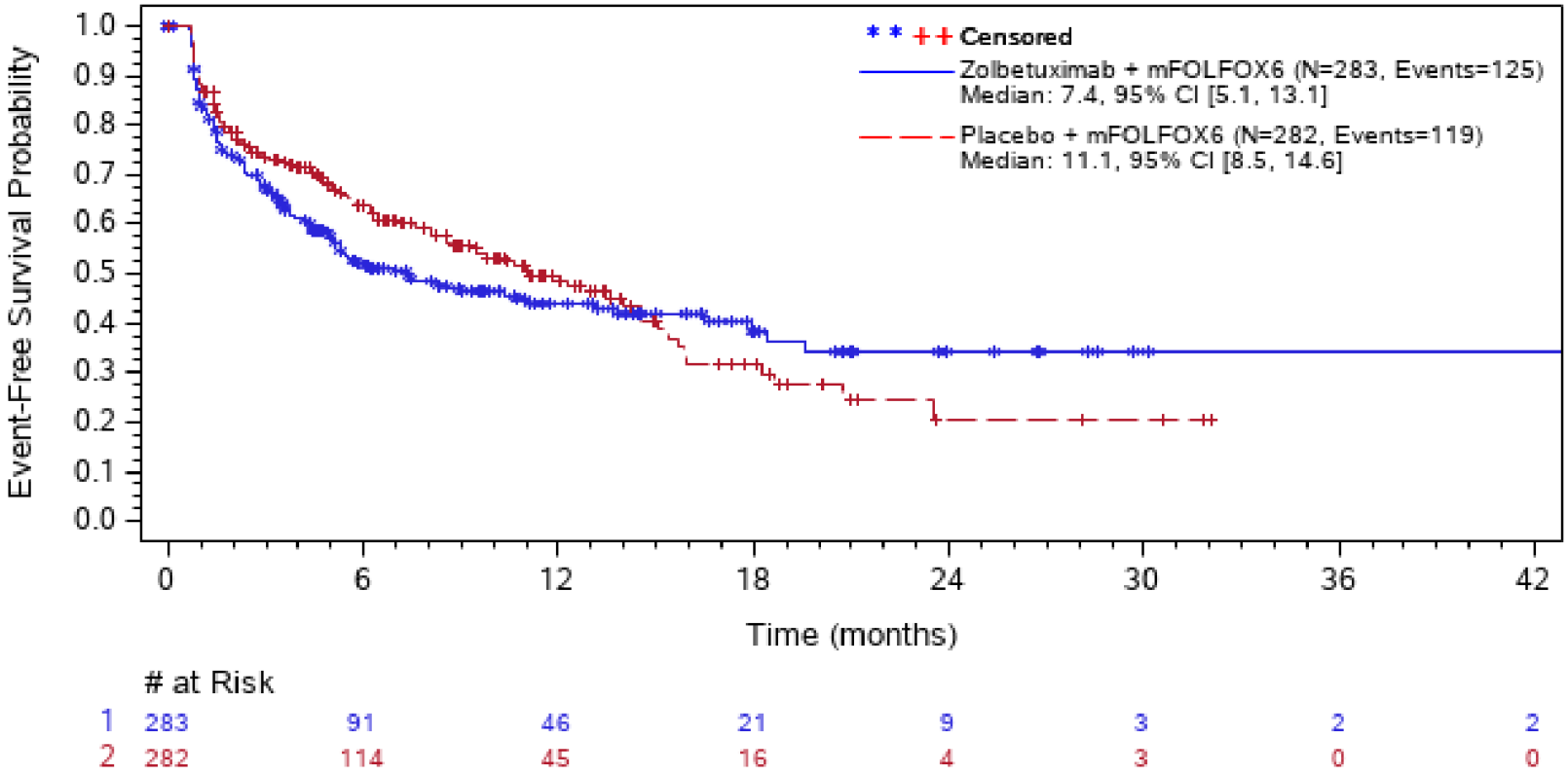
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.8: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Emotional Functioning (MID=10) - Full Analysis Set



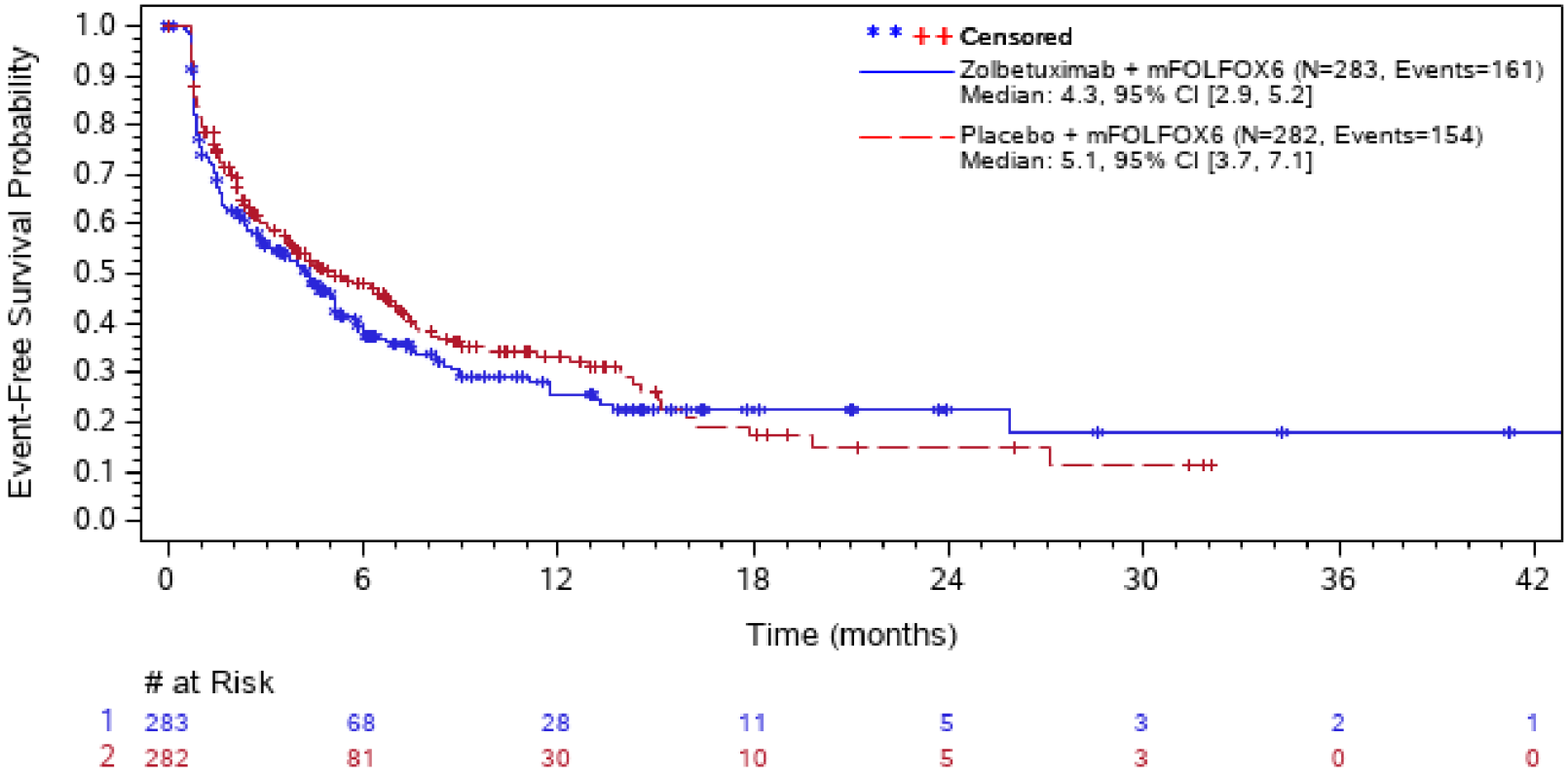
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.9: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Cognitive Functioning (MID=10) - Full Analysis Set



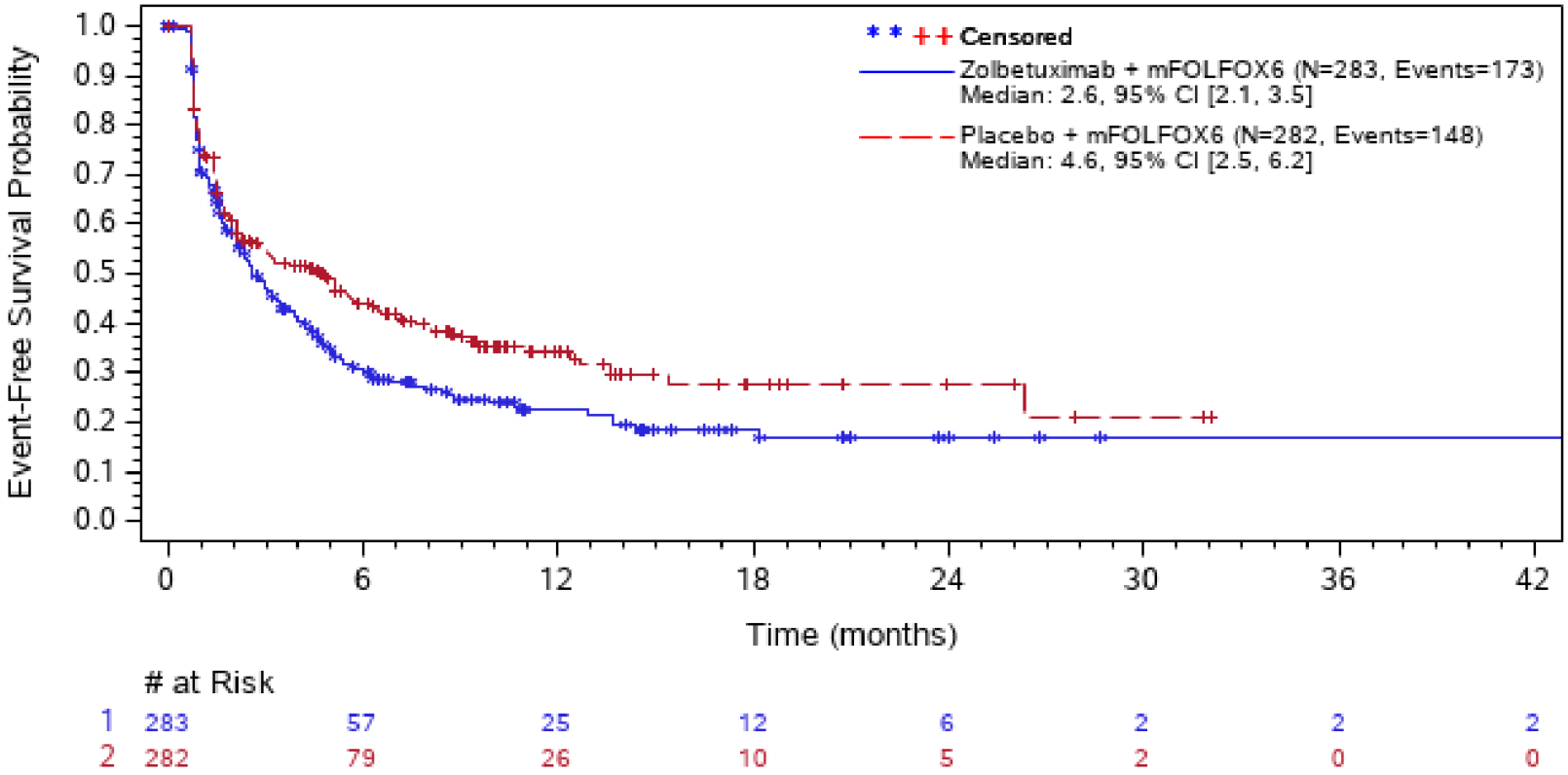
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.10: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Social Functioning (MID=10) - Full Analysis Set



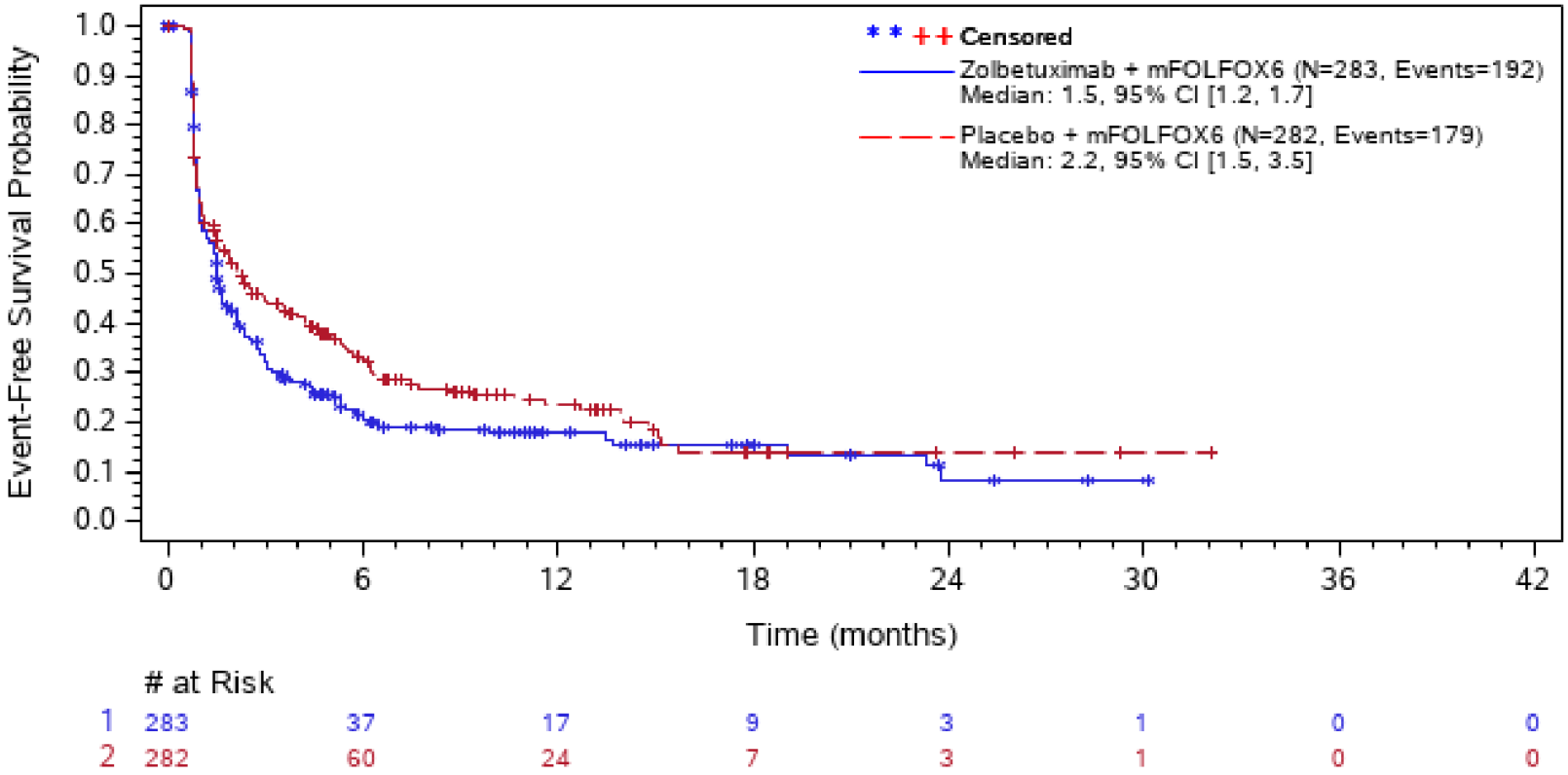
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.11: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

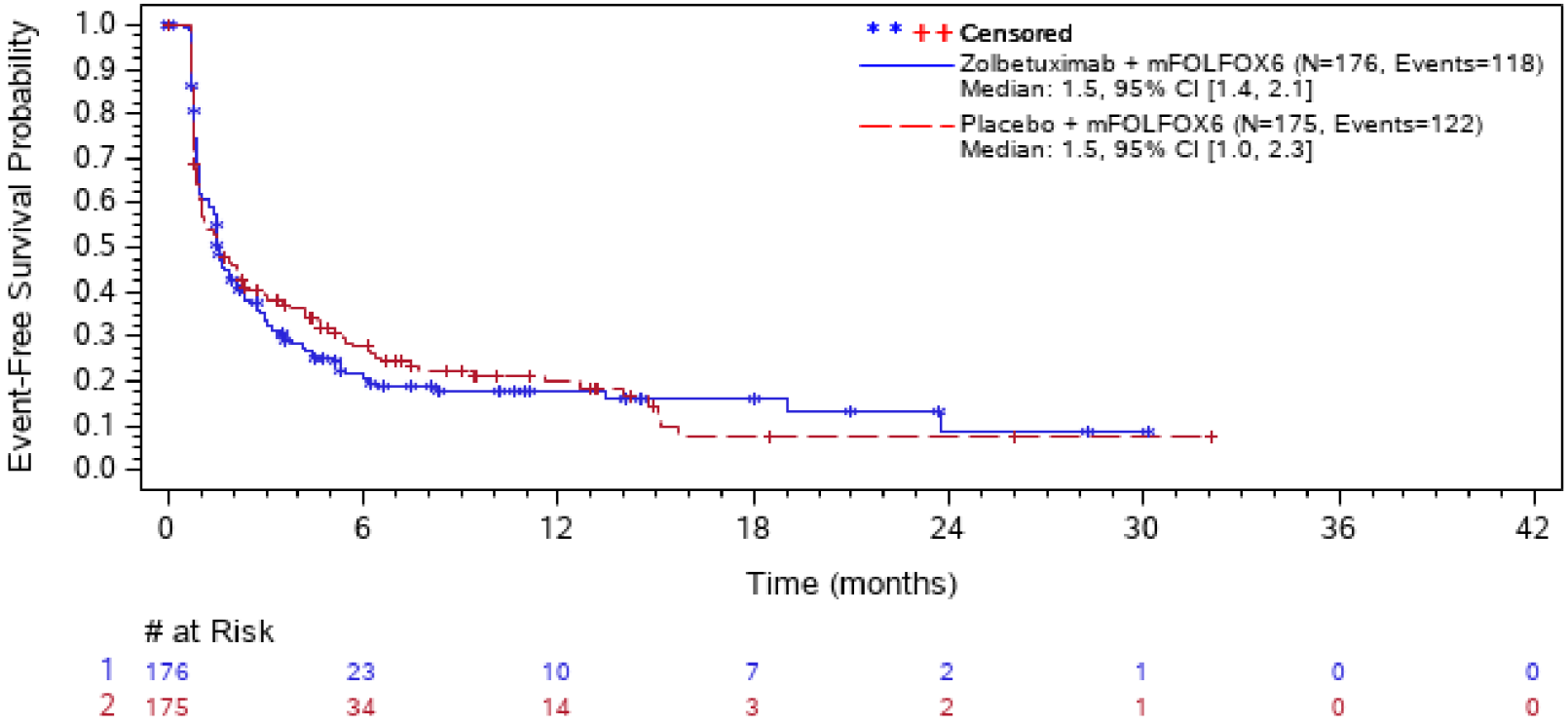
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.11.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue by Sex (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

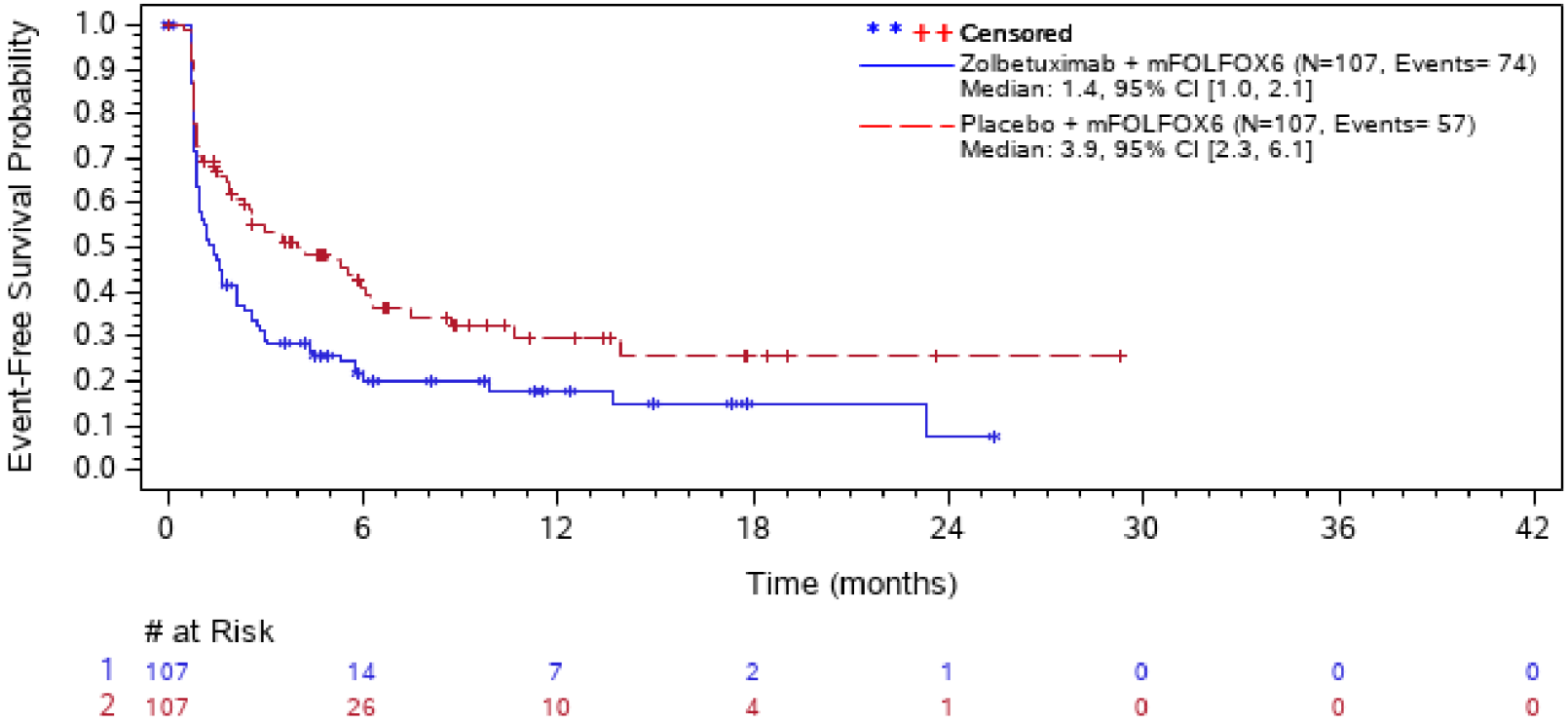
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.11.2: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Fatigue by Sex (MID=10) - Full Analysis Set

Sex: Female



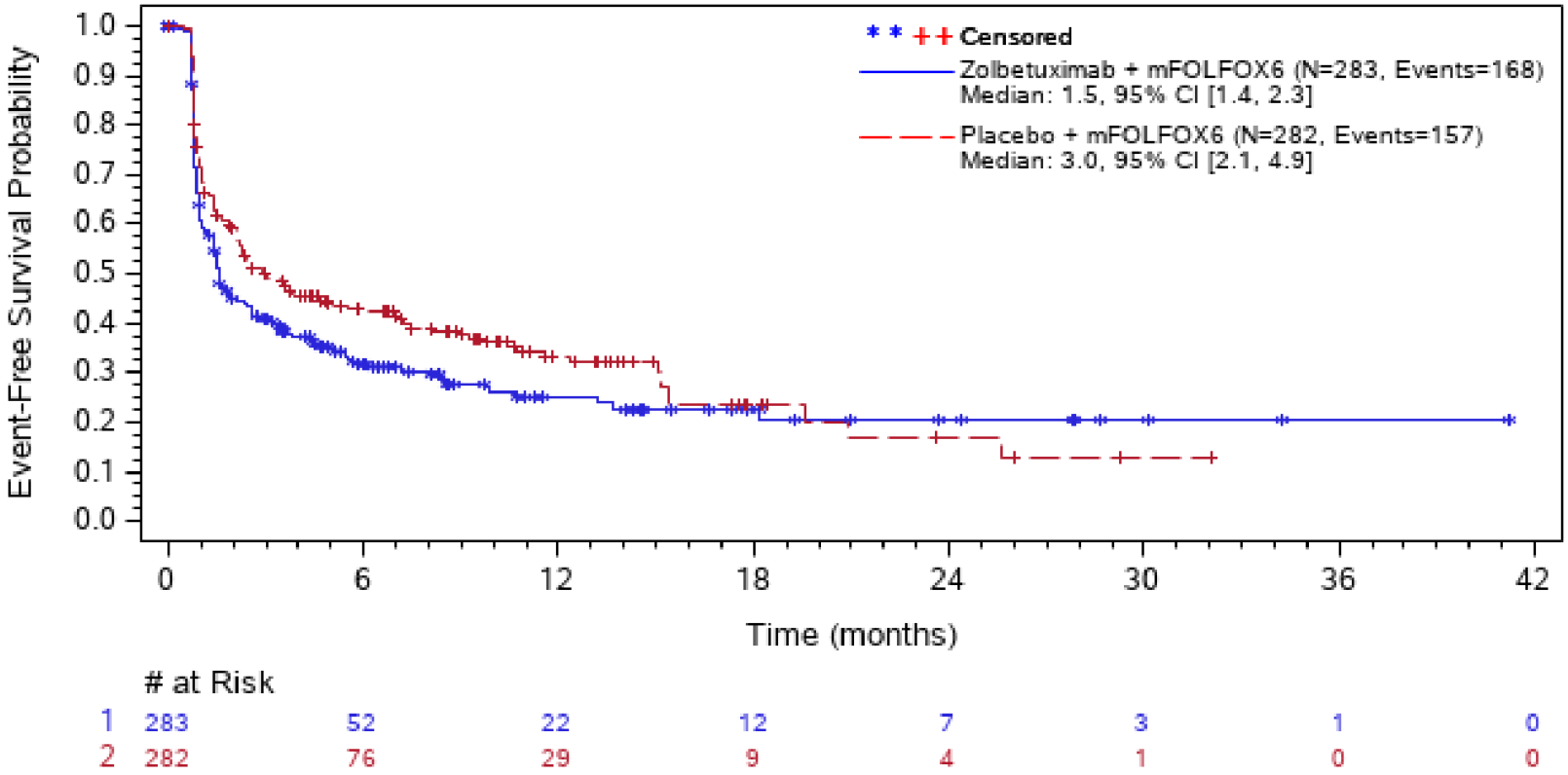
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.12: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Nausea and Vomiting (MID=10) - Full Analysis Set



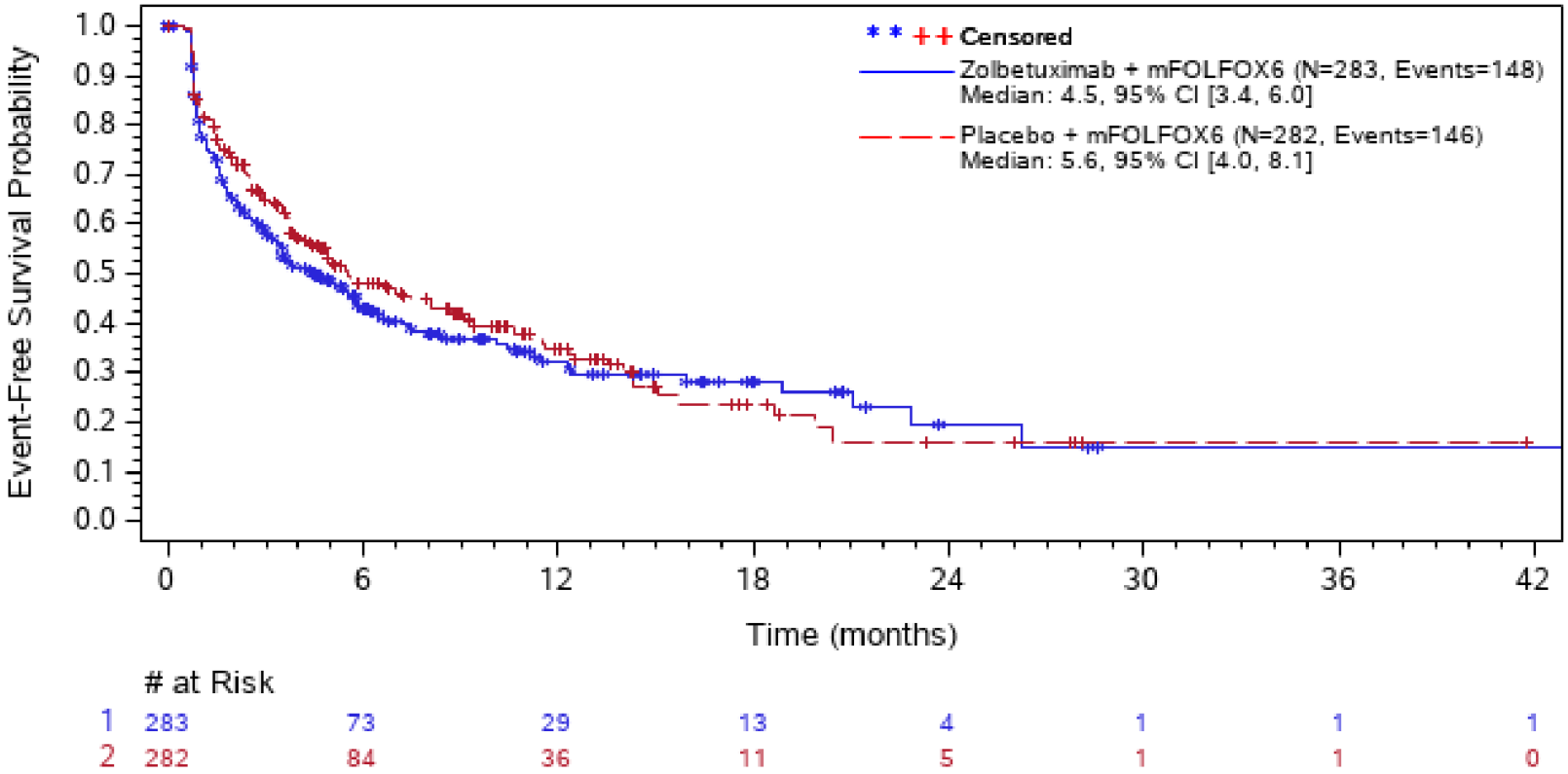
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.13: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

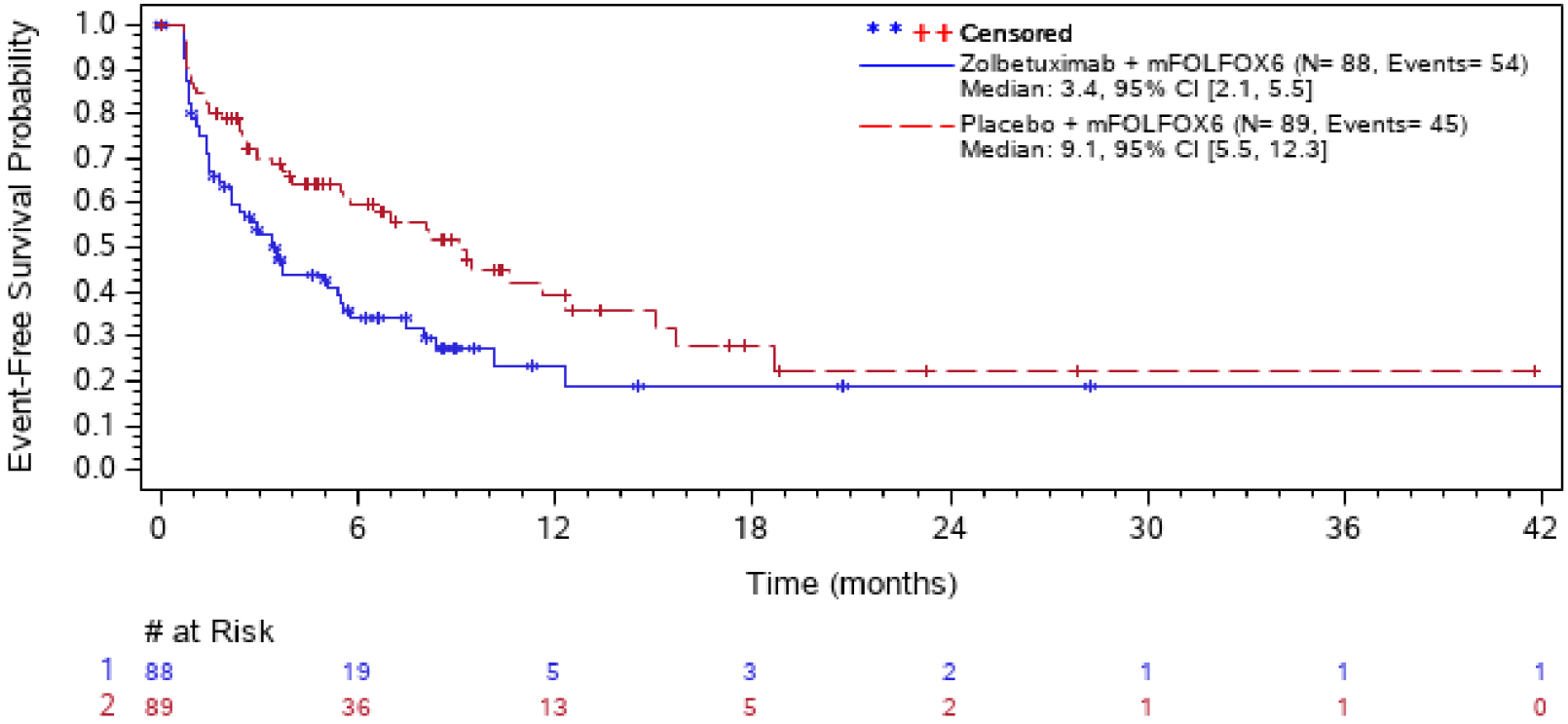
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.13.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain by Region (MID=10) - Full Analysis Set

Region: Asia



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; MID=minimally important difference; N=number of patients; NC=not calculated.

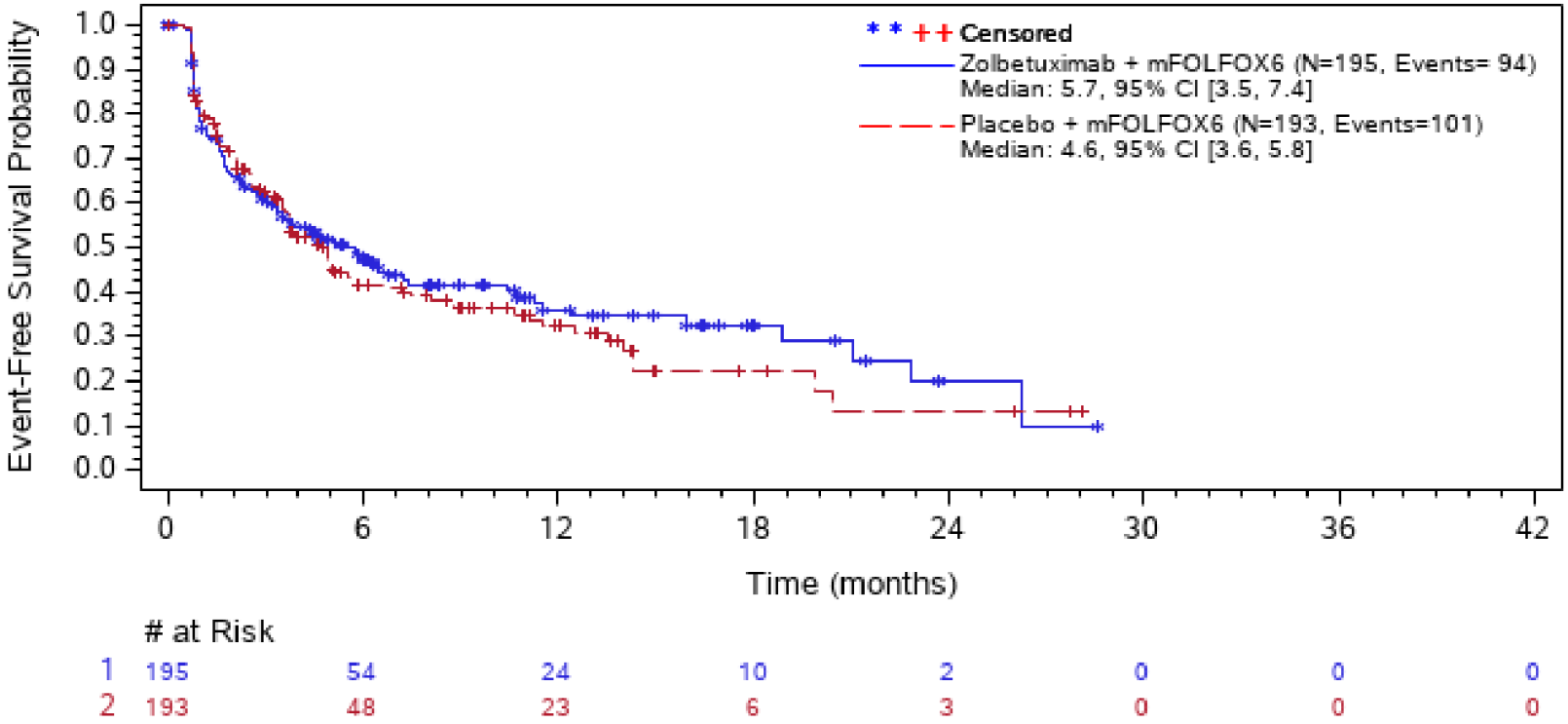
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.13.3: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Pain by Region (MID=10) - Full Analysis Set

Region: Non-Asia



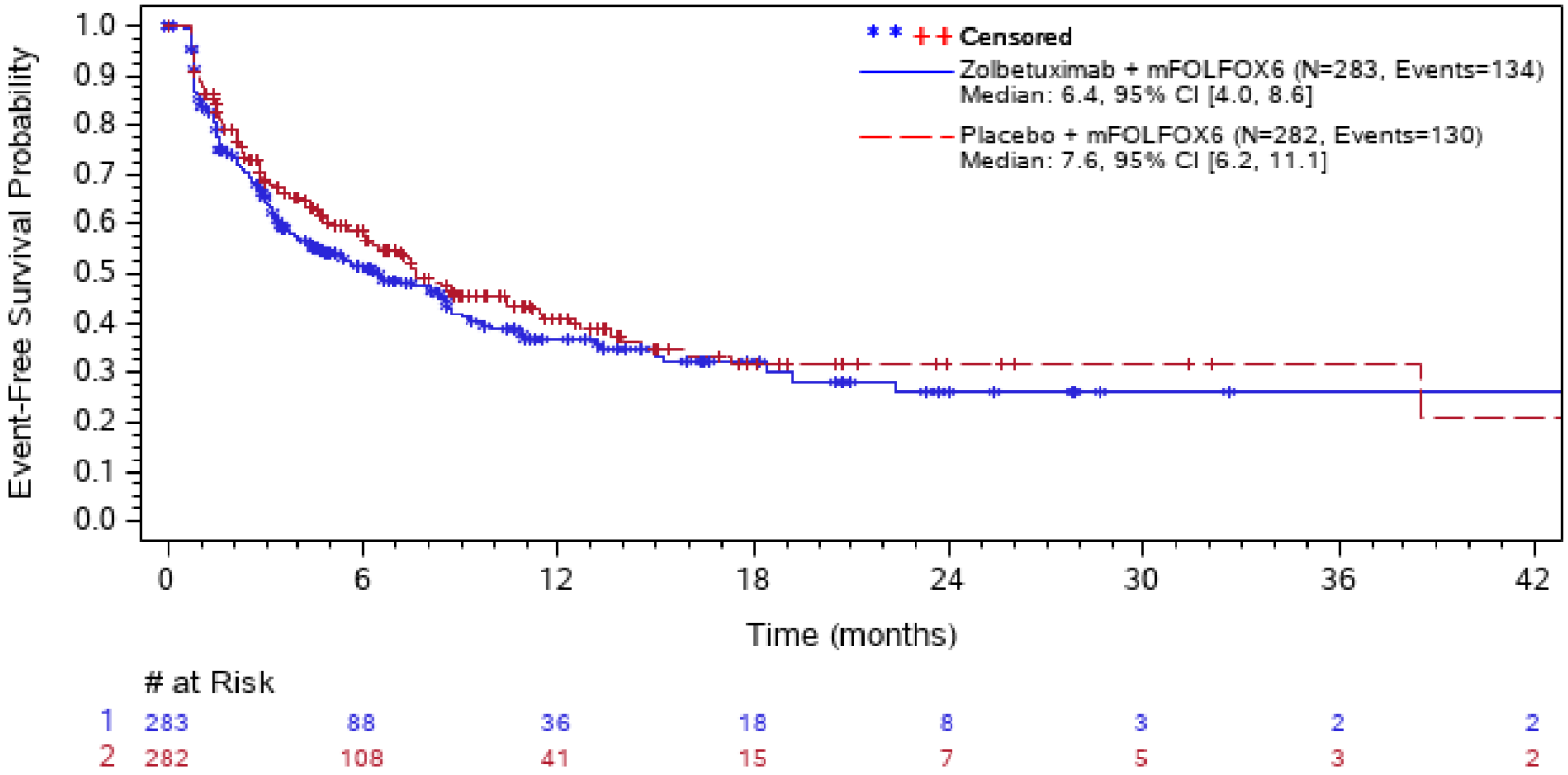
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.14: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Dyspnoea (MID=10) - Full Analysis Set



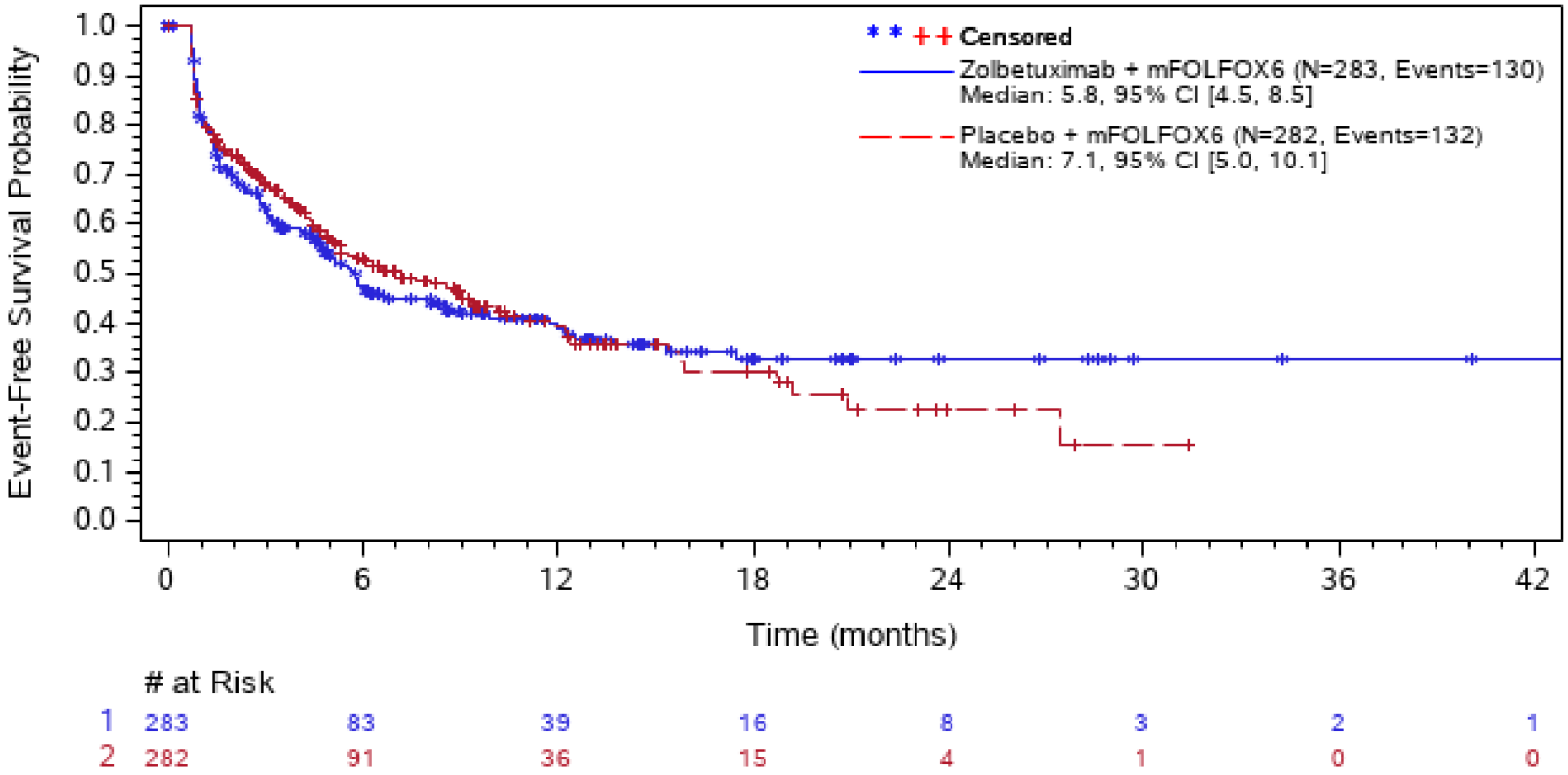
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.15: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Insomnia (MID=10) - Full Analysis Set



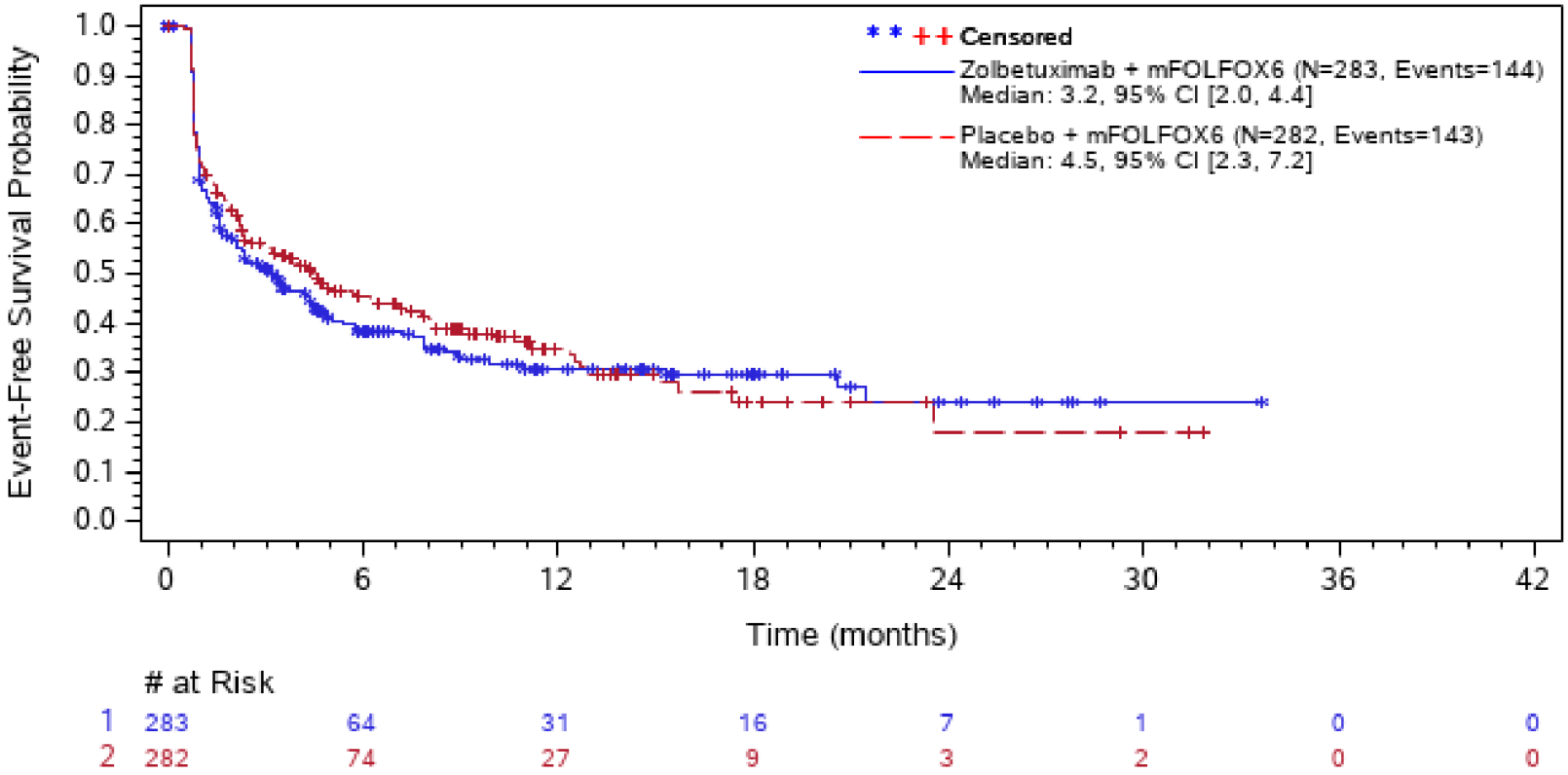
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.16: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Appetite Loss (MID=10) - Full Analysis Set



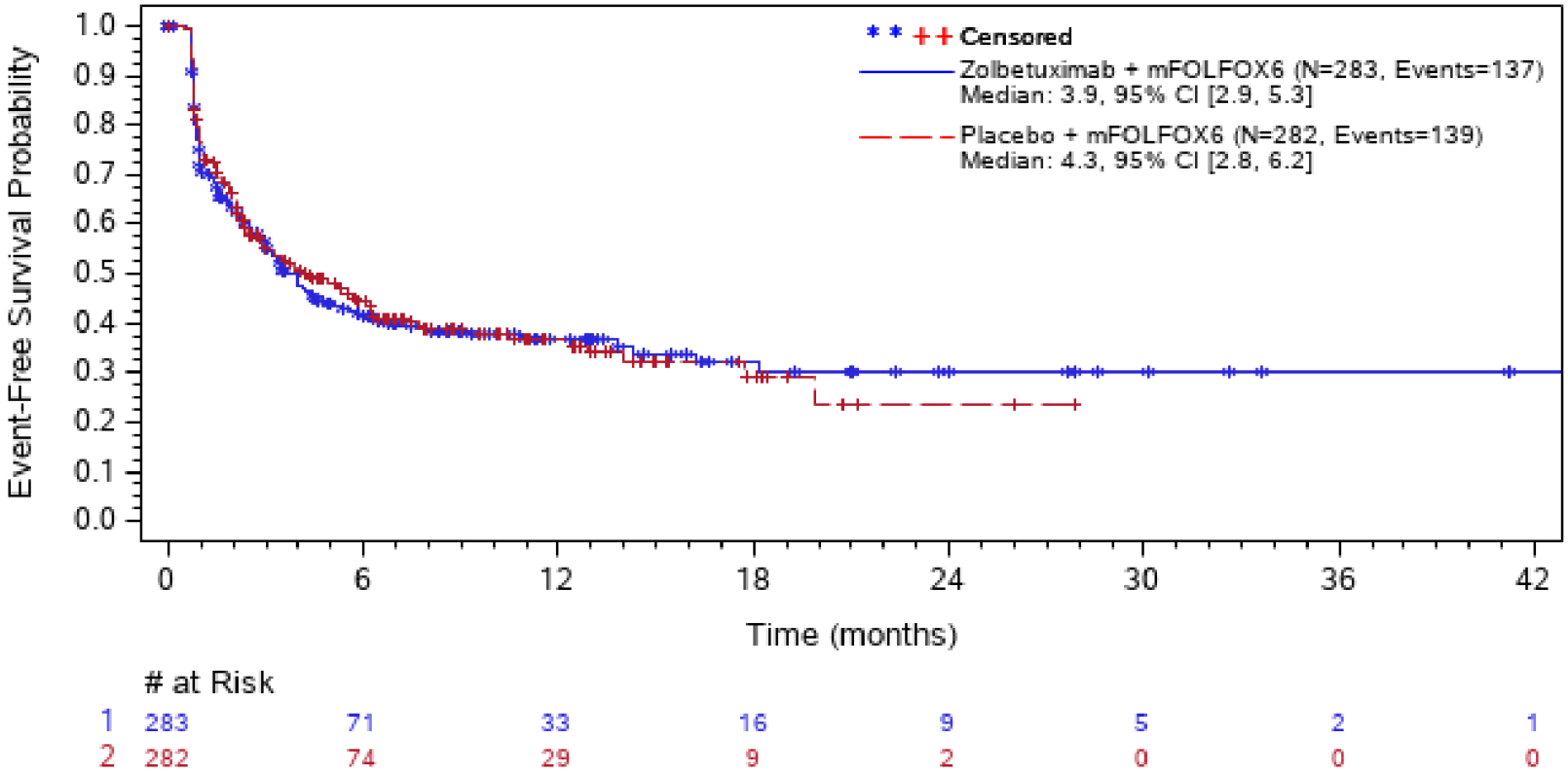
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.17: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Constipation (MID=10) - Full Analysis Set



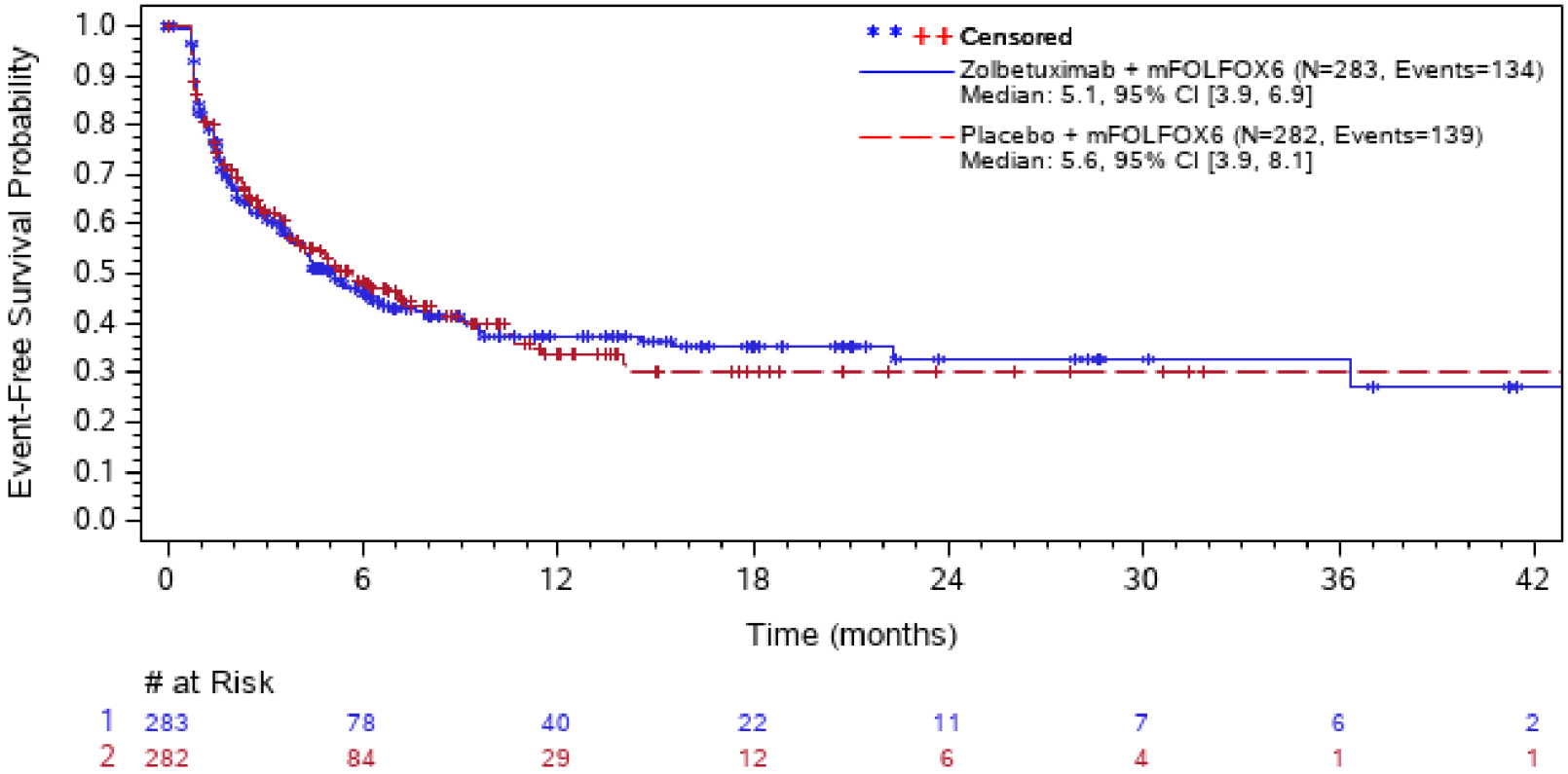
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.18: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

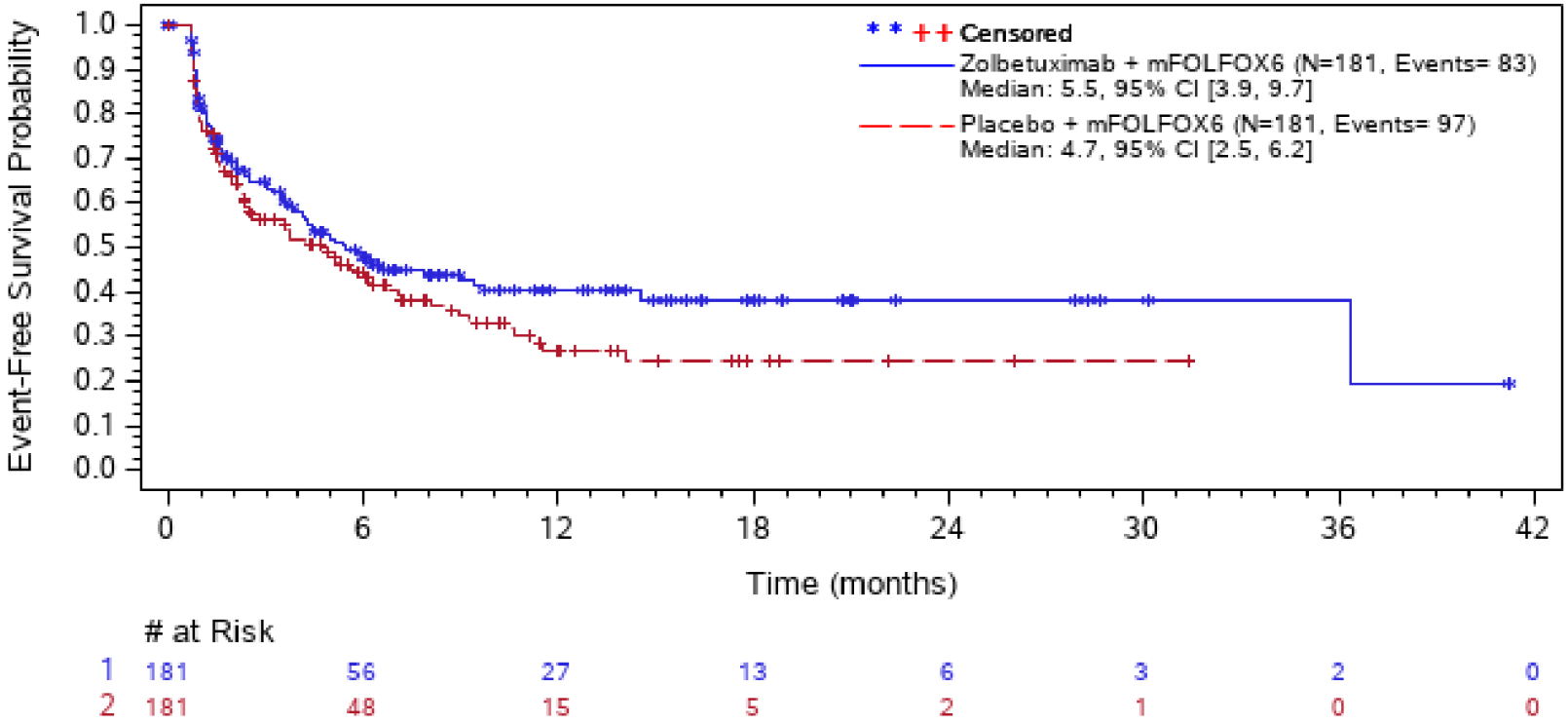
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.18.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea by Age Group 1 (MID=10) - Full 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; MID=minimally important difference; N=number of patients; NC=not calculated.

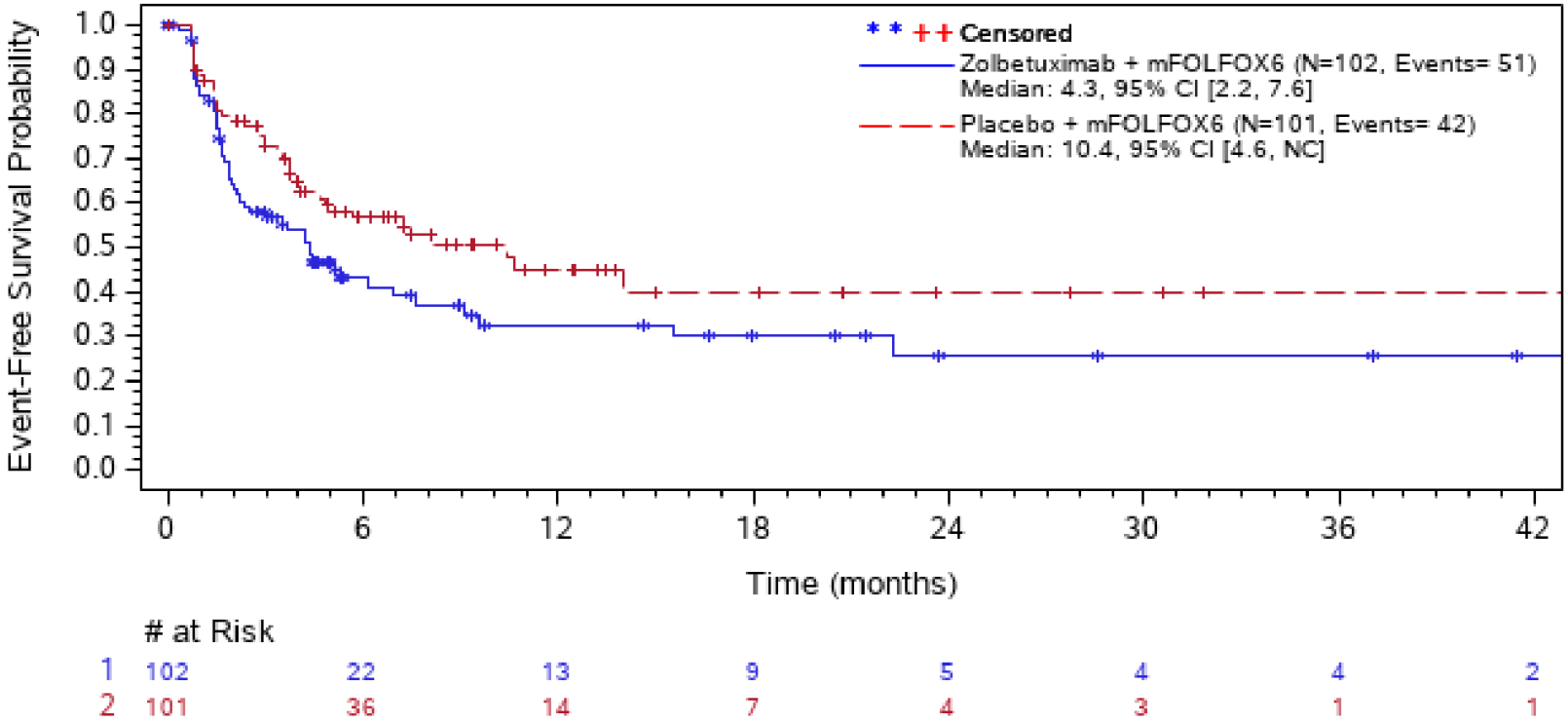
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.18.1: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Diarrhoea by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



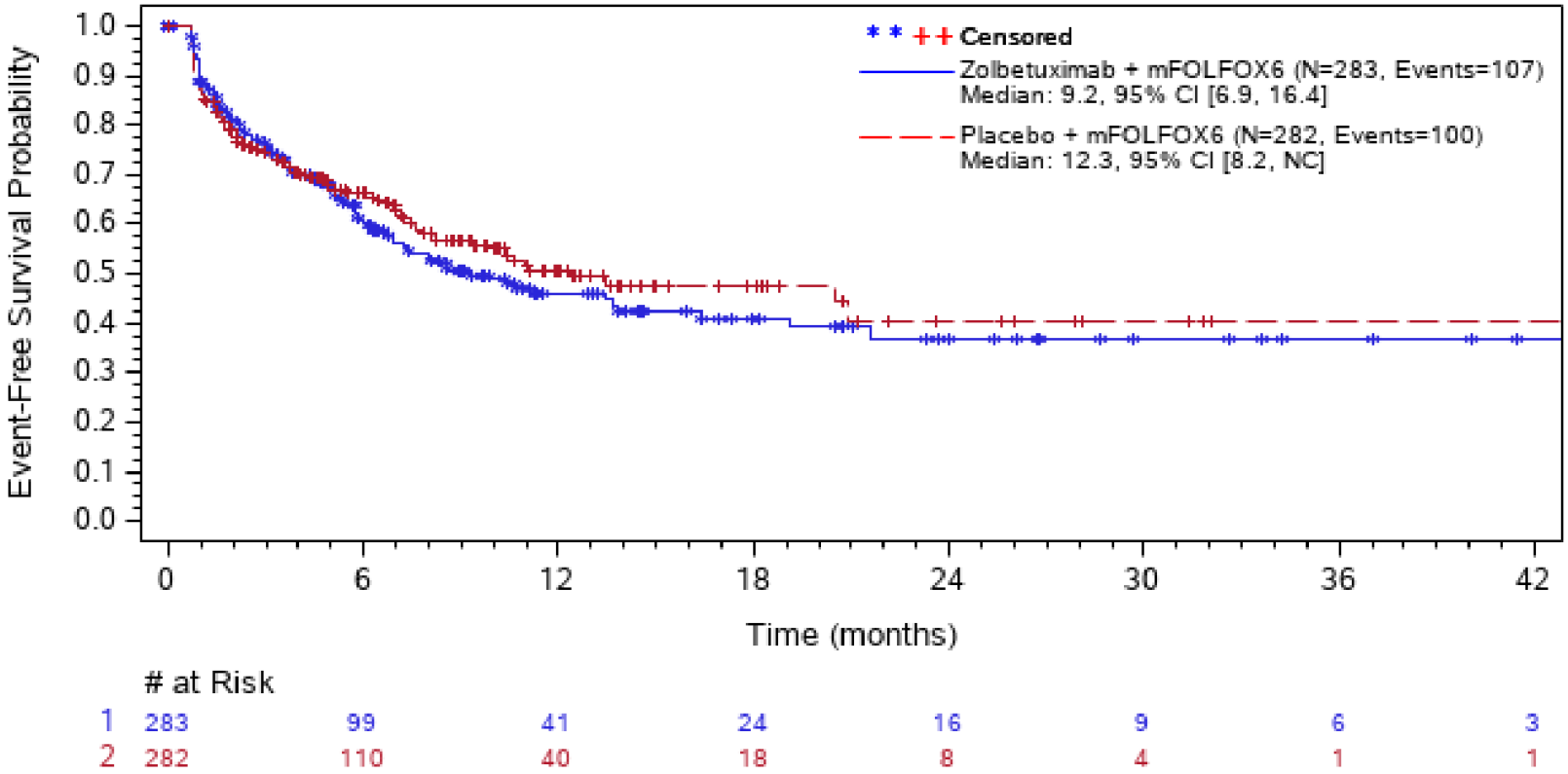
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.19: EORTC QLQ-C30 - Kaplan-Meier Plot of Time to First Deterioration of Financial Difficulties (MID=10) - Full 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; MID=minimally important difference; 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.

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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

1. Rücklaufquoten

Table 301.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	256/278 (92.1%)	256/280 (91.4%)	256/282 (90.8%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.2: EORTC QLQ-OG25 - Completion Status - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.20: EORTC QLQ-OG25 - Completion Status of Dysphagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.21: EORTC QLQ-OG25 - Completion Status of Eating Restrictions - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.22: EORTC QLQ-OG25 - Completion Status of Reflux - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.23: EORTC QLQ-OG25 - Completion Status of Odynophagia - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.24: EORTC QLQ-OG25 - Completion Status of Pain and Discomfort - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.25: EORTC QLQ-OG25 - Completion Status of Anxiety - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.26: EORTC QLQ-OG25 - Completion Status of Eating in Front of Others - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.27: EORTC QLQ-OG25 - Completion Status of Dry Mouth - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.28: EORTC QLQ-OG25 - Completion Status of Trouble with Taste - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.29: EORTC QLQ-OG25 - Completion Status of Body Image - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.30: EORTC QLQ-OG25 - Completion Status of Trouble Swallowing Saliva - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.31: EORTC QLQ-OG25 - Completion Status of Choked when Swallowing Score - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.32: EORTC QLQ-OG25 - Completion Status of Trouble with Coughing - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.33: EORTC QLQ-OG25 - Completion Status of Trouble Talking - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	185/257 (72.0%)	186/273 (68.1%)	186/283 (65.7%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	213/244 (87.3%)	213/262 (81.3%)	216/283 (76.3%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	203/228 (89.0%)	203/259 (78.4%)	203/282 (72.0%)
Cycle 3 Day 22	160/204 (78.4%)	161/248 (64.9%)	161/283 (56.9%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	127/179 (70.9%)	127/238 (53.4%)	127/283 (44.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	124/144 (86.1%)	126/244 (51.6%)	126/282 (44.7%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	40/ 61 (65.6%)	40/224 (17.9%)	40/283 (14.1%)	27/ 42 (64.3%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	20/ 26 (76.9%)	20/218 (9.2%)	20/283 (7.1%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.34: EORTC QLQ-OG25 - Completion Status of Weight Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	149/243 (61.3%)	149/269 (55.4%)	149/283 (52.7%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	83/186 (44.6%)	83/205 (40.5%)	84/282 (29.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	64/279 (22.9%)	64/282 (22.7%)	64/283 (22.6%)	66/278 (23.7%)	66/280 (23.6%)	66/282 (23.4%)
Cycle 1 Day 22	60/257 (23.3%)	61/273 (22.3%)	61/283 (21.6%)	85/266 (32.0%)	85/271 (31.4%)	85/282 (30.1%)
Cycle 2 Day 1	96/244 (39.3%)	96/262 (36.6%)	98/283 (34.6%)	106/263 (40.3%)	107/270 (39.6%)	107/282 (37.9%)
Cycle 2 Day 22	84/222 (37.8%)	84/255 (32.9%)	84/283 (29.7%)	89/243 (36.6%)	89/264 (33.7%)	89/282 (31.6%)
Cycle 3 Day 1	104/215 (48.4%)	104/252 (41.3%)	106/283 (37.5%)	99/228 (43.4%)	99/259 (38.2%)	99/282 (35.1%)
Cycle 3 Day 22	96/204 (47.1%)	96/248 (38.7%)	96/283 (33.9%)	80/219 (36.5%)	80/257 (31.1%)	80/282 (28.4%)
Cycle 4 Day 1	95/192 (49.5%)	97/241 (40.2%)	99/283 (35.0%)	87/202 (43.1%)	87/254 (34.3%)	87/282 (30.9%)
Cycle 4 Day 22	81/179 (45.3%)	81/238 (34.0%)	81/283 (28.6%)	68/185 (36.8%)	68/251 (27.1%)	68/282 (24.1%)
Cycle 5 Day 1	87/172 (50.6%)	89/236 (37.7%)	90/283 (31.8%)	81/172 (47.1%)	81/251 (32.3%)	81/282 (28.7%)
Cycle 5 Day 22	63/156 (40.4%)	63/233 (27.0%)	63/283 (22.3%)	58/155 (37.4%)	59/248 (23.8%)	59/282 (20.9%)
Cycle 6 Day 1	74/144 (51.4%)	76/233 (32.6%)	76/283 (26.9%)	60/144 (41.7%)	61/244 (25.0%)	61/282 (21.6%)
Cycle 6 Day 22	57/135 (42.2%)	57/231 (24.7%)	57/283 (20.1%)	46/128 (35.9%)	46/242 (19.0%)	46/282 (16.3%)
Cycle 7 Day 1	60/130 (46.2%)	61/231 (26.4%)	61/283 (21.6%)	49/114 (43.0%)	49/239 (20.5%)	49/282 (17.4%)
Cycle 7 Day 22	48/120 (40.0%)	48/229 (21.0%)	48/283 (17.0%)	34/105 (32.4%)	34/237 (14.3%)	34/282 (12.1%)
Cycle 8 Day 1	50/110 (45.5%)	50/226 (22.1%)	50/283 (17.7%)	39/ 97 (40.2%)	39/237 (16.5%)	39/282 (13.8%)
Cycle 8 Day 22	37/100 (37.0%)	38/226 (16.8%)	38/283 (13.4%)	30/ 87 (34.5%)	30/235 (12.8%)	30/282 (10.6%)
Cycle 9 Day 1	40/ 94 (42.6%)	40/224 (17.9%)	40/283 (14.1%)	28/ 75 (37.3%)	28/234 (12.0%)	28/282 (9.9%)
Cycle 9 Day 22	33/ 84 (39.3%)	33/224 (14.7%)	33/283 (11.7%)	27/ 71 (38.0%)	27/234 (11.5%)	27/282 (9.6%)
Cycle 10 Day 1	36/ 80 (45.0%)	37/224 (16.5%)	37/283 (13.1%)	23/ 61 (37.7%)	24/234 (10.3%)	24/282 (8.5%)
Cycle 10 Day 22	29/ 77 (37.7%)	29/224 (12.9%)	29/283 (10.2%)	16/ 55 (29.1%)	16/234 (6.8%)	16/282 (5.7%)
Cycle 11 Day 1	33/ 74 (44.6%)	33/224 (14.7%)	33/283 (11.7%)	18/ 52 (34.6%)	18/234 (7.7%)	18/282 (6.4%)
Cycle 11 Day 22	23/ 67 (34.3%)	24/224 (10.7%)	24/283 (8.5%)	12/ 48 (25.0%)	12/233 (5.2%)	12/282 (4.3%)
Cycle 12 Day 1	26/ 65 (40.0%)	26/224 (11.6%)	26/283 (9.2%)	15/ 46 (32.6%)	15/233 (6.4%)	15/282 (5.3%)
Cycle 12 Day 22	21/ 61 (34.4%)	21/224 (9.4%)	21/283 (7.4%)	13/ 42 (31.0%)	13/230 (5.7%)	13/282 (4.6%)
Cycle 13 Day 1	26/ 60 (43.3%)	26/224 (11.6%)	26/283 (9.2%)	13/ 40 (32.5%)	13/230 (5.7%)	13/282 (4.6%)
Cycle 13 Day 22	21/ 52 (40.4%)	21/222 (9.5%)	22/283 (7.8%)	8/ 37 (21.6%)	8/230 (3.5%)	8/282 (2.8%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	21/ 45 (46.7%)	21/222 (9.5%)	21/283 (7.4%)	11/ 35 (31.4%)	11/230 (4.8%)	11/282 (3.9%)
Cycle 14 Day 22	16/ 43 (37.2%)	16/222 (7.2%)	16/283 (5.7%)	7/ 33 (21.2%)	7/230 (3.0%)	7/282 (2.5%)
Cycle 15 Day 1	17/ 42 (40.5%)	17/222 (7.7%)	17/283 (6.0%)	8/ 30 (26.7%)	8/230 (3.5%)	8/282 (2.8%)
Cycle 15 Day 22	14/ 41 (34.1%)	14/222 (6.3%)	14/283 (4.9%)	5/ 27 (18.5%)	5/230 (2.2%)	5/282 (1.8%)
Cycle 16 Day 1	16/ 38 (42.1%)	16/222 (7.2%)	16/283 (5.7%)	7/ 25 (28.0%)	7/230 (3.0%)	7/282 (2.5%)
Cycle 16 Day 22	13/ 36 (36.1%)	13/222 (5.9%)	13/283 (4.6%)	4/ 21 (19.0%)	4/230 (1.7%)	4/282 (1.4%)
Cycle 17 Day 1	11/ 32 (34.4%)	11/220 (5.0%)	11/283 (3.9%)	7/ 20 (35.0%)	7/230 (3.0%)	7/282 (2.5%)
Cycle 17 Day 22	10/ 29 (34.5%)	10/219 (4.6%)	10/283 (3.5%)	4/ 19 (21.1%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 18 Day 1	10/ 28 (35.7%)	10/218 (4.6%)	10/283 (3.5%)	6/ 17 (35.3%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 18 Day 22	7/ 26 (26.9%)	7/218 (3.2%)	7/283 (2.5%)	5/ 16 (31.3%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 19 Day 1	8/ 25 (32.0%)	8/218 (3.7%)	8/283 (2.8%)	5/ 16 (31.3%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 19 Day 22	10/ 24 (41.7%)	10/218 (4.6%)	10/283 (3.5%)	5/ 16 (31.3%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 20 Day 1	9/ 24 (37.5%)	9/218 (4.1%)	9/283 (3.2%)	4/ 16 (25.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 20 Day 22	7/ 22 (31.8%)	7/218 (3.2%)	7/283 (2.5%)	7/ 16 (43.8%)	7/229 (3.1%)	7/282 (2.5%)
Cycle 21 Day 1	7/ 21 (33.3%)	7/218 (3.2%)	7/283 (2.5%)	6/ 16 (37.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 21 Day 22	4/ 18 (22.2%)	4/218 (1.8%)	4/283 (1.4%)	5/ 15 (33.3%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 22 Day 1	6/ 17 (35.3%)	6/218 (2.8%)	6/283 (2.1%)	4/ 13 (30.8%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 22 Day 22	3/ 16 (18.8%)	3/218 (1.4%)	3/283 (1.1%)	4/ 13 (30.8%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 23 Day 1	6/ 16 (37.5%)	6/218 (2.8%)	6/283 (2.1%)	5/ 13 (38.5%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 23 Day 22	4/ 16 (25.0%)	4/218 (1.8%)	4/283 (1.4%)	3/ 11 (27.3%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 24 Day 1	6/ 15 (40.0%)	6/218 (2.8%)	6/283 (2.1%)	4/ 10 (40.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 24 Day 22	4/ 13 (30.8%)	4/218 (1.8%)	4/283 (1.4%)	3/ 8 (37.5%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 25 Day 1	5/ 13 (38.5%)	5/218 (2.3%)	5/283 (1.8%)	4/ 8 (50.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 25 Day 22	4/ 13 (30.8%)	4/218 (1.8%)	4/283 (1.4%)	3/ 8 (37.5%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 26 Day 1	5/ 13 (38.5%)	5/218 (2.3%)	5/283 (1.8%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 26 Day 22	3/ 12 (25.0%)	3/218 (1.4%)	3/283 (1.1%)	2/ 6 (33.3%)	2/229 (0.9%)	2/282 (0.7%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	3/ 12 (25.0%)	3/218 (1.4%)	3/283 (1.1%)	2/ 6 (33.3%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 27 Day 22	2/ 12 (16.7%)	2/218 (0.9%)	2/283 (0.7%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 28 Day 1	4/ 12 (33.3%)	4/218 (1.8%)	4/283 (1.4%)	2/ 6 (33.3%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 28 Day 22	3/ 12 (25.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	2/ 10 (20.0%)	2/218 (0.9%)	2/283 (0.7%)	2/ 5 (40.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 29 Day 22	2/ 10 (20.0%)	2/218 (0.9%)	2/283 (0.7%)	2/ 5 (40.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 30 Day 1	2/ 9 (22.2%)	2/218 (0.9%)	2/283 (0.7%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 30 Day 22	1/ 9 (11.1%)	1/218 (0.5%)	1/283 (0.4%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	0/ 7 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	1/ 4 (25.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 31 Day 22	0/ 6 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	1/ 6 (16.7%)	1/218 (0.5%)	1/283 (0.4%)	0/ 3 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 32 Day 22	0/ 5 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	1/ 4 (25.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 33 Day 22	1/ 3 (33.3%)	1/218 (0.5%)	1/283 (0.4%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	0/ 3 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 22	0/ 3 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	0/ 2 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 22	0/ 2 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 36 Day 1	0/ 2 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 36 Day 22	0/ 2 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 1	0/ 2 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	0/ 1 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	0/ 1 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	0/ 1 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	0/ 1 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	0/ 1 (0.0%)	0/218 (0.0%)	0/283 (0.0%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.35: EORTC QLQ-OG25 - Completion Status of Hair Loss - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	66/243 (27.2%)	66/269 (24.5%)	66/283 (23.3%)	65/246 (26.4%)	65/263 (24.7%)	65/282 (23.0%)
30 D SFU Z/P	34/220 (15.5%)	34/247 (13.8%)	34/283 (12.0%)	37/222 (16.7%)	37/240 (15.4%)	37/282 (13.1%)
90 D SFU Z/P	54/193 (28.0%)	54/222 (24.3%)	54/283 (19.1%)	46/186 (24.7%)	46/205 (22.4%)	46/282 (16.3%)

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

Table 301.3.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	18.50	24.39	0.0	11.11	100.0						
Cycle 1 Day 22	186	20.07	22.59	0.0	11.11	100.0	176	2.90	21.18	-66.7	0.00	66.7
Cycle 2 Day 1	216	13.12	18.06	0.0	11.11	100.0	206	-3.83	23.11	-77.8	0.00	88.9
Cycle 2 Day 22	157	13.52	19.50	0.0	11.11	100.0	150	-4.00	22.34	-88.9	0.00	66.7
Cycle 3 Day 1	200	8.89	15.07	0.0	0.00	100.0	190	-8.30	23.64	-100.0	0.00	88.9
Cycle 3 Day 22	161	13.32	16.89	0.0	11.11	77.8	152	-4.02	23.60	-88.9	0.00	55.6
Cycle 4 Day 1	177	10.55	15.36	0.0	0.00	77.8	169	-6.64	23.49	-88.9	0.00	55.6
Cycle 4 Day 22	127	12.42	16.89	0.0	0.00	77.8	122	-2.82	22.11	-88.9	0.00	66.7
Cycle 5 Day 1	156	10.47	16.80	0.0	0.00	100.0	148	-6.31	22.64	-88.9	0.00	66.7
Cycle 5 Day 22	117	11.21	18.31	0.0	0.00	100.0	110	-4.85	21.84	-100.0	0.00	55.6
Cycle 6 Day 1	131	9.25	16.43	0.0	0.00	88.9	122	-5.37	20.46	-88.9	0.00	44.4
Cycle 6 Day 22	108	10.60	17.35	0.0	0.00	100.0	103	-5.07	20.45	-88.9	0.00	33.3
Cycle 7 Day 1	119	7.84	17.01	0.0	0.00	100.0	113	-6.88	19.66	-66.7	0.00	66.7
Cycle 7 Day 22	87	8.17	14.72	0.0	0.00	55.6	81	-6.04	20.49	-66.7	0.00	44.4
Cycle 8 Day 1	88	8.08	16.82	0.0	0.00	77.8	80	-3.89	18.38	-55.6	0.00	55.6
Cycle 8 Day 22	77	7.22	13.46	0.0	0.00	55.6	71	-5.63	17.90	-55.6	0.00	44.4
Cycle 9 Day 1	82	7.18	14.33	0.0	0.00	77.8	75	-6.67	17.62	-55.6	0.00	33.3
Cycle 9 Day 22	65	7.01	13.11	0.0	0.00	66.7	60	-5.93	18.35	-55.6	0.00	33.3
Cycle 10 Day 1	72	7.10	13.36	0.0	0.00	66.7	66	-5.56	18.92	-55.6	0.00	33.3
Cycle 10 Day 22	61	4.01	8.12	0.0	0.00	33.3	57	-8.38	17.73	-55.6	0.00	22.2
Cycle 11 Day 1	68	5.72	11.44	0.0	0.00	66.7	63	-6.53	20.32	-66.7	0.00	55.6
Cycle 11 Day 22	48	7.18	13.06	0.0	0.00	66.7	44	-8.59	19.59	-66.7	0.00	33.3
Cycle 12 Day 1	58	6.90	11.17	0.0	0.00	33.3	53	-4.19	16.19	-44.4	0.00	33.3
Cycle 12 Day 22	40	6.94	11.16	0.0	0.00	55.6	37	-6.61	19.15	-66.7	0.00	44.4
Cycle 13 Day 1	51	5.66	10.03	0.0	0.00	33.3	48	-6.25	18.47	-77.8	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	6.98	11.12	0.0	0.00	33.3	40	-4.72	16.28	-66.7	0.00	22.2
Cycle 14 Day 1	41	6.23	11.12	0.0	0.00	33.3	39	-4.27	12.39	-44.4	0.00	22.2
Cycle 14 Day 22	33	10.10	19.91	0.0	0.00	100.0	32	-4.17	13.16	-44.4	0.00	22.2
Cycle 15 Day 1	36	8.33	12.56	0.0	0.00	33.3	35	-2.22	12.58	-33.3	0.00	33.3
Cycle 15 Day 22	29	6.13	10.95	0.0	0.00	33.3	29	-4.98	14.72	-55.6	0.00	33.3
Cycle 16 Day 1	35	6.67	10.85	0.0	0.00	33.3	35	-4.44	15.29	-44.4	0.00	33.3
Cycle 16 Day 22	29	10.34	13.59	0.0	0.00	33.3	29	-2.30	15.82	-44.4	0.00	33.3
Cycle 17 Day 1	30	8.15	12.01	0.0	0.00	33.3	30	-2.22	15.82	-55.6	0.00	33.3
Cycle 17 Day 22	23	8.70	14.59	0.0	0.00	44.4	23	-4.35	18.87	-44.4	0.00	33.3
Cycle 18 Day 1	27	5.35	9.92	0.0	0.00	33.3	27	-5.76	15.83	-55.6	0.00	33.3
Cycle 18 Day 22	20	3.89	8.28	0.0	0.00	33.3	20	-6.11	14.18	-55.6	0.00	11.1
Cycle 19 Day 1	23	5.80	11.05	0.0	0.00	33.3	23	-3.38	14.38	-44.4	0.00	33.3
Cycle 19 Day 22	20	5.00	9.86	0.0	0.00	33.3	20	-3.89	10.37	-33.3	0.00	22.2
Cycle 20 Day 1	23	3.38	9.73	0.0	0.00	33.3	23	-4.35	11.96	-33.3	0.00	33.3
Cycle 20 Day 22	18	3.70	9.34	0.0	0.00	33.3	18	-6.17	14.87	-44.4	-5.56	33.3
Cycle 21 Day 1	20	4.44	9.12	0.0	0.00	33.3	20	-3.89	10.37	-33.3	0.00	11.1
Cycle 21 Day 22	14	3.17	9.17	0.0	0.00	33.3	14	-4.76	18.34	-55.6	0.00	33.3
Cycle 22 Day 1	15	5.93	11.00	0.0	0.00	33.3	15	-3.70	12.36	-33.3	0.00	22.2
Cycle 22 Day 22	10	11.11	16.56	0.0	0.00	44.4	10	-2.22	26.60	-44.4	0.00	44.4
Cycle 23 Day 1	15	5.93	11.78	0.0	0.00	33.3	15	-4.44	18.69	-55.6	0.00	33.3
Cycle 23 Day 22	11	6.06	11.51	0.0	0.00	33.3	11	-7.07	16.68	-55.6	0.00	0.0
Cycle 24 Day 1	14	6.35	9.46	0.0	0.00	22.2	14	-3.17	19.21	-55.6	0.00	22.2
Cycle 25 Day 1	12	7.41	12.83	0.0	0.00	33.3	12	-4.63	10.00	-33.3	0.00	0.0
Cycle 25 Day 22	11	13.13	19.13	0.0	0.00	55.6	11	0.00	12.17	-11.1	0.00	33.3
Cycle 26 Day 1	13	9.40	14.23	0.0	0.00	33.3	13	-1.71	14.23	-33.3	0.00	33.3
Cycle 27 Day 1	11	8.08	13.23	0.0	0.00	33.3	11	1.01	12.62	-11.1	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	6.48	12.94	0.0	0.00	33.3	12	0.00	12.54	-22.2	0.00	33.3
Study Disc 1	144	21.91	29.64	0.0	11.11	100.0	136	3.43	26.00	-100.0	0.00	100.0
30 D SFU Z/P	77	17.75	24.67	0.0	11.11	100.0	72	0.93	21.65	-55.6	0.00	66.7
90 D SFU Z/P	89	14.98	20.59	0.0	0.00	88.9	86	-2.20	25.56	-66.7	0.00	88.9
Placebo + mFOLFOX6 (N=282)												
Baseline	257	20.02	26.71	0.0	11.11	100.0						
Cycle 1 Day 22	211	17.69	23.79	0.0	11.11	100.0	208	-1.66	22.31	-77.8	0.00	100.0
Cycle 2 Day 1	230	12.27	20.58	0.0	0.00	100.0	223	-7.92	25.87	-100.0	0.00	88.9
Cycle 2 Day 22	185	10.51	17.67	0.0	0.00	100.0	180	-8.46	23.70	-100.0	0.00	77.8
Cycle 3 Day 1	203	9.85	19.12	0.0	0.00	100.0	196	-8.45	24.83	-100.0	0.00	77.8
Cycle 3 Day 22	156	9.90	16.72	0.0	0.00	88.9	148	-9.16	26.55	-100.0	0.00	77.8
Cycle 4 Day 1	170	8.56	16.75	0.0	0.00	100.0	161	-8.70	23.49	-100.0	0.00	77.8
Cycle 4 Day 22	133	10.19	17.99	0.0	0.00	100.0	127	-7.26	24.74	-100.0	0.00	77.8
Cycle 5 Day 1	149	8.58	16.29	0.0	0.00	100.0	144	-8.02	24.60	-100.0	0.00	44.4
Cycle 5 Day 22	122	8.29	16.01	0.0	0.00	77.8	115	-7.25	22.94	-100.0	0.00	66.7
Cycle 6 Day 1	126	8.73	17.08	0.0	0.00	100.0	121	-5.42	20.34	-88.9	0.00	66.7
Cycle 6 Day 22	96	5.79	13.00	0.0	0.00	66.7	92	-7.61	21.28	-88.9	0.00	44.4
Cycle 7 Day 1	101	5.61	11.72	0.0	0.00	66.7	98	-6.35	20.49	-88.9	0.00	66.7
Cycle 7 Day 22	75	4.30	10.15	0.0	0.00	44.4	73	-8.07	20.73	-88.9	0.00	33.3
Cycle 8 Day 1	82	4.20	9.97	0.0	0.00	44.4	81	-5.62	16.02	-88.9	0.00	22.2
Cycle 8 Day 22	67	4.98	11.65	0.0	0.00	66.7	65	-5.64	20.42	-88.9	0.00	66.7
Cycle 9 Day 1	64	4.17	8.96	0.0	0.00	33.3	62	-6.81	18.80	-88.9	0.00	33.3
Cycle 9 Day 22	57	5.85	11.52	0.0	0.00	44.4	55	-3.03	19.65	-88.9	0.00	44.4
Cycle 10 Day 1	58	4.60	9.99	0.0	0.00	33.3	56	-4.76	19.40	-88.9	0.00	33.3
Cycle 10 Day 22	44	6.06	11.36	0.0	0.00	33.3	43	-3.10	20.19	-88.9	0.00	33.3
Cycle 11 Day 1	48	7.87	19.44	0.0	0.00	100.0	46	-0.24	23.13	-88.9	0.00	55.6

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	3.03	6.96	0.0	0.00	22.2	31	-1.08	10.48	-44.4	0.00	22.2
Cycle 12 Day 1	43	3.62	9.30	0.0	0.00	44.4	41	-4.34	18.90	-88.9	0.00	33.3
Cycle 12 Day 22	27	3.70	8.15	0.0	0.00	33.3	25	-5.33	14.74	-44.4	0.00	33.3
Cycle 13 Day 1	37	4.20	9.20	0.0	0.00	33.3	35	-4.76	17.93	-77.8	0.00	22.2
Cycle 13 Day 22	22	4.55	9.49	0.0	0.00	33.3	21	-6.88	24.21	-88.9	0.00	33.3
Cycle 14 Day 1	31	4.66	10.65	0.0	0.00	44.4	30	-5.56	20.37	-88.9	0.00	33.3
Cycle 14 Day 22	20	6.67	13.20	0.0	0.00	44.4	19	-7.02	25.45	-88.9	0.00	33.3
Cycle 15 Day 1	27	5.35	9.43	0.0	0.00	33.3	27	-5.76	19.58	-77.8	0.00	22.2
Cycle 15 Day 22	17	3.92	11.07	0.0	0.00	44.4	17	-6.54	27.23	-88.9	0.00	44.4
Cycle 16 Day 1	22	4.55	14.81	0.0	0.00	66.7	22	-4.55	26.49	-88.9	0.00	66.7
Cycle 16 Day 22	14	3.97	10.32	0.0	0.00	33.3	14	-8.73	28.97	-88.9	0.00	33.3
Cycle 17 Day 1	18	3.70	8.52	0.0	0.00	33.3	18	-6.79	24.74	-88.9	0.00	22.2
Cycle 18 Day 1	16	4.17	8.96	0.0	0.00	33.3	16	-7.64	23.21	-77.8	0.00	22.2
Cycle 18 Day 22	11	2.02	6.70	0.0	0.00	22.2	10	-6.67	16.73	-44.4	-5.56	22.2
Cycle 19 Day 1	16	4.17	11.39	0.0	0.00	33.3	15	-2.22	16.90	-44.4	0.00	33.3
Cycle 19 Day 22	12	3.70	9.86	0.0	0.00	33.3	11	-4.04	16.68	-44.4	0.00	22.2
Cycle 20 Day 1	16	2.78	6.42	0.0	0.00	22.2	15	-3.70	12.36	-44.4	0.00	11.1
Cycle 20 Day 22	11	2.02	4.49	0.0	0.00	11.1	10	-5.56	15.04	-44.4	0.00	11.1
Cycle 21 Day 1	15	1.48	3.91	0.0	0.00	11.1	14	-4.76	12.87	-44.4	0.00	11.1
Cycle 22 Day 1	12	1.85	4.32	0.0	0.00	11.1	12	-5.56	13.81	-44.4	0.00	11.1
Cycle 23 Day 1	13	3.42	9.50	0.0	0.00	33.3	13	-4.27	14.73	-44.4	0.00	22.2
Study Disc 1	153	19.75	28.73	0.0	0.00	100.0	149	-2.09	30.05	-100.0	0.00	100.0
Study Disc 2	12	18.52	21.88	0.0	11.11	66.7	11	3.03	22.82	-55.6	0.00	22.2
30 D SFU Z/P	93	16.73	23.83	0.0	11.11	100.0	90	-5.93	28.47	-100.0	0.00	66.7
90 D SFU Z/P	84	15.21	22.67	0.0	0.00	100.0	82	-5.42	34.62	-100.0	0.00	88.9

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	19.93	25.11	0.0	11.11	100.0						
	Cycle 1 Day 22	124	18.82	22.77	0.0	11.11	100.0	116	0.67	19.95	-66.7	0.00	55.6
	Cycle 2 Day 1	137	12.00	17.78	0.0	0.00	100.0	129	-7.24	21.18	-77.8	0.00	55.6
	Cycle 2 Day 22	103	13.81	21.47	0.0	0.00	100.0	97	-6.76	23.10	-88.9	0.00	44.4
	Cycle 3 Day 1	125	8.89	14.80	0.0	0.00	88.9	117	-9.50	21.85	-100.0	0.00	44.4
	Cycle 3 Day 22	97	14.20	18.48	0.0	11.11	77.8	90	-4.32	23.24	-88.9	0.00	44.4
	Cycle 4 Day 1	112	10.62	15.31	0.0	0.00	77.8	104	-8.01	23.76	-88.9	0.00	44.4
	Cycle 4 Day 22	83	13.92	18.19	0.0	0.00	77.8	78	-3.56	23.04	-88.9	0.00	44.4
	Cycle 5 Day 1	101	11.66	18.42	0.0	0.00	100.0	94	-6.03	22.62	-88.9	0.00	66.7
	Cycle 5 Day 22	72	12.96	20.77	0.0	0.00	100.0	66	-4.38	20.62	-55.6	0.00	55.6
	Cycle 6 Day 1	78	9.12	16.39	0.0	0.00	88.9	70	-6.98	20.99	-88.9	0.00	33.3
	Cycle 6 Day 22	67	11.44	18.55	0.0	0.00	100.0	63	-5.82	21.57	-88.9	0.00	33.3
	Cycle 7 Day 1	75	8.44	19.06	0.0	0.00	100.0	69	-7.89	20.27	-66.7	0.00	66.7
	Cycle 7 Day 22	57	8.77	14.96	0.0	0.00	55.6	51	-6.97	21.54	-66.7	0.00	44.4
	Cycle 8 Day 1	59	8.47	17.18	0.0	0.00	77.8	51	-5.88	20.41	-55.6	0.00	55.6
	Cycle 8 Day 22	48	6.94	14.24	0.0	0.00	55.6	42	-8.47	19.29	-55.6	0.00	44.4
	Cycle 9 Day 1	49	9.30	16.87	0.0	0.00	77.8	42	-7.41	20.19	-55.6	0.00	33.3
	Cycle 9 Day 22	38	7.60	14.41	0.0	0.00	66.7	33	-9.09	19.14	-55.6	0.00	33.3
	Cycle 10 Day 1	46	7.73	14.60	0.0	0.00	66.7	40	-7.22	19.42	-55.6	0.00	33.3
	Cycle 10 Day 22	37	5.41	9.30	0.0	0.00	33.3	33	-9.43	18.03	-55.6	0.00	11.1
	Cycle 11 Day 1	43	6.98	12.84	0.0	0.00	66.7	38	-7.31	22.41	-66.7	0.00	55.6
	Cycle 11 Day 22	30	9.26	14.90	0.0	0.00	66.7	26	-10.26	20.59	-66.7	0.00	33.3
	Cycle 12 Day 1	33	7.07	11.05	0.0	0.00	33.3	28	-7.14	15.78	-44.4	0.00	33.3
	Cycle 12 Day 22	23	8.70	13.80	0.0	0.00	55.6	20	-8.33	22.19	-66.7	0.00	44.4
	Cycle 13 Day 1	29	6.90	11.27	0.0	0.00	33.3	26	-7.69	19.06	-77.8	0.00	22.2

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	25	6.67	11.11	0.0	0.00	33.3	22	-8.59	18.44	-66.7	0.00	22.2
	Cycle 14 Day 1	21	6.88	11.90	0.0	0.00	33.3	19	-8.19	13.27	-44.4	-11.11	22.2
	Cycle 14 Day 22	20	12.22	24.16	0.0	0.00	100.0	19	-8.19	14.74	-44.4	0.00	22.2
	Cycle 15 Day 1	19	9.36	13.49	0.0	0.00	33.3	18	-6.79	10.18	-33.3	-5.56	11.1
	Cycle 15 Day 22	18	6.79	11.52	0.0	0.00	33.3	18	-8.02	13.64	-55.6	0.00	0.0
	Cycle 16 Day 1	19	4.09	7.60	0.0	0.00	22.2	19	-11.70	12.55	-44.4	-11.11	0.0
	Cycle 16 Day 22	18	7.41	12.05	0.0	0.00	33.3	18	-8.64	14.03	-44.4	0.00	11.1
	Cycle 17 Day 1	17	3.92	8.73	0.0	0.00	33.3	17	-9.80	14.64	-55.6	-11.11	11.1
	Cycle 17 Day 22	14	3.97	10.32	0.0	0.00	33.3	14	-11.90	13.41	-44.4	-11.11	0.0
	Cycle 18 Day 1	16	1.39	3.80	0.0	0.00	11.1	16	-13.19	14.75	-55.6	-11.11	0.0
	Cycle 18 Day 22	13	0.85	3.08	0.0	0.00	11.1	13	-11.11	15.04	-55.6	-11.11	0.0
	Cycle 19 Day 1	14	2.38	6.43	0.0	0.00	22.2	14	-9.52	12.22	-44.4	-11.11	0.0
	Cycle 19 Day 22	13	5.13	10.75	0.0	0.00	33.3	13	-7.69	9.50	-33.3	-11.11	0.0
	Cycle 20 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-9.52	9.60	-33.3	-11.11	0.0
	Cycle 20 Day 22	13	1.71	6.16	0.0	0.00	22.2	13	-11.11	12.00	-44.4	-11.11	0.0
	Cycle 21 Day 1	13	3.42	9.50	0.0	0.00	33.3	13	-8.55	9.25	-33.3	-11.11	0.0
	Cycle 21 Day 22	10	1.11	3.51	0.0	0.00	11.1	10	-10.00	16.93	-55.6	-5.56	0.0
	Cycle 23 Day 1	10	4.44	10.73	0.0	0.00	33.3	10	-11.11	17.37	-55.6	-5.56	0.0
	Study Disc 1	93	23.42	31.83	0.0	11.11	100.0	85	5.23	27.25	-55.6	0.00	100.0
	30 D SFU Z/P	50	18.44	26.52	0.0	5.56	100.0	46	-0.48	21.33	-55.6	0.00	33.3
	90 D SFU Z/P	52	12.61	20.41	0.0	0.00	88.9	50	-6.44	27.41	-66.7	0.00	88.9
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	21.10	28.24	0.0	11.11	100.0						
	Cycle 1 Day 22	138	19.48	24.93	0.0	11.11	100.0	135	-0.33	23.59	-66.7	0.00	100.0
	Cycle 2 Day 1	151	13.69	21.79	0.0	0.00	100.0	144	-7.18	26.82	-88.9	0.00	88.9
	Cycle 2 Day 22	128	11.98	19.15	0.0	0.00	100.0	123	-7.14	22.59	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 3 Day 1	130	9.40	17.19	0.0	0.00	77.8	124	-8.60	25.61	-100.0	0.00	77.8
	Cycle 3 Day 22	105	11.85	19.14	0.0	0.00	88.9	99	-7.30	27.82	-100.0	0.00	77.8
	Cycle 4 Day 1	109	8.97	16.94	0.0	0.00	77.8	101	-8.36	25.01	-88.9	0.00	77.8
	Cycle 4 Day 22	88	11.87	18.52	0.0	0.00	88.9	83	-4.95	24.68	-100.0	0.00	77.8
	Cycle 5 Day 1	94	9.46	17.62	0.0	0.00	100.0	90	-8.15	25.79	-100.0	0.00	44.4
	Cycle 5 Day 22	85	9.54	17.91	0.0	0.00	77.8	79	-5.49	22.98	-88.9	0.00	66.7
	Cycle 6 Day 1	76	10.53	19.36	0.0	0.00	100.0	72	-4.48	23.86	-88.9	0.00	66.7
	Cycle 6 Day 22	63	8.47	15.29	0.0	0.00	66.7	60	-7.41	24.43	-88.9	0.00	44.4
	Cycle 7 Day 1	63	7.41	13.83	0.0	0.00	66.7	60	-6.30	24.49	-88.9	0.00	66.7
	Cycle 7 Day 22	46	6.28	12.09	0.0	0.00	44.4	44	-7.58	24.64	-88.9	0.00	33.3
	Cycle 8 Day 1	49	5.44	12.03	0.0	0.00	44.4	48	-5.79	18.62	-88.9	0.00	22.2
	Cycle 8 Day 22	39	6.55	13.90	0.0	0.00	66.7	37	-6.31	23.94	-88.9	0.00	66.7
	Cycle 9 Day 1	38	6.14	10.87	0.0	0.00	33.3	36	-6.48	22.28	-88.9	0.00	33.3
	Cycle 9 Day 22	34	7.19	13.37	0.0	0.00	44.4	32	-2.43	23.40	-88.9	0.00	44.4
	Cycle 10 Day 1	31	5.73	11.43	0.0	0.00	33.3	29	-4.60	24.76	-88.9	0.00	33.3
	Cycle 10 Day 22	27	7.41	12.71	0.0	0.00	33.3	26	-3.42	24.30	-88.9	0.00	33.3
	Cycle 11 Day 1	28	11.90	24.37	0.0	0.00	100.0	26	1.71	30.26	-88.9	0.00	55.6
	Cycle 11 Day 22	20	3.89	7.45	0.0	0.00	22.2	18	-1.23	11.98	-44.4	0.00	11.1
	Cycle 12 Day 1	23	4.83	11.52	0.0	0.00	44.4	21	-3.70	24.93	-88.9	0.00	33.3
	Cycle 12 Day 22	15	4.44	10.11	0.0	0.00	33.3	13	-3.42	17.20	-44.4	0.00	33.3
	Cycle 13 Day 1	21	4.76	10.29	0.0	0.00	33.3	19	-4.68	22.32	-77.8	0.00	22.2
	Cycle 13 Day 22	11	7.07	11.41	0.0	0.00	33.3	10	-8.89	35.06	-88.9	0.00	33.3
	Cycle 14 Day 1	14	5.56	10.45	0.0	0.00	33.3	13	-6.84	30.27	-88.9	0.00	33.3
	Cycle 14 Day 22	10	7.78	14.86	0.0	0.00	44.4	9	-12.35	34.00	-88.9	0.00	22.2
	Cycle 15 Day 1	14	6.35	9.46	0.0	0.00	22.2	14	-4.76	26.41	-77.8	0.00	22.2
	Cycle 15 Day 22	10	5.56	14.10	0.0	0.00	44.4	10	-8.89	35.45	-88.9	0.00	44.4

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 16 Day 1	14	7.14	18.29	0.0	0.00	66.7	14	-3.97	33.36	-88.9	0.00	66.7
	Cycle 17 Day 1	11	6.06	10.38	0.0	0.00	33.3	11	-7.07	31.92	-88.9	0.00	22.2
	Cycle 18 Day 1	10	6.67	10.73	0.0	0.00	33.3	10	-8.89	29.54	-77.8	0.00	22.2
	Cycle 19 Day 1	10	6.67	14.05	0.0	0.00	33.3	9	0.00	21.52	-44.4	0.00	33.3
	Cycle 20 Day 1	10	3.33	7.50	0.0	0.00	22.2	9	-3.70	15.71	-44.4	0.00	11.1
	Study Disc 1	94	22.70	31.08	0.0	5.56	100.0	92	0.85	31.78	-100.0	0.00	100.0
	30 D SFU Z/P	65	19.66	26.63	0.0	11.11	100.0	63	-4.41	31.40	-100.0	0.00	66.7
	90 D SFU Z/P	57	15.40	23.07	0.0	11.11	100.0	55	-7.27	37.66	-100.0	0.00	88.9

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	16.15	23.08	0.0	0.00	100.0						
	Cycle 1 Day 22	62	22.58	22.22	0.0	16.67	100.0	60	7.22	22.95	-55.6	5.56	66.7
	Cycle 2 Day 1	79	15.05	18.49	0.0	11.11	88.9	77	1.88	25.13	-55.6	0.00	88.9
	Cycle 2 Day 22	54	12.96	15.22	0.0	11.11	66.7	53	1.05	20.12	-55.6	0.00	66.7
	Cycle 3 Day 1	75	8.89	15.61	0.0	0.00	100.0	73	-6.39	26.31	-100.0	0.00	88.9
	Cycle 3 Day 22	64	11.98	14.18	0.0	11.11	55.6	62	-3.58	24.29	-77.8	0.00	55.6
	Cycle 4 Day 1	65	10.43	15.58	0.0	0.00	66.7	65	-4.44	23.06	-66.7	0.00	55.6
	Cycle 4 Day 22	44	9.60	13.89	0.0	5.56	66.7	44	-1.52	20.56	-66.7	0.00	66.7
	Cycle 5 Day 1	55	8.28	13.22	0.0	0.00	66.7	54	-6.79	22.88	-66.7	0.00	66.7
	Cycle 5 Day 22	45	8.40	13.22	0.0	0.00	44.4	44	-5.56	23.78	-100.0	0.00	33.3
	Cycle 6 Day 1	53	9.43	16.65	0.0	0.00	66.7	52	-3.21	19.72	-66.7	0.00	44.4
	Cycle 6 Day 22	41	9.21	15.30	0.0	0.00	55.6	40	-3.89	18.75	-55.6	0.00	33.3
	Cycle 7 Day 1	44	6.82	12.95	0.0	0.00	44.4	44	-5.30	18.79	-66.7	0.00	44.4
	Cycle 7 Day 22	30	7.04	14.44	0.0	0.00	44.4	30	-4.44	18.82	-66.7	0.00	44.4
	Cycle 8 Day 1	29	7.28	16.34	0.0	0.00	66.7	29	-0.38	13.76	-33.3	0.00	33.3
	Cycle 8 Day 22	29	7.66	12.28	0.0	0.00	33.3	29	-1.53	15.06	-33.3	0.00	33.3
	Cycle 9 Day 1	33	4.04	8.70	0.0	0.00	33.3	33	-5.72	13.92	-44.4	0.00	11.1
	Cycle 9 Day 22	27	6.17	11.25	0.0	0.00	33.3	27	-2.06	16.89	-44.4	0.00	33.3
	Cycle 10 Day 1	26	5.98	10.99	0.0	0.00	33.3	26	-2.99	18.21	-55.6	0.00	33.3
	Cycle 10 Day 22	24	1.85	5.35	0.0	0.00	22.2	24	-6.94	17.59	-55.6	0.00	22.2
	Cycle 11 Day 1	25	3.56	8.31	0.0	0.00	33.3	25	-5.33	17.01	-44.4	0.00	33.3
	Cycle 11 Day 22	18	3.70	8.52	0.0	0.00	33.3	18	-6.17	18.37	-44.4	0.00	33.3
	Cycle 12 Day 1	25	6.67	11.56	0.0	0.00	33.3	25	-0.89	16.33	-44.4	0.00	33.3
	Cycle 12 Day 22	17	4.58	5.64	0.0	0.00	11.1	17	-4.58	15.24	-44.4	0.00	11.1
	Cycle 13 Day 1	22	4.04	8.07	0.0	0.00	33.3	22	-4.55	18.03	-55.6	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	18	7.41	11.43	0.0	0.00	33.3	18	0.00	12.05	-33.3	0.00	22.2
	Cycle 14 Day 1	20	5.56	10.51	0.0	0.00	33.3	20	-0.56	10.49	-33.3	0.00	22.2
	Cycle 14 Day 22	13	6.84	10.68	0.0	0.00	33.3	13	1.71	7.65	-11.1	0.00	22.2
	Cycle 15 Day 1	17	7.19	11.75	0.0	0.00	33.3	17	2.61	13.34	-33.3	0.00	33.3
	Cycle 15 Day 22	11	5.05	10.38	0.0	0.00	33.3	11	0.00	15.71	-33.3	0.00	33.3
	Cycle 16 Day 1	16	9.72	13.38	0.0	0.00	33.3	16	4.17	13.98	-11.1	0.00	33.3
	Cycle 16 Day 22	11	15.15	15.13	0.0	11.11	33.3	11	8.08	13.23	0.0	0.00	33.3
	Cycle 17 Day 1	13	13.68	13.72	0.0	11.11	33.3	13	7.69	11.46	0.0	0.00	33.3
	Cycle 18 Day 1	11	11.11	13.15	0.0	11.11	33.3	11	5.05	10.38	0.0	0.00	33.3
	Study Disc 1	51	19.17	25.25	0.0	11.11	100.0	51	0.44	23.72	-100.0	0.00	44.4
	30 D SFU Z/P	27	16.46	21.21	0.0	11.11	66.7	26	3.42	22.39	-33.3	0.00	66.7
	90 D SFU Z/P	37	18.32	20.66	0.0	11.11	77.8	36	3.70	21.74	-55.6	0.00	44.4
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	18.25	24.05	0.0	11.11	100.0						
	Cycle 1 Day 22	73	14.31	21.23	0.0	11.11	100.0	73	-4.11	19.64	-77.8	0.00	33.3
	Cycle 2 Day 1	79	9.56	17.86	0.0	0.00	100.0	79	-9.28	24.16	-100.0	0.00	55.6
	Cycle 2 Day 22	57	7.21	13.36	0.0	0.00	77.8	57	-11.31	25.93	-100.0	-11.11	77.8
	Cycle 3 Day 1	73	10.65	22.26	0.0	0.00	100.0	72	-8.18	23.59	-100.0	0.00	66.7
	Cycle 3 Day 22	51	5.88	8.99	0.0	0.00	33.3	49	-12.93	23.61	-100.0	0.00	11.1
	Cycle 4 Day 1	61	7.83	16.52	0.0	0.00	100.0	60	-9.26	20.88	-100.0	0.00	22.2
	Cycle 4 Day 22	45	6.91	16.63	0.0	0.00	100.0	44	-11.62	24.55	-100.0	0.00	22.2
	Cycle 5 Day 1	55	7.07	13.75	0.0	0.00	66.7	54	-7.82	22.70	-100.0	0.00	44.4
	Cycle 5 Day 22	37	5.41	10.01	0.0	0.00	44.4	36	-11.11	22.69	-100.0	0.00	11.1
	Cycle 6 Day 1	50	6.00	12.54	0.0	0.00	66.7	49	-6.80	13.76	-66.7	0.00	11.1
	Cycle 6 Day 22	33	0.67	2.69	0.0	0.00	11.1	32	-7.99	13.89	-44.4	0.00	11.1
	Cycle 7 Day 1	38	2.63	6.02	0.0	0.00	22.2	38	-6.43	12.01	-44.4	0.00	11.1

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.20.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dysphagia by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	29	1.15	4.55	0.0	0.00	22.2	29	-8.81	13.07	-44.4	0.00	0.0
	Cycle 8 Day 1	33	2.36	5.38	0.0	0.00	22.2	33	-5.39	11.49	-44.4	0.00	11.1
	Cycle 8 Day 22	28	2.78	7.17	0.0	0.00	33.3	28	-4.76	14.95	-44.4	0.00	33.3
	Cycle 9 Day 1	26	1.28	3.62	0.0	0.00	11.1	26	-7.26	12.94	-44.4	0.00	11.1
	Cycle 9 Day 22	23	3.86	7.93	0.0	0.00	33.3	23	-3.86	13.24	-44.4	0.00	22.2
	Cycle 10 Day 1	27	3.29	8.04	0.0	0.00	33.3	27	-4.94	11.67	-44.4	0.00	11.1
	Cycle 10 Day 22	17	3.92	8.73	0.0	0.00	33.3	17	-2.61	12.13	-33.3	0.00	22.2
	Cycle 11 Day 1	20	2.22	5.81	0.0	0.00	22.2	20	-2.78	7.10	-22.2	0.00	11.1
	Cycle 11 Day 22	13	1.71	6.16	0.0	0.00	22.2	13	-0.85	8.44	-11.1	0.00	22.2
	Cycle 12 Day 1	20	2.22	5.81	0.0	0.00	22.2	20	-5.00	9.86	-33.3	0.00	11.1
	Cycle 12 Day 22	12	2.78	5.03	0.0	0.00	11.1	12	-7.41	11.92	-33.3	-5.56	11.1
	Cycle 13 Day 1	16	3.47	7.82	0.0	0.00	22.2	16	-4.86	11.45	-33.3	0.00	22.2
	Cycle 13 Day 22	11	2.02	6.70	0.0	0.00	22.2	11	-5.05	7.64	-22.2	0.00	0.0
	Cycle 14 Day 1	17	3.92	11.07	0.0	0.00	44.4	17	-4.58	7.91	-22.2	0.00	11.1
	Cycle 14 Day 22	10	5.56	12.00	0.0	0.00	33.3	10	-2.22	14.63	-22.2	0.00	33.3
	Cycle 15 Day 1	13	4.27	9.66	0.0	0.00	33.3	13	-6.84	8.53	-22.2	-11.11	11.1
	Study Disc 1	59	15.07	24.04	0.0	0.00	100.0	57	-6.82	26.62	-100.0	0.00	55.6
	30 D SFU Z/P	28	9.92	13.64	0.0	0.00	33.3	27	-9.47	20.14	-77.8	0.00	22.2
	90 D SFU Z/P	27	14.81	22.22	0.0	0.00	66.7	27	-1.65	27.68	-77.8	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	30.54	29.05	0.0	25.00	100.0						
Cycle 1 Day 22	186	32.08	25.79	0.0	33.33	100.0	176	4.40	22.82	-66.7	0.00	100.0
Cycle 2 Day 1	216	24.96	25.09	0.0	16.67	100.0	206	-3.32	27.60	-91.7	0.00	75.0
Cycle 2 Day 22	157	24.42	22.77	0.0	16.67	100.0	150	-5.00	26.41	-83.3	0.00	75.0
Cycle 3 Day 1	200	20.17	21.31	0.0	16.67	100.0	190	-8.77	27.65	-100.0	-4.17	66.7
Cycle 3 Day 22	161	29.04	25.26	0.0	25.00	100.0	152	-0.38	27.39	-83.3	0.00	100.0
Cycle 4 Day 1	177	23.12	22.55	0.0	16.67	100.0	169	-6.41	29.50	-91.7	0.00	75.0
Cycle 4 Day 22	127	25.00	23.22	0.0	25.00	91.7	122	-1.09	28.26	-83.3	0.00	66.7
Cycle 5 Day 1	156	23.45	22.66	0.0	16.67	100.0	148	-4.84	27.80	-91.7	0.00	66.7
Cycle 5 Day 22	117	22.08	22.91	0.0	16.67	100.0	110	-3.86	29.62	-100.0	0.00	75.0
Cycle 6 Day 1	131	17.94	21.04	0.0	8.33	100.0	122	-7.79	26.48	-100.0	-4.17	50.0
Cycle 6 Day 22	108	18.36	19.76	0.0	16.67	100.0	103	-8.25	27.94	-83.3	0.00	66.7
Cycle 7 Day 1	119	16.60	21.52	0.0	8.33	100.0	113	-9.14	26.63	-83.3	-8.33	66.7
Cycle 7 Day 22	87	17.72	21.14	0.0	8.33	83.3	81	-8.13	28.41	-83.3	0.00	66.7
Cycle 8 Day 1	88	16.19	22.44	0.0	8.33	100.0	80	-8.02	21.72	-75.0	-8.33	75.0
Cycle 8 Day 22	77	16.67	19.87	0.0	8.33	83.3	71	-8.92	23.41	-75.0	-8.33	50.0
Cycle 9 Day 1	82	14.63	20.10	0.0	8.33	91.7	75	-10.89	24.12	-75.0	-8.33	58.3
Cycle 9 Day 22	65	17.95	21.61	0.0	8.33	83.3	60	-5.97	26.80	-66.7	-8.33	75.0
Cycle 10 Day 1	72	15.62	19.53	0.0	8.33	83.3	66	-7.45	25.20	-66.7	-8.33	50.0
Cycle 10 Day 22	61	15.85	18.74	0.0	8.33	91.7	57	-7.60	25.11	-66.7	0.00	50.0
Cycle 11 Day 1	68	12.75	16.32	0.0	8.33	66.7	63	-10.05	24.05	-66.7	-8.33	58.3
Cycle 11 Day 22	48	16.49	21.02	0.0	8.33	83.3	44	-8.33	23.23	-66.7	-4.17	50.0
Cycle 12 Day 1	58	15.09	17.13	0.0	8.33	83.3	53	-7.39	21.10	-58.3	-8.33	50.0
Cycle 12 Day 22	40	17.29	19.56	0.0	8.33	75.0	37	-4.95	20.64	-50.0	0.00	50.0
Cycle 13 Day 1	51	14.05	18.29	0.0	8.33	83.3	48	-7.47	20.72	-58.3	-8.33	41.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	16.47	20.37	0.0	8.33	75.0	40	-4.17	19.06	-58.3	0.00	41.7
Cycle 14 Day 1	41	16.06	22.70	0.0	8.33	91.7	39	-6.84	22.45	-58.3	-8.33	58.3
Cycle 14 Day 22	33	17.42	23.70	0.0	8.33	100.0	32	-7.29	21.77	-66.7	-8.33	50.0
Cycle 15 Day 1	36	17.13	20.50	0.0	8.33	83.3	35	-1.90	20.32	-33.3	0.00	50.0
Cycle 15 Day 22	29	15.23	20.05	0.0	8.33	75.0	29	-5.17	18.56	-41.7	-8.33	41.7
Cycle 16 Day 1	35	14.52	17.43	0.0	8.33	66.7	35	-6.19	18.89	-66.7	0.00	50.0
Cycle 16 Day 22	29	20.69	27.78	0.0	8.33	100.0	29	-2.30	26.72	-66.7	0.00	83.3
Cycle 17 Day 1	30	14.17	18.97	0.0	8.33	66.7	30	-5.56	16.86	-41.7	-8.33	33.3
Cycle 17 Day 22	23	19.20	23.36	0.0	8.33	83.3	23	-2.17	17.63	-50.0	0.00	33.3
Cycle 18 Day 1	27	13.89	20.54	0.0	0.00	91.7	27	-6.17	17.54	-41.7	0.00	33.3
Cycle 18 Day 22	20	10.00	12.85	0.0	0.00	33.3	20	-5.00	15.86	-41.7	0.00	33.3
Cycle 19 Day 1	23	10.14	14.20	0.0	8.33	50.0	23	-5.80	13.63	-41.7	0.00	16.7
Cycle 19 Day 22	20	10.42	14.27	0.0	0.00	41.7	20	-3.33	15.63	-41.7	0.00	41.7
Cycle 20 Day 1	23	11.23	20.96	0.0	0.00	75.0	23	-2.17	21.35	-41.7	0.00	66.7
Cycle 20 Day 22	18	9.72	16.48	0.0	0.00	58.3	18	-4.63	17.90	-41.7	0.00	33.3
Cycle 21 Day 1	20	11.67	19.19	0.0	0.00	75.0	20	-0.83	15.74	-33.3	0.00	41.7
Cycle 21 Day 22	14	8.93	17.13	0.0	0.00	58.3	14	-3.57	12.10	-25.0	0.00	25.0
Cycle 22 Day 1	15	10.00	11.87	0.0	0.00	25.0	15	-5.00	12.52	-25.0	0.00	25.0
Cycle 22 Day 22	10	15.83	15.93	0.0	16.67	41.7	10	-2.50	18.02	-25.0	0.00	41.7
Cycle 23 Day 1	15	10.00	13.44	0.0	0.00	33.3	15	-6.11	11.12	-33.3	0.00	8.3
Cycle 23 Day 22	11	9.85	13.85	0.0	0.00	33.3	11	-4.55	14.12	-25.0	0.00	25.0
Cycle 24 Day 1	14	15.48	20.11	0.0	0.00	58.3	14	0.00	19.88	-25.0	0.00	41.7
Cycle 25 Day 1	12	11.81	14.85	0.0	4.17	41.7	12	-4.86	13.51	-25.0	0.00	25.0
Cycle 25 Day 22	11	17.42	17.26	0.0	25.00	41.7	11	-0.76	13.15	-25.0	0.00	25.0
Cycle 26 Day 1	13	13.46	14.65	0.0	8.33	33.3	13	-4.49	11.59	-25.0	0.00	16.7
Cycle 27 Day 1	11	10.61	15.41	0.0	0.00	33.3	11	-6.06	10.60	-25.0	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	11.11	14.36	0.0	4.17	33.3	12	-4.17	14.86	-25.0	0.00	33.3
Study Disc 1	144	34.84	31.36	0.0	25.00	100.0	136	3.25	31.15	-91.7	0.00	91.7
30 D SFU Z/P	77	31.17	26.92	0.0	25.00	100.0	72	2.31	25.03	-58.3	0.00	58.3
90 D SFU Z/P	89	23.03	23.13	0.0	16.67	100.0	86	-5.62	30.80	-83.3	0.00	91.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	33.01	30.26	0.0	25.00	100.0						
Cycle 1 Day 22	211	30.45	25.37	0.0	33.33	100.0	208	-1.32	23.11	-66.7	0.00	83.3
Cycle 2 Day 1	230	22.17	22.57	0.0	16.67	100.0	223	-9.94	29.44	-100.0	-8.33	91.7
Cycle 2 Day 22	185	22.61	23.89	0.0	16.67	100.0	180	-7.92	30.90	-100.0	0.00	91.7
Cycle 3 Day 1	203	17.69	19.46	0.0	16.67	100.0	196	-13.52	28.28	-100.0	-8.33	50.0
Cycle 3 Day 22	156	19.98	22.89	0.0	16.67	100.0	148	-10.98	29.80	-100.0	-8.33	66.7
Cycle 4 Day 1	170	17.75	20.34	0.0	8.33	100.0	161	-13.15	28.12	-100.0	-8.33	50.0
Cycle 4 Day 22	133	20.49	21.36	0.0	16.67	100.0	127	-10.96	28.79	-100.0	0.00	58.3
Cycle 5 Day 1	149	16.95	19.65	0.0	8.33	100.0	144	-13.43	30.02	-100.0	-8.33	50.0
Cycle 5 Day 22	122	18.78	19.54	0.0	16.67	83.3	115	-11.09	28.33	-100.0	-8.33	58.3
Cycle 6 Day 1	126	17.92	21.76	0.0	8.33	100.0	121	-9.92	27.41	-100.0	0.00	50.0
Cycle 6 Day 22	96	13.89	16.03	0.0	8.33	66.7	92	-14.67	26.99	-100.0	-8.33	41.7
Cycle 7 Day 1	101	13.12	17.53	0.0	8.33	100.0	98	-12.16	24.29	-100.0	-8.33	50.0
Cycle 7 Day 22	75	11.00	16.73	0.0	8.33	100.0	73	-14.16	25.26	-100.0	-8.33	33.3
Cycle 8 Day 1	82	10.98	15.21	0.0	8.33	66.7	81	-10.60	23.68	-100.0	0.00	25.0
Cycle 8 Day 22	67	12.81	15.51	0.0	8.33	58.3	65	-10.13	26.62	-100.0	0.00	58.3
Cycle 9 Day 1	64	12.11	15.06	0.0	8.33	58.3	62	-12.63	24.78	-100.0	-8.33	58.3
Cycle 9 Day 22	57	13.89	16.39	0.0	8.33	58.3	55	-7.73	25.60	-100.0	0.00	50.0
Cycle 10 Day 1	58	11.49	14.46	0.0	8.33	58.3	56	-9.97	25.45	-100.0	0.00	33.3
Cycle 10 Day 22	44	14.96	18.55	0.0	8.33	66.7	43	-5.81	29.07	-100.0	0.00	66.7
Cycle 11 Day 1	48	14.24	20.84	0.0	8.33	75.0	46	-6.16	28.57	-100.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.21: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating Restrictions - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	11.62	13.81	0.0	8.33	50.0	31	-5.38	20.25	-66.7	0.00	41.7
Cycle 12 Day 1	43	12.02	15.25	0.0	8.33	66.7	41	-7.32	24.94	-91.7	0.00	41.7
Cycle 12 Day 22	27	11.11	13.67	0.0	8.33	41.7	25	-10.67	20.91	-66.7	0.00	33.3
Cycle 13 Day 1	37	11.94	13.96	0.0	8.33	58.3	35	-9.52	25.26	-91.7	0.00	33.3
Cycle 13 Day 22	22	16.67	17.63	0.0	12.50	58.3	21	-7.94	30.79	-100.0	0.00	50.0
Cycle 14 Day 1	31	15.32	20.20	0.0	8.33	66.7	30	-8.61	28.91	-100.0	-4.17	33.3
Cycle 14 Day 22	20	18.75	20.21	0.0	12.50	58.3	19	-8.33	28.87	-100.0	0.00	33.3
Cycle 15 Day 1	27	15.12	18.78	0.0	8.33	66.7	27	-6.17	30.97	-100.0	0.00	41.7
Cycle 15 Day 22	17	12.25	19.35	0.0	8.33	75.0	17	-12.75	35.49	-100.0	0.00	58.3
Cycle 16 Day 1	22	15.15	23.09	0.0	8.33	100.0	22	-5.68	36.95	-100.0	0.00	83.3
Cycle 16 Day 22	14	16.07	20.79	0.0	4.17	58.3	14	-10.12	37.15	-100.0	0.00	50.0
Cycle 17 Day 1	18	7.41	11.03	0.0	0.00	33.3	18	-13.89	30.92	-100.0	-8.33	25.0
Cycle 18 Day 1	16	10.42	18.88	0.0	0.00	66.7	16	-12.50	31.77	-83.3	-4.17	58.3
Cycle 18 Day 22	11	6.06	11.84	0.0	0.00	33.3	10	-15.00	23.17	-66.7	-12.50	16.7
Cycle 19 Day 1	16	8.33	18.00	0.0	0.00	66.7	15	-8.89	26.81	-66.7	-8.33	58.3
Cycle 19 Day 22	12	11.81	14.42	0.0	4.17	33.3	11	-7.58	20.23	-50.0	0.00	25.0
Cycle 20 Day 1	16	7.29	13.90	0.0	0.00	41.7	15	-10.00	21.87	-66.7	-8.33	25.0
Cycle 20 Day 22	11	7.58	10.84	0.0	0.00	25.0	10	-10.00	19.16	-50.0	-4.17	16.7
Cycle 21 Day 1	15	6.67	12.28	0.0	0.00	41.7	14	-11.31	20.57	-66.7	-4.17	16.7
Cycle 22 Day 1	12	8.33	13.76	0.0	0.00	33.3	12	-9.72	25.33	-66.7	-4.17	25.0
Cycle 23 Day 1	13	10.90	17.14	0.0	0.00	50.0	13	-8.97	24.64	-66.7	-8.33	41.7
Study Disc 1	153	31.21	30.66	0.0	25.00	100.0	149	-2.40	34.13	-100.0	0.00	100.0
Study Disc 2	12	27.08	29.76	0.0	20.83	100.0	11	1.52	28.09	-41.7	0.00	50.0
30 D SFU Z/P	93	27.87	25.96	0.0	25.00	100.0	90	-5.46	33.57	-100.0	0.00	91.7
90 D SFU Z/P	84	27.68	28.73	0.0	16.67	100.0	82	-5.08	38.53	-100.0	0.00	91.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	17.64	24.43	0.0	0.00	100.0						
Cycle 1 Day 22	186	16.13	22.59	0.0	0.00	100.0	176	-1.70	21.61	-100.0	0.00	50.0
Cycle 2 Day 1	216	12.81	21.34	0.0	0.00	100.0	206	-2.99	24.32	-100.0	0.00	100.0
Cycle 2 Day 22	157	10.83	18.95	0.0	0.00	100.0	150	-4.56	23.00	-100.0	0.00	83.3
Cycle 3 Day 1	200	10.25	17.89	0.0	0.00	100.0	190	-5.61	23.71	-100.0	0.00	66.7
Cycle 3 Day 22	161	11.59	18.17	0.0	0.00	83.3	152	-4.39	21.16	-100.0	0.00	50.0
Cycle 4 Day 1	177	9.60	17.55	0.0	0.00	100.0	169	-5.52	22.18	-100.0	0.00	66.7
Cycle 4 Day 22	127	11.15	18.43	0.0	0.00	100.0	122	-2.46	21.18	-100.0	0.00	66.7
Cycle 5 Day 1	156	10.47	17.58	0.0	0.00	100.0	148	-4.95	22.46	-100.0	0.00	66.7
Cycle 5 Day 22	117	12.82	19.86	0.0	0.00	100.0	110	-2.88	21.76	-66.7	0.00	66.7
Cycle 6 Day 1	131	9.03	16.83	0.0	0.00	83.3	122	-5.87	23.66	-100.0	0.00	50.0
Cycle 6 Day 22	108	10.65	17.12	0.0	0.00	100.0	103	-4.53	20.50	-66.7	0.00	66.7
Cycle 7 Day 1	119	9.66	16.02	0.0	0.00	66.7	113	-4.13	19.74	-66.7	0.00	66.7
Cycle 7 Day 22	87	9.00	14.78	0.0	0.00	50.0	81	-5.14	21.99	-100.0	0.00	50.0
Cycle 8 Day 1	88	9.28	16.74	0.0	0.00	100.0	80	-5.63	21.37	-100.0	0.00	33.3
Cycle 8 Day 22	77	11.04	16.58	0.0	0.00	83.3	71	-6.34	22.95	-100.0	0.00	33.3
Cycle 9 Day 1	82	11.18	20.80	0.0	0.00	100.0	75	-6.00	23.19	-66.7	0.00	50.0
Cycle 9 Day 22	65	12.82	19.93	0.0	0.00	83.3	60	-2.22	18.27	-66.7	0.00	33.3
Cycle 10 Day 1	72	10.19	20.47	0.0	0.00	100.0	66	-4.80	23.16	-66.7	0.00	100.0
Cycle 10 Day 22	61	7.38	17.62	0.0	0.00	100.0	57	-6.43	20.11	-66.7	0.00	33.3
Cycle 11 Day 1	68	7.35	16.13	0.0	0.00	100.0	63	-7.41	21.54	-66.7	0.00	33.3
Cycle 11 Day 22	48	7.29	18.16	0.0	0.00	100.0	44	-6.82	17.36	-66.7	0.00	33.3
Cycle 12 Day 1	58	8.05	17.17	0.0	0.00	100.0	53	-4.40	19.38	-66.7	0.00	33.3
Cycle 12 Day 22	40	6.67	11.82	0.0	0.00	33.3	37	-5.86	21.95	-66.7	0.00	33.3
Cycle 13 Day 1	51	8.50	17.12	0.0	0.00	100.0	48	-4.17	20.48	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	9.30	15.98	0.0	0.00	50.0	40	-2.08	18.94	-66.7	0.00	33.3
Cycle 14 Day 1	41	11.38	20.56	0.0	0.00	100.0	39	-1.71	21.90	-66.7	0.00	33.3
Cycle 14 Day 22	33	8.08	15.09	0.0	0.00	50.0	32	-5.73	21.00	-66.7	0.00	33.3
Cycle 15 Day 1	36	8.33	14.64	0.0	0.00	50.0	35	-0.95	14.54	-33.3	0.00	33.3
Cycle 15 Day 22	29	8.62	12.30	0.0	0.00	33.3	29	-4.60	19.36	-66.7	0.00	16.7
Cycle 16 Day 1	35	9.05	13.61	0.0	0.00	33.3	35	-3.33	17.99	-50.0	0.00	33.3
Cycle 16 Day 22	29	5.17	11.87	0.0	0.00	33.3	29	-8.62	21.65	-66.7	0.00	33.3
Cycle 17 Day 1	30	10.56	17.77	0.0	0.00	66.7	30	-1.11	21.86	-66.7	0.00	33.3
Cycle 17 Day 22	23	10.87	14.74	0.0	0.00	33.3	23	-1.45	21.27	-66.7	0.00	33.3
Cycle 18 Day 1	27	6.79	12.45	0.0	0.00	33.3	27	-4.32	20.46	-66.7	0.00	33.3
Cycle 18 Day 22	20	9.17	20.57	0.0	0.00	83.3	20	0.83	22.60	-50.0	0.00	50.0
Cycle 19 Day 1	23	6.52	13.05	0.0	0.00	33.3	23	-0.72	15.47	-50.0	0.00	33.3
Cycle 19 Day 22	20	5.00	10.95	0.0	0.00	33.3	20	-1.67	14.20	-50.0	0.00	16.7
Cycle 20 Day 1	23	5.80	10.79	0.0	0.00	33.3	23	0.00	15.08	-50.0	0.00	16.7
Cycle 20 Day 22	18	4.63	9.58	0.0	0.00	33.3	18	-2.78	15.39	-50.0	0.00	16.7
Cycle 21 Day 1	20	4.17	9.17	0.0	0.00	33.3	20	0.00	9.37	-33.3	0.00	16.7
Cycle 21 Day 22	14	4.76	10.19	0.0	0.00	33.3	14	0.00	11.32	-33.3	0.00	16.7
Cycle 22 Day 1	15	6.67	12.28	0.0	0.00	33.3	15	0.00	19.92	-50.0	0.00	33.3
Cycle 22 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	19.56	-50.0	0.00	16.7
Cycle 23 Day 1	15	1.11	4.30	0.0	0.00	16.7	15	-5.56	15.00	-50.0	0.00	0.0
Cycle 23 Day 22	11	1.52	5.03	0.0	0.00	16.7	11	-6.06	18.67	-50.0	0.00	16.7
Cycle 24 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-4.76	16.57	-50.0	0.00	16.7
Cycle 25 Day 1	12	2.78	6.49	0.0	0.00	16.7	12	-5.56	19.25	-50.0	0.00	16.7
Cycle 25 Day 22	11	4.55	10.78	0.0	0.00	33.3	11	-4.55	15.08	-33.3	0.00	16.7
Cycle 26 Day 1	13	6.41	10.84	0.0	0.00	33.3	13	-1.28	17.30	-33.3	0.00	33.3
Cycle 27 Day 1	11	4.55	10.78	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	4.17	10.36	0.0	0.00	33.3	12	0.00	12.31	-33.3	0.00	16.7
Study Disc 1	144	17.71	25.94	0.0	0.00	100.0	136	0.61	24.29	-66.7	0.00	100.0
30 D SFU Z/P	77	16.67	24.93	0.0	0.00	100.0	72	-1.85	26.32	-83.3	0.00	66.7
90 D SFU Z/P	89	15.36	23.33	0.0	0.00	100.0	86	-0.78	24.91	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	16.60	24.00	0.0	0.00	100.0						
Cycle 1 Day 22	211	14.69	21.33	0.0	0.00	100.0	208	-1.28	21.70	-100.0	0.00	66.7
Cycle 2 Day 1	230	10.87	19.02	0.0	0.00	100.0	223	-5.31	26.20	-100.0	0.00	100.0
Cycle 2 Day 22	185	11.35	19.59	0.0	0.00	100.0	180	-5.00	23.43	-100.0	0.00	66.7
Cycle 3 Day 1	203	9.52	16.74	0.0	0.00	66.7	196	-6.46	23.10	-100.0	0.00	66.7
Cycle 3 Day 22	156	8.97	15.07	0.0	0.00	83.3	148	-5.86	21.19	-100.0	0.00	50.0
Cycle 4 Day 1	170	9.51	16.70	0.0	0.00	100.0	161	-5.28	20.95	-83.3	0.00	50.0
Cycle 4 Day 22	133	7.77	15.01	0.0	0.00	83.3	127	-5.64	20.49	-66.7	0.00	50.0
Cycle 5 Day 1	149	10.51	17.79	0.0	0.00	83.3	144	-3.24	22.92	-100.0	0.00	66.7
Cycle 5 Day 22	122	10.66	18.44	0.0	0.00	83.3	115	-2.75	22.72	-66.7	0.00	83.3
Cycle 6 Day 1	126	10.58	18.21	0.0	0.00	83.3	121	-1.38	20.82	-66.7	0.00	66.7
Cycle 6 Day 22	96	9.20	17.25	0.0	0.00	83.3	92	-1.81	20.44	-66.7	0.00	83.3
Cycle 7 Day 1	101	10.40	17.30	0.0	0.00	66.7	98	1.36	18.64	-50.0	0.00	66.7
Cycle 7 Day 22	75	7.56	13.78	0.0	0.00	66.7	73	-1.14	16.97	-50.0	0.00	33.3
Cycle 8 Day 1	82	7.52	15.75	0.0	0.00	83.3	81	0.41	14.19	-33.3	0.00	50.0
Cycle 8 Day 22	67	7.71	15.17	0.0	0.00	66.7	65	1.03	18.13	-33.3	0.00	66.7
Cycle 9 Day 1	64	5.73	11.96	0.0	0.00	50.0	62	-0.81	16.65	-50.0	0.00	50.0
Cycle 9 Day 22	57	7.31	11.36	0.0	0.00	33.3	55	1.82	14.58	-50.0	0.00	33.3
Cycle 10 Day 1	58	6.32	13.55	0.0	0.00	66.7	56	0.30	17.26	-50.0	0.00	66.7
Cycle 10 Day 22	44	10.61	16.11	0.0	0.00	66.7	43	5.04	19.43	-50.0	0.00	66.7
Cycle 11 Day 1	48	13.54	21.65	0.0	0.00	66.7	46	7.97	24.02	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	13.64	19.74	0.0	0.00	83.3	31	7.53	21.45	-33.3	0.00	66.7
Cycle 12 Day 1	43	13.18	21.07	0.0	0.00	66.7	41	8.13	24.75	-33.3	0.00	66.7
Cycle 12 Day 22	27	11.73	16.55	0.0	0.00	50.0	25	2.67	19.65	-50.0	0.00	33.3
Cycle 13 Day 1	37	11.26	18.03	0.0	0.00	66.7	35	4.76	21.23	-50.0	0.00	66.7
Cycle 13 Day 22	22	9.85	14.23	0.0	0.00	33.3	21	5.56	13.26	-16.7	0.00	33.3
Cycle 14 Day 1	31	4.84	9.81	0.0	0.00	33.3	30	-0.56	15.46	-50.0	0.00	33.3
Cycle 14 Day 22	20	11.67	18.81	0.0	0.00	66.7	19	7.02	13.96	-16.7	0.00	33.3
Cycle 15 Day 1	27	7.41	16.23	0.0	0.00	66.7	27	2.47	21.03	-50.0	0.00	66.7
Cycle 15 Day 22	17	6.86	11.87	0.0	0.00	33.3	17	2.94	15.85	-33.3	0.00	33.3
Cycle 16 Day 1	22	10.61	17.48	0.0	0.00	66.7	22	6.06	22.74	-50.0	0.00	66.7
Cycle 16 Day 22	14	11.90	22.10	0.0	0.00	66.7	14	7.14	28.28	-50.0	0.00	66.7
Cycle 17 Day 1	18	7.41	14.26	0.0	0.00	50.0	18	1.85	20.52	-50.0	0.00	50.0
Cycle 18 Day 1	16	3.13	9.07	0.0	0.00	33.3	16	-3.13	17.45	-50.0	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	0.00	23.57	-50.0	0.00	33.3
Cycle 19 Day 1	16	5.21	11.74	0.0	0.00	33.3	15	-1.11	20.38	-50.0	0.00	33.3
Cycle 19 Day 22	12	8.33	13.30	0.0	0.00	33.3	11	3.03	14.56	-16.7	0.00	33.3
Cycle 20 Day 1	16	3.13	9.07	0.0	0.00	33.3	15	-3.33	14.36	-33.3	0.00	33.3
Cycle 20 Day 22	11	7.58	13.67	0.0	0.00	33.3	10	1.67	14.59	-16.7	0.00	33.3
Cycle 21 Day 1	15	5.56	10.29	0.0	0.00	33.3	14	-1.19	12.17	-16.7	0.00	16.7
Cycle 22 Day 1	12	1.39	4.81	0.0	0.00	16.7	12	-6.94	16.60	-50.0	0.00	16.7
Cycle 23 Day 1	13	7.69	12.94	0.0	0.00	33.3	13	0.00	19.25	-33.3	0.00	33.3
Study Disc 1	153	13.07	21.96	0.0	0.00	100.0	149	-3.24	26.89	-100.0	0.00	100.0
Study Disc 2	12	20.83	29.41	0.0	16.67	100.0	11	0.00	19.72	-33.3	0.00	33.3
30 D SFU Z/P	93	13.80	21.65	0.0	0.00	100.0	90	-2.96	26.63	-83.3	0.00	66.7
90 D SFU Z/P	84	14.68	20.92	0.0	0.00	83.3	82	1.02	26.49	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	16.87	23.94	0.0	0.00	100.0						
	Cycle 1 Day 22	124	14.65	22.75	0.0	0.00	100.0	116	-1.87	19.13	-100.0	0.00	33.3
	Cycle 2 Day 1	137	11.56	19.65	0.0	0.00	100.0	129	-2.97	19.92	-83.3	0.00	83.3
	Cycle 2 Day 22	103	10.52	19.10	0.0	0.00	100.0	97	-3.26	20.92	-100.0	0.00	66.7
	Cycle 3 Day 1	125	10.53	18.15	0.0	0.00	100.0	117	-3.42	19.64	-66.7	0.00	33.3
	Cycle 3 Day 22	97	12.20	19.17	0.0	0.00	83.3	90	-1.11	15.36	-50.0	0.00	33.3
	Cycle 4 Day 1	112	9.23	17.59	0.0	0.00	100.0	104	-3.53	18.09	-50.0	0.00	66.7
	Cycle 4 Day 22	83	13.05	20.50	0.0	0.00	100.0	78	1.07	16.41	-33.3	0.00	66.7
	Cycle 5 Day 1	101	10.40	18.23	0.0	0.00	100.0	94	-3.72	19.88	-100.0	0.00	66.7
	Cycle 5 Day 22	72	13.89	22.03	0.0	0.00	100.0	66	-1.26	20.53	-50.0	0.00	66.7
	Cycle 6 Day 1	78	7.69	16.05	0.0	0.00	83.3	70	-5.24	20.37	-100.0	0.00	33.3
	Cycle 6 Day 22	67	8.46	14.03	0.0	0.00	66.7	63	-3.44	18.25	-50.0	0.00	66.7
	Cycle 7 Day 1	75	9.33	16.27	0.0	0.00	66.7	69	-2.90	17.61	-66.7	0.00	50.0
	Cycle 7 Day 22	57	8.19	15.15	0.0	0.00	50.0	51	-5.23	21.98	-100.0	0.00	50.0
	Cycle 8 Day 1	59	9.04	17.60	0.0	0.00	100.0	51	-6.21	20.81	-100.0	0.00	33.3
	Cycle 8 Day 22	48	11.81	18.18	0.0	0.00	83.3	42	-4.37	18.43	-50.0	0.00	33.3
	Cycle 9 Day 1	49	11.90	23.32	0.0	0.00	100.0	42	-4.37	20.51	-50.0	0.00	50.0
	Cycle 9 Day 22	38	14.04	20.33	0.0	0.00	66.7	33	-1.52	17.86	-33.3	0.00	33.3
	Cycle 10 Day 1	46	11.23	22.51	0.0	0.00	100.0	40	-3.75	23.41	-50.0	0.00	100.0
	Cycle 10 Day 22	37	8.56	20.27	0.0	0.00	100.0	33	-5.56	18.48	-50.0	0.00	33.3
	Cycle 11 Day 1	43	8.53	18.32	0.0	0.00	100.0	38	-6.14	17.51	-50.0	0.00	16.7
	Cycle 11 Day 22	30	8.33	21.33	0.0	0.00	100.0	26	-8.97	15.08	-33.3	0.00	16.7
	Cycle 12 Day 1	33	9.60	20.00	0.0	0.00	100.0	28	-4.76	15.62	-33.3	0.00	16.7
	Cycle 12 Day 22	23	7.97	13.17	0.0	0.00	33.3	20	-5.00	18.02	-50.0	0.00	33.3
	Cycle 13 Day 1	29	8.05	20.23	0.0	0.00	100.0	26	-5.77	15.59	-50.0	0.00	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	25	10.67	17.92	0.0	0.00	50.0	22	-1.52	16.19	-50.0	0.00	33.3
	Cycle 14 Day 1	21	12.70	25.22	0.0	0.00	100.0	19	-4.39	22.11	-50.0	0.00	33.3
	Cycle 14 Day 22	20	9.17	15.74	0.0	0.00	50.0	19	-5.26	20.83	-50.0	0.00	33.3
	Cycle 15 Day 1	19	7.89	14.02	0.0	0.00	33.3	18	-2.78	15.39	-33.3	0.00	33.3
	Cycle 15 Day 22	18	9.26	11.75	0.0	0.00	33.3	18	-4.63	17.90	-50.0	0.00	16.7
	Cycle 16 Day 1	19	7.02	12.81	0.0	0.00	33.3	19	-7.02	19.50	-50.0	0.00	33.3
	Cycle 16 Day 22	18	4.63	11.15	0.0	0.00	33.3	18	-10.19	19.08	-50.0	0.00	16.7
	Cycle 17 Day 1	17	7.84	17.79	0.0	0.00	66.7	17	-2.94	18.85	-50.0	0.00	33.3
	Cycle 17 Day 22	14	8.33	12.66	0.0	0.00	33.3	14	0.00	17.30	-33.3	0.00	33.3
	Cycle 18 Day 1	16	5.21	10.03	0.0	0.00	33.3	16	-5.21	17.97	-50.0	0.00	16.7
	Cycle 18 Day 22	13	5.13	10.51	0.0	0.00	33.3	13	-2.56	23.42	-50.0	0.00	33.3
	Cycle 19 Day 1	14	7.14	14.19	0.0	0.00	33.3	14	0.00	19.61	-50.0	0.00	33.3
	Cycle 19 Day 22	13	5.13	10.51	0.0	0.00	33.3	13	-2.56	16.45	-50.0	0.00	16.7
	Cycle 20 Day 1	14	3.57	7.10	0.0	0.00	16.7	14	-3.57	17.52	-50.0	0.00	16.7
	Cycle 20 Day 22	13	2.56	6.26	0.0	0.00	16.7	13	-5.13	17.19	-50.0	0.00	16.7
	Cycle 21 Day 1	13	2.56	6.26	0.0	0.00	16.7	13	-1.28	10.68	-33.3	0.00	16.7
	Cycle 21 Day 22	10	3.33	7.03	0.0	0.00	16.7	10	-1.67	12.30	-33.3	0.00	16.7
	Cycle 23 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	-8.33	18.00	-50.0	0.00	0.0
	Study Disc 1	93	18.46	27.96	0.0	0.00	100.0	85	1.57	24.48	-50.0	0.00	100.0
	30 D SFU Z/P	50	15.33	24.24	0.0	0.00	100.0	46	-3.99	23.09	-83.3	0.00	66.7
	90 D SFU Z/P	52	11.86	20.17	0.0	0.00	100.0	50	-2.00	25.12	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	15.62	22.32	0.0	0.00	100.0						
	Cycle 1 Day 22	138	13.65	20.76	0.0	0.00	100.0	135	-0.86	18.13	-50.0	0.00	50.0
	Cycle 2 Day 1	151	9.27	17.28	0.0	0.00	100.0	144	-5.32	23.04	-100.0	0.00	83.3
	Cycle 2 Day 22	128	8.85	17.62	0.0	0.00	100.0	123	-6.50	19.63	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 3 Day 1	130	7.82	15.42	0.0	0.00	66.7	124	-6.05	21.71	-100.0	0.00	66.7
	Cycle 3 Day 22	105	8.57	14.27	0.0	0.00	50.0	99	-6.57	21.54	-100.0	0.00	33.3
	Cycle 4 Day 1	109	8.72	15.15	0.0	0.00	83.3	101	-4.46	19.56	-66.7	0.00	50.0
	Cycle 4 Day 22	88	6.63	13.02	0.0	0.00	50.0	83	-5.22	17.64	-50.0	0.00	50.0
	Cycle 5 Day 1	94	9.04	14.80	0.0	0.00	66.7	90	-4.26	20.99	-100.0	0.00	33.3
	Cycle 5 Day 22	85	9.61	15.93	0.0	0.00	66.7	79	-3.16	20.51	-50.0	0.00	66.7
	Cycle 6 Day 1	76	10.53	18.02	0.0	0.00	83.3	72	-0.69	21.20	-66.7	0.00	66.7
	Cycle 6 Day 22	63	10.05	18.09	0.0	0.00	83.3	60	-0.56	22.12	-66.7	0.00	83.3
	Cycle 7 Day 1	63	10.85	15.88	0.0	0.00	66.7	60	2.78	18.45	-50.0	0.00	66.7
	Cycle 7 Day 22	46	6.88	12.46	0.0	0.00	33.3	44	-0.76	15.23	-50.0	0.00	33.3
	Cycle 8 Day 1	49	8.16	14.88	0.0	0.00	50.0	48	1.74	12.03	-16.7	0.00	50.0
	Cycle 8 Day 22	39	8.12	14.24	0.0	0.00	50.0	37	1.35	14.90	-33.3	0.00	33.3
	Cycle 9 Day 1	38	6.14	11.89	0.0	0.00	50.0	36	0.46	13.50	-33.3	0.00	50.0
	Cycle 9 Day 22	34	7.35	12.44	0.0	0.00	33.3	32	3.13	10.74	-16.7	0.00	33.3
	Cycle 10 Day 1	31	5.38	10.88	0.0	0.00	33.3	29	0.57	10.43	-16.7	0.00	33.3
	Cycle 10 Day 22	27	10.49	13.98	0.0	0.00	33.3	26	5.77	14.10	-16.7	0.00	33.3
	Cycle 11 Day 1	28	13.69	20.31	0.0	0.00	66.7	26	8.97	19.57	-16.7	0.00	66.7
	Cycle 11 Day 22	20	11.67	16.31	0.0	0.00	50.0	18	5.56	20.61	-33.3	0.00	50.0
	Cycle 12 Day 1	23	13.77	19.88	0.0	0.00	66.7	21	10.32	23.26	-33.3	0.00	66.7
	Cycle 12 Day 22	15	11.11	17.44	0.0	0.00	50.0	13	2.56	14.98	-16.7	0.00	33.3
	Cycle 13 Day 1	21	13.49	17.97	0.0	0.00	66.7	19	8.77	19.54	-16.7	0.00	66.7
	Cycle 13 Day 22	11	12.12	15.08	0.0	0.00	33.3	10	6.67	16.10	-16.7	0.00	33.3
	Cycle 14 Day 1	14	3.57	7.10	0.0	0.00	16.7	13	1.28	10.68	-16.7	0.00	16.7
	Cycle 14 Day 22	10	15.00	22.84	0.0	0.00	66.7	9	7.41	16.90	-16.7	0.00	33.3
	Cycle 15 Day 1	14	8.33	14.25	0.0	0.00	33.3	14	5.95	14.03	-16.7	0.00	33.3
	Cycle 15 Day 22	10	10.00	14.05	0.0	0.00	33.3	10	8.33	16.20	-16.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 16 Day 1	14	10.71	20.26	0.0	0.00	66.7	14	8.33	22.41	-16.7	0.00	66.7
	Cycle 17 Day 1	11	7.58	11.46	0.0	0.00	33.3	11	4.55	13.10	-16.7	0.00	33.3
	Cycle 18 Day 1	10	5.00	11.25	0.0	0.00	33.3	10	1.67	14.59	-16.7	0.00	33.3
	Cycle 19 Day 1	10	8.33	14.16	0.0	0.00	33.3	9	5.56	18.63	-16.7	0.00	33.3
	Cycle 20 Day 1	10	3.33	10.54	0.0	0.00	33.3	9	0.00	14.43	-16.7	0.00	33.3
	Study Disc 1	94	15.25	24.28	0.0	0.00	100.0	92	-0.18	28.23	-100.0	0.00	100.0
	30 D SFU Z/P	65	10.77	18.96	0.0	0.00	100.0	63	-5.03	22.73	-66.7	0.00	50.0
	90 D SFU Z/P	57	11.40	18.68	0.0	0.00	66.7	55	-2.12	23.36	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	18.90	25.30	0.0	16.67	100.0						
	Cycle 1 Day 22	62	19.09	22.15	0.0	16.67	100.0	60	-1.39	25.91	-83.3	0.00	50.0
	Cycle 2 Day 1	79	14.98	23.96	0.0	0.00	100.0	77	-3.03	30.44	-100.0	0.00	100.0
	Cycle 2 Day 22	54	11.42	18.83	0.0	0.00	83.3	53	-6.92	26.44	-66.7	0.00	83.3
	Cycle 3 Day 1	75	9.78	17.56	0.0	0.00	100.0	73	-9.13	28.87	-100.0	0.00	66.7
	Cycle 3 Day 22	64	10.68	16.63	0.0	0.00	83.3	62	-9.14	26.94	-100.0	0.00	50.0
	Cycle 4 Day 1	65	10.26	17.60	0.0	0.00	66.7	65	-8.72	27.34	-100.0	0.00	66.7
	Cycle 4 Day 22	44	7.58	13.18	0.0	0.00	50.0	44	-8.71	26.78	-100.0	0.00	33.3
	Cycle 5 Day 1	55	10.61	16.47	0.0	0.00	66.7	54	-7.10	26.42	-83.3	0.00	66.7
	Cycle 5 Day 22	45	11.11	15.89	0.0	0.00	66.7	44	-5.30	23.51	-66.7	0.00	33.3
	Cycle 6 Day 1	53	11.01	17.89	0.0	0.00	66.7	52	-6.73	27.67	-100.0	0.00	50.0
	Cycle 6 Day 22	41	14.23	20.94	0.0	0.00	100.0	40	-6.25	23.78	-66.7	0.00	33.3
	Cycle 7 Day 1	44	10.23	15.76	0.0	0.00	66.7	44	-6.06	22.76	-66.7	0.00	66.7
	Cycle 7 Day 22	30	10.56	14.17	0.0	0.00	33.3	30	-5.00	22.38	-66.7	0.00	33.3
	Cycle 8 Day 1	29	9.77	15.12	0.0	0.00	33.3	29	-4.60	22.67	-66.7	0.00	33.3
	Cycle 8 Day 22	29	9.77	13.74	0.0	0.00	33.3	29	-9.20	28.38	-100.0	0.00	33.3
	Cycle 9 Day 1	33	10.10	16.64	0.0	0.00	66.7	33	-8.08	26.39	-66.7	0.00	33.3
	Cycle 9 Day 22	27	11.11	19.61	0.0	0.00	83.3	27	-3.09	19.08	-66.7	0.00	33.3
	Cycle 10 Day 1	26	8.33	16.50	0.0	0.00	66.7	26	-6.41	23.13	-66.7	0.00	33.3
	Cycle 10 Day 22	24	5.56	12.69	0.0	0.00	33.3	24	-7.64	22.51	-66.7	0.00	33.3
	Cycle 11 Day 1	25	5.33	11.51	0.0	0.00	33.3	25	-9.33	26.82	-66.7	0.00	33.3
	Cycle 11 Day 22	18	5.56	11.43	0.0	0.00	33.3	18	-3.70	20.26	-66.7	0.00	33.3
	Cycle 12 Day 1	25	6.00	12.62	0.0	0.00	33.3	25	-4.00	23.21	-66.7	0.00	33.3
	Cycle 12 Day 22	17	4.90	9.80	0.0	0.00	33.3	17	-6.86	26.39	-66.7	0.00	33.3
	Cycle 13 Day 1	22	9.09	12.31	0.0	0.00	33.3	22	-2.27	25.35	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	18	7.41	13.06	0.0	0.00	33.3	18	-2.78	22.32	-66.7	0.00	33.3
	Cycle 14 Day 1	20	10.00	14.71	0.0	0.00	33.3	20	0.83	21.95	-66.7	0.00	33.3
	Cycle 14 Day 22	13	6.41	14.50	0.0	0.00	50.0	13	-6.41	22.09	-66.7	0.00	16.7
	Cycle 15 Day 1	17	8.82	15.72	0.0	0.00	50.0	17	0.98	13.78	-33.3	0.00	33.3
	Cycle 15 Day 22	11	7.58	13.67	0.0	0.00	33.3	11	-4.55	22.47	-66.7	0.00	16.7
	Cycle 16 Day 1	16	11.46	14.55	0.0	0.00	33.3	16	1.04	15.48	-33.3	0.00	33.3
	Cycle 16 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	26.11	-66.7	0.00	33.3
	Cycle 17 Day 1	13	14.10	17.80	0.0	0.00	50.0	13	1.28	25.88	-66.7	0.00	33.3
	Cycle 18 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	-3.03	24.52	-66.7	0.00	33.3
	Study Disc 1	51	16.34	21.98	0.0	0.00	66.7	51	-0.98	24.13	-66.7	0.00	66.7
	30 D SFU Z/P	27	19.14	26.43	0.0	0.00	66.7	26	1.92	31.39	-66.7	0.00	50.0
	90 D SFU Z/P	37	20.27	26.68	0.0	16.67	100.0	36	0.93	24.86	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	18.20	26.55	0.0	0.00	100.0						
	Cycle 1 Day 22	73	16.67	22.40	0.0	0.00	83.3	73	-2.05	27.21	-100.0	0.00	66.7
	Cycle 2 Day 1	79	13.92	21.75	0.0	0.00	100.0	79	-5.27	31.30	-100.0	0.00	100.0
	Cycle 2 Day 22	57	16.96	22.60	0.0	0.00	66.7	57	-1.75	29.99	-100.0	0.00	66.7
	Cycle 3 Day 1	73	12.56	18.59	0.0	0.00	66.7	72	-7.18	25.46	-100.0	0.00	50.0
	Cycle 3 Day 22	51	9.80	16.73	0.0	0.00	83.3	49	-4.42	20.63	-83.3	0.00	50.0
	Cycle 4 Day 1	61	10.93	19.22	0.0	0.00	100.0	60	-6.67	23.21	-83.3	0.00	50.0
	Cycle 4 Day 22	45	10.00	18.26	0.0	0.00	83.3	44	-6.44	25.22	-66.7	0.00	50.0
	Cycle 5 Day 1	55	13.03	21.92	0.0	0.00	83.3	54	-1.54	25.96	-66.7	0.00	66.7
	Cycle 5 Day 22	37	13.06	23.29	0.0	0.00	83.3	36	-1.85	27.25	-66.7	0.00	83.3
	Cycle 6 Day 1	50	10.67	18.67	0.0	0.00	66.7	49	-2.38	20.41	-50.0	0.00	66.7
	Cycle 6 Day 22	33	7.58	15.64	0.0	0.00	66.7	32	-4.17	16.93	-50.0	0.00	33.3
	Cycle 7 Day 1	38	9.65	19.62	0.0	0.00	66.7	38	-0.88	18.96	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.22.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Reflux by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	29	8.62	15.82	0.0	0.00	66.7	29	-1.72	19.59	-50.0	0.00	33.3
	Cycle 8 Day 1	33	6.57	17.15	0.0	0.00	83.3	33	-1.52	16.85	-33.3	0.00	33.3
	Cycle 8 Day 22	28	7.14	16.62	0.0	0.00	66.7	28	0.60	21.98	-33.3	0.00	66.7
	Cycle 9 Day 1	26	5.13	12.26	0.0	0.00	50.0	26	-2.56	20.38	-50.0	0.00	50.0
	Cycle 9 Day 22	23	7.25	9.83	0.0	0.00	33.3	23	0.00	18.80	-50.0	0.00	33.3
	Cycle 10 Day 1	27	7.41	16.23	0.0	0.00	66.7	27	0.00	22.65	-50.0	0.00	66.7
	Cycle 10 Day 22	17	10.78	19.49	0.0	0.00	66.7	17	3.92	26.04	-50.0	0.00	66.7
	Cycle 11 Day 1	20	13.33	23.94	0.0	0.00	66.7	20	6.67	29.32	-50.0	0.00	66.7
	Cycle 11 Day 22	13	16.67	24.53	0.0	0.00	83.3	13	10.26	23.11	-16.7	0.00	66.7
	Cycle 12 Day 1	20	12.50	22.86	0.0	0.00	66.7	20	5.83	26.64	-33.3	0.00	66.7
	Cycle 12 Day 22	12	12.50	16.09	0.0	0.00	33.3	12	2.78	24.45	-50.0	0.00	33.3
	Cycle 13 Day 1	16	8.33	18.26	0.0	0.00	66.7	16	0.00	22.77	-50.0	0.00	50.0
	Cycle 13 Day 22	11	7.58	13.67	0.0	0.00	33.3	11	4.55	10.78	0.0	0.00	33.3
	Cycle 14 Day 1	17	5.88	11.70	0.0	0.00	33.3	17	-1.96	18.52	-50.0	0.00	33.3
	Cycle 14 Day 22	10	8.33	14.16	0.0	0.00	33.3	10	6.67	11.65	0.0	0.00	33.3
	Cycle 15 Day 1	13	6.41	18.68	0.0	0.00	66.7	13	-1.28	26.75	-50.0	0.00	66.7
	Study Disc 1	59	9.60	17.29	0.0	0.00	66.7	57	-8.19	24.01	-83.3	0.00	50.0
	30 D SFU Z/P	28	20.83	25.91	0.0	16.67	83.3	27	1.85	34.07	-83.3	0.00	66.7
	90 D SFU Z/P	27	21.60	23.94	0.0	16.67	83.3	27	7.41	31.46	-83.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	22.18	25.96	0.0	16.67	100.0						
Cycle 1 Day 22	186	18.19	21.49	0.0	16.67	100.0	176	-2.37	24.22	-100.0	0.00	83.3
Cycle 2 Day 1	216	15.51	20.96	0.0	16.67	100.0	206	-4.77	24.64	-83.3	0.00	66.7
Cycle 2 Day 22	157	14.54	19.95	0.0	0.00	100.0	150	-6.22	24.62	-66.7	0.00	66.7
Cycle 3 Day 1	200	10.92	16.25	0.0	0.00	100.0	190	-9.39	24.63	-100.0	0.00	83.3
Cycle 3 Day 22	161	14.29	18.43	0.0	0.00	66.7	152	-6.36	22.77	-100.0	0.00	50.0
Cycle 4 Day 1	177	10.83	17.33	0.0	0.00	100.0	169	-9.66	24.84	-83.3	0.00	50.0
Cycle 4 Day 22	127	14.04	18.71	0.0	0.00	100.0	122	-3.69	25.67	-100.0	0.00	66.7
Cycle 5 Day 1	156	13.78	19.69	0.0	0.00	100.0	148	-4.73	23.49	-100.0	0.00	66.7
Cycle 5 Day 22	117	13.68	21.17	0.0	0.00	100.0	110	-4.85	26.17	-83.3	0.00	83.3
Cycle 6 Day 1	131	10.31	17.35	0.0	0.00	100.0	122	-7.92	20.24	-83.3	0.00	50.0
Cycle 6 Day 22	108	9.57	14.45	0.0	0.00	66.7	103	-8.41	22.49	-83.3	0.00	33.3
Cycle 7 Day 1	119	8.68	15.17	0.0	0.00	66.7	113	-9.44	21.92	-83.3	0.00	33.3
Cycle 7 Day 22	87	10.54	16.49	0.0	0.00	66.7	81	-8.23	22.99	-83.3	0.00	33.3
Cycle 8 Day 1	88	10.61	17.36	0.0	0.00	83.3	80	-5.21	20.81	-66.7	0.00	50.0
Cycle 8 Day 22	77	9.52	16.09	0.0	0.00	66.7	71	-8.69	22.16	-83.3	0.00	50.0
Cycle 9 Day 1	82	9.35	16.38	0.0	0.00	66.7	75	-8.67	20.20	-66.7	0.00	50.0
Cycle 9 Day 22	65	10.00	15.53	0.0	0.00	66.7	60	-5.56	20.74	-66.7	0.00	33.3
Cycle 10 Day 1	72	9.72	15.76	0.0	0.00	66.7	66	-6.31	18.89	-66.7	0.00	50.0
Cycle 10 Day 22	61	8.74	14.78	0.0	0.00	66.7	57	-4.09	18.44	-66.7	0.00	50.0
Cycle 11 Day 1	68	7.84	15.36	0.0	0.00	66.7	63	-5.56	17.96	-50.0	0.00	50.0
Cycle 11 Day 22	48	10.07	17.44	0.0	0.00	66.7	44	-3.41	14.19	-50.0	0.00	33.3
Cycle 12 Day 1	58	10.06	18.45	0.0	0.00	66.7	53	-4.40	20.45	-66.7	0.00	50.0
Cycle 12 Day 22	40	10.00	15.47	0.0	0.00	66.7	37	-2.25	17.64	-33.3	0.00	50.0
Cycle 13 Day 1	51	9.48	18.03	0.0	0.00	83.3	48	-3.82	16.93	-50.0	0.00	50.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	8.14	17.20	0.0	0.00	83.3	40	-4.17	18.78	-50.0	0.00	66.7
Cycle 14 Day 1	41	12.20	22.98	0.0	0.00	100.0	39	-2.56	23.43	-50.0	0.00	83.3
Cycle 14 Day 22	33	8.08	16.20	0.0	0.00	66.7	32	-5.73	15.03	-33.3	0.00	50.0
Cycle 15 Day 1	36	10.65	18.32	0.0	0.00	66.7	35	-1.43	15.85	-33.3	0.00	50.0
Cycle 15 Day 22	29	11.49	18.95	0.0	0.00	66.7	29	-1.72	16.87	-33.3	0.00	50.0
Cycle 16 Day 1	35	9.52	13.58	0.0	0.00	33.3	35	-3.81	13.46	-33.3	0.00	16.7
Cycle 16 Day 22	29	11.49	17.87	0.0	0.00	66.7	29	-4.02	15.21	-33.3	0.00	33.3
Cycle 17 Day 1	30	8.33	15.63	0.0	0.00	66.7	30	-4.44	16.34	-33.3	0.00	33.3
Cycle 17 Day 22	23	15.94	25.37	0.0	0.00	100.0	23	1.45	25.08	-33.3	0.00	100.0
Cycle 18 Day 1	27	8.02	17.52	0.0	0.00	66.7	27	-5.56	16.67	-33.3	0.00	33.3
Cycle 18 Day 22	20	7.50	12.65	0.0	0.00	33.3	20	-2.50	13.55	-33.3	0.00	16.7
Cycle 19 Day 1	23	5.07	9.31	0.0	0.00	33.3	23	-5.80	13.86	-33.3	0.00	16.7
Cycle 19 Day 22	20	5.00	10.95	0.0	0.00	33.3	20	-5.00	13.36	-33.3	0.00	16.7
Cycle 20 Day 1	23	8.70	21.83	0.0	0.00	100.0	23	-0.72	25.37	-33.3	0.00	100.0
Cycle 20 Day 22	18	4.63	9.58	0.0	0.00	33.3	18	-6.48	14.16	-33.3	0.00	16.7
Cycle 21 Day 1	20	5.83	11.18	0.0	0.00	33.3	20	-3.33	8.72	-33.3	0.00	0.0
Cycle 21 Day 22	14	4.76	10.19	0.0	0.00	33.3	14	-1.19	10.26	-33.3	0.00	16.7
Cycle 22 Day 1	15	5.56	10.29	0.0	0.00	33.3	15	-2.22	10.67	-33.3	0.00	16.7
Cycle 22 Day 22	10	10.00	14.05	0.0	0.00	33.3	10	0.00	13.61	-33.3	0.00	16.7
Cycle 23 Day 1	15	4.44	9.89	0.0	0.00	33.3	15	-4.44	9.89	-33.3	0.00	0.0
Cycle 23 Day 22	11	7.58	13.67	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
Cycle 24 Day 1	14	9.52	19.30	0.0	0.00	66.7	14	1.19	21.15	-33.3	0.00	66.7
Cycle 25 Day 1	12	8.33	13.30	0.0	0.00	33.3	12	-1.39	4.81	-16.7	0.00	0.0
Cycle 25 Day 22	11	15.15	17.41	0.0	0.00	33.3	11	4.55	7.78	0.0	0.00	16.7
Cycle 26 Day 1	13	8.97	12.94	0.0	0.00	33.3	13	-1.28	10.68	-33.3	0.00	16.7
Cycle 27 Day 1	11	6.06	11.24	0.0	0.00	33.3	11	-4.55	10.78	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	11.11	14.79	0.0	0.00	33.3	12	1.39	4.81	0.0	0.00	16.7
Study Disc 1	144	20.95	27.86	0.0	16.67	100.0	136	-1.96	26.45	-83.3	0.00	100.0
30 D SFU Z/P	77	20.56	26.48	0.0	16.67	100.0	72	-3.01	25.53	-50.0	0.00	100.0
90 D SFU Z/P	89	18.73	23.94	0.0	16.67	100.0	86	-5.62	27.49	-83.3	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	22.44	26.60	0.0	16.67	100.0						
Cycle 1 Day 22	211	15.80	21.10	0.0	16.67	100.0	208	-5.69	22.72	-83.3	0.00	66.7
Cycle 2 Day 1	230	12.32	19.84	0.0	0.00	100.0	223	-9.19	24.94	-100.0	0.00	83.3
Cycle 2 Day 22	185	12.61	20.41	0.0	0.00	100.0	180	-9.35	25.05	-100.0	0.00	83.3
Cycle 3 Day 1	203	9.93	17.59	0.0	0.00	100.0	196	-11.39	24.00	-100.0	0.00	50.0
Cycle 3 Day 22	156	8.97	16.65	0.0	0.00	100.0	148	-12.50	23.56	-100.0	0.00	33.3
Cycle 4 Day 1	170	8.63	16.34	0.0	0.00	100.0	161	-11.18	23.26	-100.0	0.00	66.7
Cycle 4 Day 22	133	11.28	18.07	0.0	0.00	100.0	127	-9.19	22.29	-83.3	0.00	50.0
Cycle 5 Day 1	149	8.84	14.95	0.0	0.00	100.0	144	-11.23	23.14	-100.0	0.00	33.3
Cycle 5 Day 22	122	9.70	16.44	0.0	0.00	100.0	115	-11.01	23.87	-100.0	0.00	50.0
Cycle 6 Day 1	126	10.05	18.87	0.0	0.00	100.0	121	-8.13	20.98	-83.3	0.00	66.7
Cycle 6 Day 22	96	7.12	11.53	0.0	0.00	33.3	92	-12.32	21.52	-100.0	0.00	33.3
Cycle 7 Day 1	101	7.76	14.06	0.0	0.00	66.7	98	-7.99	19.77	-83.3	0.00	33.3
Cycle 7 Day 22	75	8.00	14.07	0.0	0.00	50.0	73	-7.31	18.84	-66.7	0.00	33.3
Cycle 8 Day 1	82	6.50	13.03	0.0	0.00	66.7	81	-6.58	16.39	-66.7	0.00	33.3
Cycle 8 Day 22	67	7.46	12.41	0.0	0.00	50.0	65	-7.44	19.99	-83.3	0.00	33.3
Cycle 9 Day 1	64	6.77	11.77	0.0	0.00	33.3	62	-8.06	20.63	-83.3	0.00	33.3
Cycle 9 Day 22	57	9.94	15.06	0.0	0.00	50.0	55	-2.42	19.36	-83.3	0.00	50.0
Cycle 10 Day 1	58	8.33	12.97	0.0	0.00	50.0	56	-4.17	17.48	-66.7	0.00	33.3
Cycle 10 Day 22	44	9.09	15.85	0.0	0.00	66.7	43	-3.49	18.74	-66.7	0.00	33.3
Cycle 11 Day 1	48	7.99	19.14	0.0	0.00	100.0	46	-2.54	16.84	-50.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.23: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Odynophagia - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	8.59	17.74	0.0	0.00	83.3	31	0.54	11.77	-16.7	0.00	33.3
Cycle 12 Day 1	43	7.75	16.80	0.0	0.00	66.7	41	-1.22	15.09	-33.3	0.00	33.3
Cycle 12 Day 22	27	10.49	17.39	0.0	0.00	66.7	25	-2.00	17.56	-33.3	0.00	50.0
Cycle 13 Day 1	37	7.21	14.98	0.0	0.00	66.7	35	-3.33	13.89	-33.3	0.00	16.7
Cycle 13 Day 22	22	9.85	17.56	0.0	0.00	66.7	21	0.79	15.34	-33.3	0.00	33.3
Cycle 14 Day 1	31	10.75	18.53	0.0	0.00	66.7	30	0.00	13.13	-33.3	0.00	33.3
Cycle 14 Day 22	20	11.67	21.70	0.0	0.00	66.7	19	-1.75	15.61	-33.3	0.00	33.3
Cycle 15 Day 1	27	10.49	20.75	0.0	0.00	66.7	27	2.47	18.89	-33.3	0.00	66.7
Cycle 15 Day 22	17	3.92	12.54	0.0	0.00	50.0	17	-1.96	18.52	-33.3	0.00	50.0
Cycle 16 Day 1	22	8.33	16.86	0.0	0.00	66.7	22	1.52	18.48	-16.7	0.00	66.7
Cycle 16 Day 22	14	8.33	18.20	0.0	0.00	66.7	14	1.19	21.15	-16.7	0.00	66.7
Cycle 17 Day 1	18	5.56	11.43	0.0	0.00	33.3	18	-0.93	12.09	-16.7	0.00	33.3
Cycle 18 Day 1	16	8.33	17.21	0.0	0.00	66.7	16	-1.04	14.23	-16.7	0.00	33.3
Cycle 18 Day 22	11	1.52	5.03	0.0	0.00	16.7	10	-5.00	13.72	-33.3	0.00	16.7
Cycle 19 Day 1	16	7.29	13.57	0.0	0.00	50.0	15	-2.22	12.39	-16.7	0.00	16.7
Cycle 19 Day 22	12	5.56	10.86	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 20 Day 1	16	4.17	11.39	0.0	0.00	33.3	15	-5.56	16.27	-33.3	0.00	33.3
Cycle 20 Day 22	11	6.06	11.24	0.0	0.00	33.3	10	0.00	15.71	-16.7	0.00	33.3
Cycle 21 Day 1	15	4.44	9.89	0.0	0.00	33.3	14	-3.57	13.36	-16.7	0.00	33.3
Cycle 22 Day 1	12	4.17	10.36	0.0	0.00	33.3	12	-2.78	9.62	-16.7	0.00	16.7
Cycle 23 Day 1	13	3.85	9.99	0.0	0.00	33.3	13	-5.13	8.01	-16.7	0.00	0.0
Study Disc 1	153	21.13	28.93	0.0	0.00	100.0	149	-1.90	27.71	-83.3	0.00	100.0
Study Disc 2	12	19.44	31.65	0.0	0.00	100.0	11	0.00	28.87	-33.3	0.00	66.7
30 D SFU Z/P	93	19.18	24.93	0.0	16.67	100.0	90	-4.44	24.20	-66.7	0.00	50.0
90 D SFU Z/P	84	16.67	21.95	0.0	0.00	83.3	82	-3.46	29.01	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	27.04	26.61	0.0	33.33	100.0						
Cycle 1 Day 22	186	22.49	20.81	0.0	33.33	100.0	176	-4.55	21.78	-83.3	0.00	50.0
Cycle 2 Day 1	216	21.14	23.42	0.0	16.67	100.0	206	-4.94	26.72	-100.0	0.00	100.0
Cycle 2 Day 22	157	18.58	20.76	0.0	16.67	100.0	150	-8.00	25.01	-66.7	0.00	100.0
Cycle 3 Day 1	200	16.33	19.19	0.0	8.33	100.0	190	-9.56	24.26	-83.3	0.00	66.7
Cycle 3 Day 22	161	19.77	21.26	0.0	16.67	100.0	152	-6.14	23.93	-66.7	0.00	66.7
Cycle 4 Day 1	177	15.73	18.78	0.0	0.00	66.7	169	-9.76	24.30	-83.3	0.00	66.7
Cycle 4 Day 22	127	16.67	18.78	0.0	16.67	100.0	122	-6.56	21.70	-83.3	0.00	33.3
Cycle 5 Day 1	156	17.63	21.19	0.0	16.67	100.0	148	-5.29	22.84	-83.3	0.00	66.7
Cycle 5 Day 22	117	15.95	20.69	0.0	0.00	100.0	110	-7.42	26.58	-83.3	0.00	50.0
Cycle 6 Day 1	131	15.52	19.41	0.0	0.00	100.0	122	-7.51	23.77	-83.3	0.00	50.0
Cycle 6 Day 22	108	13.43	18.99	0.0	0.00	66.7	103	-9.87	26.24	-83.3	0.00	66.7
Cycle 7 Day 1	119	13.17	18.14	0.0	0.00	66.7	113	-8.41	23.05	-83.3	0.00	50.0
Cycle 7 Day 22	87	13.79	16.71	0.0	0.00	66.7	81	-9.67	21.55	-66.7	0.00	33.3
Cycle 8 Day 1	88	15.15	20.78	0.0	0.00	83.3	80	-5.42	24.42	-66.7	0.00	83.3
Cycle 8 Day 22	77	13.42	17.94	0.0	0.00	66.7	71	-10.09	23.48	-66.7	0.00	33.3
Cycle 9 Day 1	82	14.02	18.79	0.0	0.00	66.7	75	-10.00	22.26	-83.3	0.00	33.3
Cycle 9 Day 22	65	14.62	18.28	0.0	0.00	66.7	60	-6.94	22.82	-83.3	0.00	33.3
Cycle 10 Day 1	72	10.88	16.59	0.0	0.00	66.7	66	-10.35	22.22	-83.3	0.00	33.3
Cycle 10 Day 22	61	12.30	17.72	0.0	0.00	66.7	57	-6.14	22.85	-83.3	0.00	66.7
Cycle 11 Day 1	68	10.54	15.75	0.0	0.00	66.7	63	-8.47	19.37	-66.7	0.00	33.3
Cycle 11 Day 22	48	10.76	18.98	0.0	0.00	66.7	44	-7.95	19.52	-66.7	0.00	33.3
Cycle 12 Day 1	58	12.93	19.00	0.0	0.00	66.7	53	-4.40	20.71	-66.7	0.00	33.3
Cycle 12 Day 22	40	13.33	17.38	0.0	0.00	66.7	37	-4.95	19.98	-66.7	0.00	33.3
Cycle 13 Day 1	51	13.07	18.05	0.0	0.00	66.7	48	-4.86	21.18	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	13.18	18.02	0.0	0.00	66.7	40	-4.58	22.32	-66.7	0.00	33.3
Cycle 14 Day 1	41	16.26	20.58	0.0	0.00	66.7	39	-2.99	22.58	-50.0	0.00	66.7
Cycle 14 Day 22	33	10.10	14.40	0.0	0.00	33.3	32	-9.38	17.42	-66.7	0.00	16.7
Cycle 15 Day 1	36	14.35	20.76	0.0	0.00	66.7	35	-1.90	24.51	-50.0	0.00	66.7
Cycle 15 Day 22	29	13.79	17.86	0.0	0.00	66.7	29	-6.32	24.16	-66.7	0.00	33.3
Cycle 16 Day 1	35	11.90	14.89	0.0	0.00	33.3	35	-7.14	25.34	-66.7	0.00	33.3
Cycle 16 Day 22	29	13.22	19.10	0.0	0.00	66.7	29	-8.62	22.55	-66.7	0.00	33.3
Cycle 17 Day 1	30	13.33	17.73	0.0	0.00	66.7	30	-3.89	22.61	-66.7	0.00	33.3
Cycle 17 Day 22	23	12.32	17.56	0.0	0.00	66.7	23	-4.35	21.45	-66.7	0.00	33.3
Cycle 18 Day 1	27	10.49	16.76	0.0	0.00	66.7	27	-8.02	22.35	-66.7	0.00	33.3
Cycle 18 Day 22	20	9.17	13.76	0.0	0.00	33.3	20	-8.33	22.62	-66.7	0.00	16.7
Cycle 19 Day 1	23	4.35	9.01	0.0	0.00	33.3	23	-13.77	18.57	-66.7	0.00	0.0
Cycle 19 Day 22	20	10.00	14.71	0.0	0.00	33.3	20	-7.50	21.95	-66.7	0.00	16.7
Cycle 20 Day 1	23	5.07	10.58	0.0	0.00	33.3	23	-11.59	17.72	-50.0	0.00	16.7
Cycle 20 Day 22	18	6.48	11.63	0.0	0.00	33.3	18	-11.11	18.96	-66.7	0.00	0.0
Cycle 21 Day 1	20	5.83	16.47	0.0	0.00	66.7	20	-8.33	19.12	-66.7	0.00	33.3
Cycle 21 Day 22	14	3.57	9.65	0.0	0.00	33.3	14	-9.52	21.40	-66.7	0.00	16.7
Cycle 22 Day 1	15	1.11	4.30	0.0	0.00	16.7	15	-13.33	19.11	-66.7	0.00	0.0
Cycle 22 Day 22	10	5.00	8.05	0.0	0.00	16.7	10	-13.33	21.94	-66.7	0.00	0.0
Cycle 23 Day 1	15	1.11	4.30	0.0	0.00	16.7	15	-14.44	18.76	-66.7	-16.67	0.0
Cycle 23 Day 22	11	3.03	6.74	0.0	0.00	16.7	11	-10.61	18.67	-50.0	0.00	0.0
Cycle 24 Day 1	14	2.38	6.05	0.0	0.00	16.7	14	-13.10	19.81	-66.7	0.00	0.0
Cycle 25 Day 1	12	6.94	11.14	0.0	0.00	33.3	12	-11.11	19.25	-50.0	0.00	16.7
Cycle 25 Day 22	11	7.58	11.46	0.0	0.00	33.3	11	-10.61	20.10	-50.0	0.00	16.7
Cycle 26 Day 1	13	3.85	7.31	0.0	0.00	16.7	13	-14.10	20.24	-66.7	0.00	0.0
Cycle 27 Day 1	11	4.55	10.78	0.0	0.00	33.3	11	-10.61	15.41	-33.3	-16.67	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	6.94	13.22	0.0	0.00	33.3	12	-6.94	16.60	-33.3	0.00	16.7
Study Disc 1	144	25.58	27.94	0.0	16.67	100.0	136	-3.43	25.67	-83.3	0.00	66.7
30 D SFU Z/P	77	24.89	26.30	0.0	16.67	100.0	72	-6.02	29.11	-66.7	0.00	100.0
90 D SFU Z/P	89	23.60	24.72	0.0	16.67	100.0	86	-6.59	30.17	-66.7	0.00	83.3
Placebo + mFOLFOX6 (N=282)												
Baseline	257	26.39	27.45	0.0	16.67	100.0						
Cycle 1 Day 22	211	22.43	23.68	0.0	16.67	100.0	208	-3.45	23.17	-100.0	0.00	66.7
Cycle 2 Day 1	230	17.83	22.54	0.0	16.67	100.0	223	-8.37	28.25	-100.0	0.00	100.0
Cycle 2 Day 22	185	18.29	21.29	0.0	16.67	100.0	180	-8.89	26.04	-100.0	0.00	100.0
Cycle 3 Day 1	203	16.17	19.83	0.0	16.67	100.0	196	-8.50	23.48	-83.3	0.00	83.3
Cycle 3 Day 22	156	16.56	20.26	0.0	0.00	83.3	148	-8.67	24.86	-100.0	0.00	33.3
Cycle 4 Day 1	170	14.80	19.14	0.0	0.00	100.0	161	-8.70	23.13	-100.0	0.00	50.0
Cycle 4 Day 22	133	14.29	19.26	0.0	0.00	83.3	127	-8.79	23.93	-100.0	0.00	66.7
Cycle 5 Day 1	149	13.65	19.67	0.0	0.00	83.3	144	-8.68	24.14	-100.0	0.00	50.0
Cycle 5 Day 22	122	15.44	21.97	0.0	0.00	100.0	115	-8.99	22.44	-100.0	0.00	33.3
Cycle 6 Day 1	126	16.01	23.80	0.0	0.00	100.0	121	-5.79	23.64	-83.3	0.00	66.7
Cycle 6 Day 22	96	10.76	16.58	0.0	0.00	66.7	92	-12.68	24.51	-100.0	0.00	33.3
Cycle 7 Day 1	101	11.39	17.31	0.0	0.00	66.7	98	-8.50	21.30	-100.0	0.00	33.3
Cycle 7 Day 22	75	10.00	18.78	0.0	0.00	100.0	73	-8.68	20.43	-100.0	0.00	33.3
Cycle 8 Day 1	82	10.37	19.18	0.0	0.00	100.0	81	-7.82	23.29	-100.0	0.00	33.3
Cycle 8 Day 22	67	9.45	14.28	0.0	0.00	33.3	65	-9.23	23.39	-100.0	0.00	33.3
Cycle 9 Day 1	64	10.94	17.62	0.0	0.00	66.7	62	-7.53	22.11	-100.0	0.00	33.3
Cycle 9 Day 22	57	11.11	19.50	0.0	0.00	100.0	55	-7.27	21.93	-83.3	0.00	33.3
Cycle 10 Day 1	58	10.06	16.79	0.0	0.00	66.7	56	-7.14	19.81	-66.7	0.00	33.3
Cycle 10 Day 22	44	14.39	19.22	0.0	0.00	66.7	43	-3.49	21.07	-66.7	0.00	33.3
Cycle 11 Day 1	48	14.93	23.63	0.0	0.00	100.0	46	-0.72	20.47	-50.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.24: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Pain and Discomfort - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	14.14	23.61	0.0	0.00	100.0	31	-2.15	17.07	-33.3	0.00	33.3
Cycle 12 Day 1	43	14.34	21.39	0.0	0.00	66.7	41	-1.63	21.67	-33.3	0.00	66.7
Cycle 12 Day 22	27	19.75	25.33	0.0	16.67	66.7	25	-1.33	19.20	-33.3	0.00	33.3
Cycle 13 Day 1	37	14.86	18.75	0.0	0.00	66.7	35	-2.38	21.44	-66.7	0.00	50.0
Cycle 13 Day 22	22	18.94	21.39	0.0	16.67	66.7	21	0.79	23.26	-50.0	0.00	33.3
Cycle 14 Day 1	31	16.67	23.17	0.0	0.00	66.7	30	-1.67	21.15	-50.0	0.00	33.3
Cycle 14 Day 22	20	16.67	24.18	0.0	0.00	66.7	19	-5.26	20.07	-50.0	0.00	33.3
Cycle 15 Day 1	27	14.20	22.51	0.0	0.00	66.7	27	-1.23	24.43	-66.7	0.00	66.7
Cycle 15 Day 22	17	12.75	20.86	0.0	0.00	66.7	17	-2.94	25.16	-33.3	0.00	66.7
Cycle 16 Day 1	22	12.12	20.69	0.0	0.00	66.7	22	-3.03	20.98	-33.3	0.00	66.7
Cycle 16 Day 22	14	9.52	19.30	0.0	0.00	66.7	14	-3.57	23.73	-33.3	0.00	66.7
Cycle 17 Day 1	18	12.96	19.43	0.0	0.00	66.7	18	1.85	18.86	-33.3	0.00	33.3
Cycle 18 Day 1	16	11.46	18.97	0.0	0.00	66.7	16	-4.17	20.64	-33.3	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-6.67	11.65	-33.3	0.00	0.0
Cycle 19 Day 1	16	9.38	16.07	0.0	0.00	50.0	15	-6.67	23.40	-50.0	0.00	33.3
Cycle 19 Day 22	12	9.72	13.22	0.0	0.00	33.3	11	-4.55	21.20	-50.0	0.00	33.3
Cycle 20 Day 1	16	8.33	13.61	0.0	0.00	33.3	15	-7.78	20.77	-50.0	0.00	33.3
Cycle 20 Day 22	11	4.55	7.78	0.0	0.00	16.7	10	-5.00	15.81	-33.3	0.00	16.7
Cycle 21 Day 1	15	4.44	7.63	0.0	0.00	16.7	14	-10.71	19.18	-50.0	-8.33	16.7
Cycle 22 Day 1	12	6.94	19.41	0.0	0.00	66.7	12	-4.17	16.09	-33.3	0.00	33.3
Cycle 23 Day 1	13	7.69	14.62	0.0	0.00	50.0	13	-7.69	21.10	-50.0	0.00	16.7
Study Disc 1	153	25.05	28.17	0.0	16.67	100.0	149	-1.23	29.07	-83.3	0.00	100.0
Study Disc 2	12	37.50	31.08	0.0	33.33	100.0	11	9.09	26.21	-50.0	0.00	50.0
30 D SFU Z/P	93	25.81	27.31	0.0	16.67	100.0	90	-1.85	27.08	-83.3	0.00	66.7
90 D SFU Z/P	84	24.40	24.60	0.0	25.00	100.0	82	-1.83	32.50	-100.0	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	51.30	28.99	0.0	50.00	100.0						
Cycle 1 Day 22	186	42.92	26.89	0.0	33.33	100.0	176	-8.33	24.69	-66.7	0.00	66.7
Cycle 2 Day 1	216	40.74	26.83	0.0	33.33	100.0	206	-10.19	26.31	-100.0	0.00	66.7
Cycle 2 Day 22	157	39.17	25.17	0.0	33.33	100.0	150	-11.67	24.33	-100.0	0.00	66.7
Cycle 3 Day 1	200	37.08	25.85	0.0	33.33	100.0	190	-12.63	26.19	-100.0	0.00	66.7
Cycle 3 Day 22	161	42.55	27.32	0.0	33.33	100.0	152	-9.65	26.48	-100.0	0.00	66.7
Cycle 4 Day 1	177	36.63	26.89	0.0	33.33	100.0	169	-14.60	24.61	-100.0	-16.67	50.0
Cycle 4 Day 22	127	38.32	24.70	0.0	33.33	100.0	122	-11.34	26.87	-83.3	0.00	50.0
Cycle 5 Day 1	156	38.68	26.57	0.0	33.33	100.0	148	-12.16	28.61	-83.3	-16.67	66.7
Cycle 5 Day 22	117	41.60	25.49	0.0	33.33	100.0	110	-10.30	29.61	-66.7	0.00	66.7
Cycle 6 Day 1	131	37.15	27.70	0.0	33.33	100.0	122	-13.39	31.68	-100.0	0.00	66.7
Cycle 6 Day 22	108	37.35	25.77	0.0	33.33	100.0	103	-11.65	26.59	-66.7	0.00	50.0
Cycle 7 Day 1	119	35.57	24.25	0.0	33.33	100.0	113	-12.68	28.46	-100.0	0.00	66.7
Cycle 7 Day 22	87	37.55	26.07	0.0	33.33	100.0	81	-13.79	27.99	-100.0	-16.67	50.0
Cycle 8 Day 1	88	37.50	26.41	0.0	33.33	100.0	80	-11.46	28.51	-100.0	0.00	66.7
Cycle 8 Day 22	77	34.63	24.00	0.0	33.33	100.0	71	-13.62	26.92	-66.7	-16.67	33.3
Cycle 9 Day 1	82	33.33	25.12	0.0	33.33	100.0	75	-18.22	25.14	-66.7	-16.67	33.3
Cycle 9 Day 22	65	33.33	25.17	0.0	33.33	100.0	60	-16.94	25.76	-83.3	-16.67	33.3
Cycle 10 Day 1	72	34.95	26.12	0.0	33.33	100.0	66	-16.67	25.15	-66.7	-16.67	33.3
Cycle 10 Day 22	61	33.61	27.47	0.0	33.33	100.0	57	-18.71	27.65	-100.0	-16.67	33.3
Cycle 11 Day 1	68	33.09	25.67	0.0	33.33	100.0	63	-18.25	30.78	-100.0	-16.67	50.0
Cycle 11 Day 22	48	31.25	23.73	0.0	33.33	100.0	44	-20.83	27.40	-66.7	-16.67	33.3
Cycle 12 Day 1	58	33.05	29.20	0.0	33.33	100.0	53	-17.30	30.13	-66.7	-16.67	66.7
Cycle 12 Day 22	40	37.08	26.28	0.0	33.33	100.0	37	-13.06	28.64	-100.0	0.00	33.3
Cycle 13 Day 1	51	32.35	24.36	0.0	33.33	100.0	48	-15.63	29.26	-66.7	-8.33	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	36.43	29.60	0.0	33.33	100.0	40	-9.58	25.84	-66.7	0.00	50.0
Cycle 14 Day 1	41	36.18	26.06	0.0	33.33	100.0	39	-13.68	25.33	-83.3	0.00	33.3
Cycle 14 Day 22	33	29.29	28.88	0.0	33.33	100.0	32	-18.75	28.95	-100.0	-16.67	33.3
Cycle 15 Day 1	36	37.04	30.11	0.0	33.33	100.0	35	-13.33	27.65	-66.7	-16.67	33.3
Cycle 15 Day 22	29	33.91	27.99	0.0	33.33	100.0	29	-14.37	27.72	-66.7	0.00	33.3
Cycle 16 Day 1	35	30.00	27.06	0.0	33.33	100.0	35	-17.14	31.95	-83.3	-16.67	33.3
Cycle 16 Day 22	29	32.76	29.03	0.0	33.33	100.0	29	-14.94	26.48	-66.7	-16.67	50.0
Cycle 17 Day 1	30	32.78	30.48	0.0	33.33	100.0	30	-12.78	33.53	-83.3	-16.67	66.7
Cycle 17 Day 22	23	29.71	24.60	0.0	33.33	83.3	23	-11.59	22.15	-66.7	-16.67	33.3
Cycle 18 Day 1	27	30.86	27.23	0.0	33.33	100.0	27	-14.81	27.48	-66.7	-16.67	33.3
Cycle 18 Day 22	20	24.17	22.60	0.0	33.33	66.7	20	-15.83	24.47	-66.7	-8.33	16.7
Cycle 19 Day 1	23	25.36	27.92	0.0	33.33	100.0	23	-19.57	30.42	-66.7	-16.67	33.3
Cycle 19 Day 22	20	30.83	30.72	0.0	33.33	100.0	20	-10.00	30.78	-66.7	-16.67	66.7
Cycle 20 Day 1	23	23.91	26.51	0.0	33.33	83.3	23	-21.01	28.52	-100.0	-16.67	33.3
Cycle 20 Day 22	18	25.93	26.95	0.0	33.33	100.0	18	-16.67	25.57	-66.7	-16.67	50.0
Cycle 21 Day 1	20	26.67	27.25	0.0	33.33	100.0	20	-19.17	29.75	-83.3	-16.67	33.3
Cycle 21 Day 22	14	22.62	24.11	0.0	33.33	83.3	14	-14.29	21.54	-50.0	-16.67	33.3
Cycle 22 Day 1	15	27.78	29.32	0.0	33.33	100.0	15	-18.89	33.25	-66.7	-33.33	50.0
Cycle 22 Day 22	10	41.67	32.63	0.0	33.33	100.0	10	-3.33	42.16	-66.7	-16.67	50.0
Cycle 23 Day 1	15	24.44	29.46	0.0	33.33	100.0	15	-22.22	38.14	-100.0	-33.33	50.0
Cycle 23 Day 22	11	24.24	26.21	0.0	33.33	66.7	11	-16.67	29.81	-66.7	-16.67	33.3
Cycle 24 Day 1	14	29.76	30.79	0.0	33.33	100.0	14	-20.24	35.91	-83.3	-25.00	50.0
Cycle 25 Day 1	12	30.56	30.84	0.0	33.33	100.0	12	-19.44	38.82	-66.7	-33.33	50.0
Cycle 25 Day 22	11	33.33	33.33	0.0	33.33	100.0	11	-12.12	38.07	-66.7	-33.33	50.0
Cycle 26 Day 1	13	30.77	28.74	0.0	33.33	100.0	13	-21.79	36.25	-66.7	-33.33	50.0
Cycle 27 Day 1	11	24.24	21.56	0.0	33.33	66.7	11	-30.30	30.57	-66.7	-33.33	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	31.94	25.08	0.0	33.33	66.7	12	-20.83	33.43	-66.7	-25.00	33.3
Study Disc 1	144	54.05	29.52	0.0	50.00	100.0	136	-2.08	30.73	-83.3	0.00	66.7
30 D SFU Z/P	77	51.73	30.06	0.0	50.00	100.0	72	-3.47	30.25	-66.7	0.00	66.7
90 D SFU Z/P	89	48.50	28.94	0.0	50.00	100.0	86	-2.52	31.88	-83.3	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	52.92	30.74	0.0	50.00	100.0						
Cycle 1 Day 22	211	45.34	29.02	0.0	33.33	100.0	208	-6.09	25.60	-100.0	0.00	66.7
Cycle 2 Day 1	230	41.52	29.00	0.0	33.33	100.0	223	-11.29	29.40	-100.0	0.00	66.7
Cycle 2 Day 22	185	41.53	27.48	0.0	33.33	100.0	180	-11.85	30.33	-100.0	-16.67	66.7
Cycle 3 Day 1	203	38.67	26.90	0.0	33.33	100.0	196	-13.44	28.71	-100.0	0.00	66.7
Cycle 3 Day 22	156	39.00	27.21	0.0	33.33	100.0	148	-14.30	27.90	-100.0	-8.33	66.7
Cycle 4 Day 1	170	39.61	26.83	0.0	33.33	100.0	161	-12.63	26.21	-100.0	0.00	66.7
Cycle 4 Day 22	133	40.23	26.60	0.0	33.33	100.0	127	-12.99	26.97	-83.3	-16.67	66.7
Cycle 5 Day 1	149	45.75	27.89	0.0	33.33	100.0	144	-7.75	28.42	-83.3	0.00	100.0
Cycle 5 Day 22	122	42.49	28.19	0.0	33.33	100.0	115	-8.12	25.59	-66.7	0.00	100.0
Cycle 6 Day 1	126	43.92	26.80	0.0	33.33	100.0	121	-9.09	28.22	-66.7	0.00	100.0
Cycle 6 Day 22	96	40.10	26.33	0.0	33.33	100.0	92	-14.67	25.30	-66.7	-16.67	50.0
Cycle 7 Day 1	101	37.13	26.13	0.0	33.33	100.0	98	-17.18	25.49	-100.0	-16.67	33.3
Cycle 7 Day 22	75	38.89	25.46	0.0	33.33	100.0	73	-15.98	27.84	-83.3	0.00	66.7
Cycle 8 Day 1	82	39.84	29.37	0.0	33.33	100.0	81	-14.20	25.97	-66.7	-16.67	83.3
Cycle 8 Day 22	67	38.06	28.25	0.0	33.33	100.0	65	-16.92	28.79	-83.3	-16.67	50.0
Cycle 9 Day 1	64	41.15	25.19	0.0	33.33	100.0	62	-15.86	27.06	-100.0	-16.67	66.7
Cycle 9 Day 22	57	35.96	27.42	0.0	33.33	100.0	55	-20.30	26.97	-83.3	-16.67	33.3
Cycle 10 Day 1	58	37.07	29.46	0.0	33.33	100.0	56	-18.15	31.51	-100.0	-16.67	66.7
Cycle 10 Day 22	44	40.91	29.08	0.0	33.33	100.0	43	-13.95	29.08	-83.3	0.00	66.7
Cycle 11 Day 1	48	43.75	28.48	0.0	33.33	100.0	46	-9.06	24.77	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	41.92	30.93	0.0	33.33	100.0	31	-14.52	29.73	-83.3	0.00	33.3
Cycle 12 Day 1	43	44.96	28.76	0.0	33.33	100.0	41	-10.57	22.59	-66.7	0.00	16.7
Cycle 12 Day 22	27	41.36	31.48	0.0	33.33	100.0	25	-19.33	29.53	-100.0	-16.67	33.3
Cycle 13 Day 1	37	41.89	33.71	0.0	33.33	100.0	35	-15.24	25.36	-100.0	0.00	16.7
Cycle 13 Day 22	22	44.70	33.88	0.0	41.67	100.0	21	-10.32	26.07	-66.7	0.00	33.3
Cycle 14 Day 1	31	40.32	34.10	0.0	33.33	100.0	30	-15.00	24.11	-83.3	0.00	16.7
Cycle 14 Day 22	20	45.83	31.93	0.0	50.00	100.0	19	-10.53	23.71	-66.7	0.00	16.7
Cycle 15 Day 1	27	37.65	34.77	0.0	33.33	100.0	27	-16.67	30.66	-100.0	0.00	33.3
Cycle 15 Day 22	17	39.22	33.30	0.0	33.33	100.0	17	-17.65	33.06	-100.0	0.00	33.3
Cycle 16 Day 1	22	39.39	38.68	0.0	33.33	100.0	22	-15.91	29.76	-100.0	-16.67	33.3
Cycle 16 Day 22	14	30.95	38.04	0.0	16.67	100.0	14	-20.24	31.47	-100.0	-33.33	16.7
Cycle 17 Day 1	18	30.56	27.56	0.0	33.33	100.0	18	-20.37	29.46	-100.0	-16.67	16.7
Cycle 18 Day 1	16	34.37	30.10	0.0	33.33	100.0	16	-15.63	25.44	-66.7	-16.67	33.3
Cycle 18 Day 22	11	33.33	30.73	0.0	33.33	100.0	10	-16.67	30.43	-83.3	-8.33	16.7
Cycle 19 Day 1	16	28.12	30.86	0.0	33.33	100.0	15	-21.11	32.41	-100.0	-16.67	16.7
Cycle 19 Day 22	12	31.94	30.53	0.0	33.33	100.0	11	-16.67	29.81	-66.7	0.00	16.7
Cycle 20 Day 1	16	28.12	29.64	0.0	33.33	100.0	15	-21.11	26.33	-66.7	-16.67	16.7
Cycle 20 Day 22	11	30.30	31.46	0.0	33.33	100.0	10	-18.33	22.84	-66.7	-8.33	0.0
Cycle 21 Day 1	15	31.11	32.04	0.0	16.67	100.0	14	-15.48	33.63	-83.3	-8.33	33.3
Cycle 22 Day 1	12	34.72	27.94	0.0	33.33	100.0	12	-16.67	26.59	-66.7	-8.33	16.7
Cycle 23 Day 1	13	28.21	33.60	0.0	16.67	100.0	13	-23.08	29.30	-100.0	-33.33	16.7
Study Disc 1	153	49.78	32.33	0.0	33.33	100.0	149	-5.03	32.69	-100.0	0.00	66.7
Study Disc 2	12	51.39	32.92	0.0	33.33	100.0	11	9.09	20.23	-33.3	0.00	33.3
30 D SFU Z/P	93	47.31	27.72	0.0	33.33	100.0	90	-6.30	33.39	-100.0	0.00	66.7
90 D SFU Z/P	84	50.00	31.90	0.0	33.33	100.0	82	-2.44	33.86	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full 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 + mFOLFOX6 (N=176)												
	Baseline	160	49.90	28.19	0.0	41.67	100.0						
	Cycle 1 Day 22	124	39.78	26.18	0.0	33.33	100.0	116	-7.90	21.70	-66.7	0.00	66.7
	Cycle 2 Day 1	137	38.20	26.21	0.0	33.33	100.0	129	-11.11	24.94	-100.0	0.00	66.7
	Cycle 2 Day 22	103	36.89	24.55	0.0	33.33	100.0	97	-11.34	24.60	-100.0	0.00	50.0
	Cycle 3 Day 1	125	34.40	25.73	0.0	33.33	100.0	117	-13.25	25.29	-83.3	-16.67	33.3
	Cycle 3 Day 22	97	41.58	27.23	0.0	33.33	100.0	90	-7.41	26.22	-66.7	0.00	66.7
	Cycle 4 Day 1	112	35.57	26.71	0.0	33.33	100.0	104	-13.78	24.52	-66.7	-16.67	50.0
	Cycle 4 Day 22	83	39.16	26.21	0.0	33.33	100.0	78	-7.91	27.09	-83.3	0.00	50.0
	Cycle 5 Day 1	101	38.28	27.54	0.0	33.33	100.0	94	-11.35	26.80	-83.3	0.00	33.3
	Cycle 5 Day 22	72	41.44	26.54	0.0	33.33	100.0	66	-7.32	28.21	-66.7	0.00	66.7
	Cycle 6 Day 1	78	34.83	27.55	0.0	33.33	100.0	70	-12.14	27.94	-100.0	-8.33	33.3
	Cycle 6 Day 22	67	37.56	28.18	0.0	33.33	100.0	63	-8.73	27.57	-66.7	0.00	50.0
	Cycle 7 Day 1	75	35.33	24.81	0.0	33.33	100.0	69	-10.14	27.00	-83.3	0.00	50.0
	Cycle 7 Day 22	57	37.72	27.55	0.0	33.33	100.0	51	-11.44	29.53	-100.0	0.00	50.0
	Cycle 8 Day 1	59	36.44	27.76	0.0	33.33	100.0	51	-10.13	30.01	-100.0	0.00	66.7
	Cycle 8 Day 22	48	33.68	26.74	0.0	33.33	100.0	42	-14.29	27.69	-66.7	-16.67	33.3
	Cycle 9 Day 1	49	32.65	28.05	0.0	33.33	100.0	42	-19.05	26.69	-66.7	-16.67	33.3
	Cycle 9 Day 22	38	35.53	29.30	0.0	33.33	100.0	33	-17.68	29.44	-83.3	-16.67	33.3
	Cycle 10 Day 1	46	36.23	29.04	0.0	33.33	100.0	40	-16.25	27.08	-66.7	-16.67	33.3
	Cycle 10 Day 22	37	36.04	29.79	0.0	33.33	100.0	33	-19.70	29.89	-100.0	-16.67	33.3
	Cycle 11 Day 1	43	35.66	28.77	0.0	33.33	100.0	38	-17.11	32.30	-100.0	-16.67	33.3
	Cycle 11 Day 22	30	36.11	24.01	0.0	33.33	100.0	26	-21.79	30.47	-66.7	-25.00	33.3
	Cycle 12 Day 1	33	37.37	29.76	0.0	33.33	100.0	28	-17.26	30.25	-66.7	-25.00	66.7
	Cycle 12 Day 22	23	41.30	29.25	0.0	33.33	100.0	20	-14.17	33.89	-100.0	-8.33	33.3
	Cycle 13 Day 1	29	35.06	27.58	0.0	33.33	100.0	26	-13.46	26.67	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	25	39.33	33.98	0.0	33.33	100.0	22	-11.36	26.42	-66.7	0.00	33.3
	Cycle 14 Day 1	21	39.68	27.63	0.0	33.33	100.0	19	-14.91	26.00	-83.3	-16.67	33.3
	Cycle 14 Day 22	20	30.00	28.92	0.0	33.33	100.0	19	-23.68	33.48	-100.0	-16.67	33.3
	Cycle 15 Day 1	19	37.72	34.18	0.0	33.33	100.0	18	-17.59	27.70	-66.7	-16.67	33.3
	Cycle 15 Day 22	18	35.19	27.35	0.0	33.33	100.0	18	-17.59	28.85	-66.7	-8.33	33.3
	Cycle 16 Day 1	19	27.19	24.98	0.0	33.33	83.3	19	-21.93	30.96	-83.3	-16.67	33.3
	Cycle 16 Day 22	18	32.41	27.10	0.0	33.33	100.0	18	-20.37	29.46	-66.7	-25.00	50.0
	Cycle 17 Day 1	17	29.41	27.97	0.0	33.33	100.0	17	-20.59	26.04	-66.7	-16.67	33.3
	Cycle 17 Day 22	14	29.76	24.62	0.0	33.33	83.3	14	-16.67	23.57	-66.7	-16.67	33.3
	Cycle 18 Day 1	16	27.08	24.25	0.0	33.33	66.7	16	-19.79	22.13	-66.7	-25.00	16.7
	Cycle 18 Day 22	13	20.51	21.68	0.0	33.33	66.7	13	-23.08	26.82	-66.7	-16.67	16.7
	Cycle 19 Day 1	14	23.81	26.73	0.0	25.00	83.3	14	-20.24	32.14	-66.7	-16.67	33.3
	Cycle 19 Day 22	13	34.62	33.65	0.0	33.33	100.0	13	-10.26	36.35	-66.7	-16.67	66.7
	Cycle 20 Day 1	14	20.24	27.09	0.0	0.00	83.3	14	-23.81	32.50	-100.0	-25.00	33.3
	Cycle 20 Day 22	13	25.64	27.74	0.0	33.33	100.0	13	-19.23	28.74	-66.7	-16.67	50.0
	Cycle 21 Day 1	13	23.08	24.09	0.0	33.33	83.3	13	-19.23	28.74	-83.3	-16.67	33.3
	Cycle 21 Day 22	10	25.00	26.35	0.0	33.33	83.3	10	-15.00	24.15	-50.0	-16.67	33.3
	Cycle 23 Day 1	10	30.00	33.15	0.0	33.33	100.0	10	-13.33	36.68	-66.7	-16.67	50.0
	Study Disc 1	93	54.12	30.26	0.0	50.00	100.0	85	0.00	27.22	-66.7	0.00	66.7
	30 D SFU Z/P	50	50.67	32.11	0.0	50.00	100.0	46	-2.54	30.42	-66.7	0.00	66.7
	90 D SFU Z/P	52	42.31	31.22	0.0	33.33	100.0	50	-6.33	31.75	-83.3	0.00	66.7
	Placebo + mFOLFOX6 (N=175)												
	Baseline	159	50.84	30.80	0.0	50.00	100.0						
	Cycle 1 Day 22	138	45.05	28.79	0.0	33.33	100.0	135	-5.68	25.93	-100.0	0.00	50.0
	Cycle 2 Day 1	151	40.95	28.07	0.0	33.33	100.0	144	-10.76	29.00	-100.0	0.00	66.7
	Cycle 2 Day 22	128	39.71	27.91	0.0	33.33	100.0	123	-11.92	29.76	-100.0	-16.67	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 3 Day 1	130	36.92	27.69	0.0	33.33	100.0	124	-13.31	27.30	-100.0	0.00	66.7
	Cycle 3 Day 22	105	38.25	27.82	0.0	33.33	100.0	99	-13.13	30.05	-100.0	0.00	66.7
	Cycle 4 Day 1	109	38.53	27.56	0.0	33.33	100.0	101	-11.55	27.56	-100.0	0.00	66.7
	Cycle 4 Day 22	88	39.02	27.90	0.0	33.33	100.0	83	-11.85	26.87	-83.3	-16.67	66.7
	Cycle 5 Day 1	94	43.79	28.40	0.0	33.33	100.0	90	-7.96	28.40	-66.7	0.00	100.0
	Cycle 5 Day 22	85	41.76	27.41	0.0	33.33	100.0	79	-7.81	26.40	-66.7	0.00	100.0
	Cycle 6 Day 1	76	42.54	27.00	0.0	33.33	100.0	72	-7.87	28.11	-66.7	0.00	100.0
	Cycle 6 Day 22	63	37.83	26.64	0.0	33.33	100.0	60	-14.72	23.98	-66.7	-16.67	33.3
	Cycle 7 Day 1	63	34.39	27.58	0.0	33.33	100.0	60	-17.22	25.30	-100.0	-16.67	33.3
	Cycle 7 Day 22	46	36.96	28.31	0.0	33.33	100.0	44	-15.53	24.22	-66.7	-8.33	33.3
	Cycle 8 Day 1	49	35.71	29.46	0.0	33.33	100.0	48	-14.58	21.64	-66.7	-16.67	33.3
	Cycle 8 Day 22	39	33.33	28.36	0.0	33.33	100.0	37	-19.82	23.84	-66.7	-16.67	50.0
	Cycle 9 Day 1	38	37.72	26.76	0.0	33.33	100.0	36	-17.13	21.26	-66.7	-16.67	16.7
	Cycle 9 Day 22	34	34.80	29.69	0.0	33.33	100.0	32	-18.75	26.01	-66.7	-16.67	33.3
	Cycle 10 Day 1	31	31.72	29.92	0.0	33.33	100.0	29	-19.54	28.20	-100.0	-16.67	16.7
	Cycle 10 Day 22	27	37.65	29.81	0.0	33.33	100.0	26	-16.67	25.82	-83.3	-8.33	33.3
	Cycle 11 Day 1	28	37.50	28.91	0.0	33.33	100.0	26	-13.46	21.09	-66.7	0.00	16.7
	Cycle 11 Day 22	20	38.33	27.09	0.0	33.33	100.0	18	-18.52	26.13	-66.7	-25.00	33.3
	Cycle 12 Day 1	23	40.58	29.23	0.0	50.00	100.0	21	-12.70	22.30	-50.0	0.00	16.7
	Cycle 12 Day 22	15	38.89	33.13	0.0	33.33	100.0	13	-23.08	25.94	-66.7	-16.67	16.7
	Cycle 13 Day 1	21	39.68	31.83	0.0	33.33	100.0	19	-17.54	23.22	-50.0	-16.67	16.7
	Cycle 13 Day 22	11	45.45	38.79	0.0	50.00	100.0	10	-15.00	29.87	-66.7	-8.33	16.7
	Cycle 14 Day 1	14	35.71	35.12	0.0	33.33	100.0	13	-17.95	25.88	-66.7	-16.67	16.7
	Cycle 14 Day 22	10	48.33	29.87	0.0	50.00	100.0	9	-12.96	28.60	-66.7	0.00	16.7
	Cycle 15 Day 1	14	35.71	33.24	0.0	33.33	100.0	14	-14.29	31.25	-66.7	0.00	33.3
	Cycle 15 Day 22	10	40.00	34.43	0.0	33.33	100.0	10	-16.67	27.22	-66.7	-16.67	16.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 16 Day 1	14	35.71	35.12	0.0	33.33	100.0	14	-14.29	20.52	-50.0	-16.67	16.7
	Cycle 17 Day 1	11	24.24	17.26	0.0	33.33	50.0	11	-16.67	23.57	-50.0	0.00	16.7
	Cycle 18 Day 1	10	30.00	29.19	0.0	33.33	66.7	10	-8.33	22.57	-33.3	-8.33	33.3
	Cycle 19 Day 1	10	18.33	25.40	0.0	0.00	66.7	9	-18.52	29.40	-66.7	-16.67	16.7
	Cycle 20 Day 1	10	18.33	22.84	0.0	8.33	66.7	9	-18.52	28.19	-66.7	0.00	16.7
	Study Disc 1	94	46.63	32.39	0.0	33.33	100.0	92	-4.17	33.57	-100.0	0.00	66.7
	30 D SFU Z/P	65	42.82	26.18	0.0	33.33	100.0	63	-6.88	34.47	-100.0	0.00	66.7
	90 D SFU Z/P	57	43.57	31.14	0.0	33.33	100.0	55	-4.24	33.37	-83.3	0.00	83.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Female	Zolbetuximab + mFOLFOX6 (N=107)												
	Baseline	97	53.61	30.26	0.0	50.00	100.0						
	Cycle 1 Day 22	62	49.19	27.40	0.0	50.00	100.0	60	-9.17	29.82	-66.7	0.00	66.7
	Cycle 2 Day 1	79	45.15	27.50	0.0	33.33	100.0	77	-8.66	28.56	-100.0	0.00	66.7
	Cycle 2 Day 22	54	43.52	25.99	0.0	33.33	100.0	53	-12.26	24.05	-66.7	0.00	66.7
	Cycle 3 Day 1	75	41.56	25.61	0.0	33.33	100.0	73	-11.64	27.73	-100.0	0.00	66.7
	Cycle 3 Day 22	64	44.01	27.60	0.0	33.33	100.0	62	-12.90	26.72	-100.0	0.00	33.3
	Cycle 4 Day 1	65	38.46	27.31	0.0	33.33	100.0	65	-15.90	24.90	-100.0	0.00	33.3
	Cycle 4 Day 22	44	36.74	21.74	0.0	33.33	100.0	44	-17.42	25.66	-66.7	-16.67	50.0
	Cycle 5 Day 1	55	39.39	24.92	0.0	33.33	100.0	54	-13.58	31.73	-83.3	-16.67	66.7
	Cycle 5 Day 22	45	41.85	24.00	0.0	33.33	100.0	44	-14.77	31.38	-66.7	-16.67	66.7
	Cycle 6 Day 1	53	40.57	27.83	0.0	33.33	100.0	52	-15.06	36.34	-100.0	0.00	66.7
	Cycle 6 Day 22	41	36.99	21.57	0.0	33.33	83.3	40	-16.25	24.60	-66.7	-8.33	16.7
	Cycle 7 Day 1	44	35.98	23.55	0.0	33.33	100.0	44	-16.67	30.50	-100.0	-8.33	66.7
	Cycle 7 Day 22	30	37.22	23.44	0.0	33.33	100.0	30	-17.78	25.12	-66.7	-16.67	33.3
	Cycle 8 Day 1	29	39.66	23.74	0.0	33.33	100.0	29	-13.79	26.00	-66.7	0.00	66.7
	Cycle 8 Day 22	29	36.21	18.93	0.0	33.33	66.7	29	-12.64	26.22	-66.7	-16.67	33.3
	Cycle 9 Day 1	33	34.34	20.39	0.0	33.33	66.7	33	-17.17	23.38	-66.7	-16.67	33.3
	Cycle 9 Day 22	27	30.25	17.92	0.0	33.33	66.7	27	-16.05	20.92	-66.7	-16.67	16.7
	Cycle 10 Day 1	26	32.69	20.27	0.0	33.33	66.7	26	-17.31	22.35	-66.7	-16.67	33.3
	Cycle 10 Day 22	24	29.86	23.56	0.0	33.33	100.0	24	-17.36	24.81	-66.7	-16.67	33.3
	Cycle 11 Day 1	25	28.67	18.95	0.0	33.33	66.7	25	-20.00	28.87	-83.3	-16.67	50.0
	Cycle 11 Day 22	18	23.15	21.50	0.0	25.00	66.7	18	-19.44	23.04	-66.7	-16.67	16.7
	Cycle 12 Day 1	25	27.33	28.00	0.0	33.33	100.0	25	-17.33	30.61	-66.7	-16.67	66.7
	Cycle 12 Day 22	17	31.37	21.15	0.0	33.33	66.7	17	-11.76	21.86	-66.7	0.00	16.7
	Cycle 13 Day 1	22	28.79	19.37	0.0	33.33	66.7	22	-18.18	32.49	-66.7	-16.67	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	18	32.41	22.49	0.0	33.33	83.3	18	-7.41	25.71	-66.7	0.00	50.0
	Cycle 14 Day 1	20	32.50	24.47	0.0	33.33	100.0	20	-12.50	25.29	-66.7	0.00	33.3
	Cycle 14 Day 22	13	28.21	29.96	0.0	33.33	100.0	13	-11.54	19.70	-33.3	-16.67	33.3
	Cycle 15 Day 1	17	36.27	25.84	0.0	33.33	66.7	17	-8.82	27.71	-66.7	0.00	33.3
	Cycle 15 Day 22	11	31.82	30.23	0.0	33.33	100.0	11	-9.09	26.21	-66.7	0.00	33.3
	Cycle 16 Day 1	16	33.33	29.81	0.0	33.33	100.0	16	-11.46	33.18	-66.7	-16.67	33.3
	Cycle 16 Day 22	11	33.33	33.33	0.0	33.33	100.0	11	-6.06	18.67	-33.3	0.00	33.3
	Cycle 17 Day 1	13	37.18	34.13	0.0	33.33	100.0	13	-2.56	40.17	-83.3	0.00	66.7
	Cycle 18 Day 1	11	36.36	31.46	0.0	33.33	100.0	11	-7.58	33.63	-66.7	0.00	33.3
	Study Disc 1	51	53.92	28.40	0.0	50.00	100.0	51	-5.56	35.85	-83.3	0.00	66.7
	30 D SFU Z/P	27	53.70	26.28	0.0	50.00	100.0	26	-5.13	30.47	-66.7	0.00	50.0
	90 D SFU Z/P	37	57.21	23.09	16.7	66.67	100.0	36	2.78	31.75	-66.7	0.00	50.0
	Placebo + mFOLFOX6 (N=107)												
	Baseline	98	56.29	30.51	0.0	66.67	100.0						
	Cycle 1 Day 22	73	45.89	29.63	0.0	33.33	100.0	73	-6.85	25.13	-66.7	0.00	66.7
	Cycle 2 Day 1	79	42.62	30.86	0.0	33.33	100.0	79	-12.24	30.28	-100.0	0.00	66.7
	Cycle 2 Day 22	57	45.61	26.26	0.0	33.33	100.0	57	-11.70	31.80	-66.7	-16.67	66.7
	Cycle 3 Day 1	73	41.78	25.33	0.0	33.33	100.0	72	-13.66	31.19	-66.7	-16.67	66.7
	Cycle 3 Day 22	51	40.52	26.09	0.0	33.33	100.0	49	-16.67	23.07	-66.7	-16.67	50.0
	Cycle 4 Day 1	61	41.53	25.57	0.0	33.33	100.0	60	-14.44	23.86	-66.7	-16.67	50.0
	Cycle 4 Day 22	45	42.59	23.98	0.0	33.33	100.0	44	-15.15	27.33	-83.3	-16.67	66.7
	Cycle 5 Day 1	55	49.09	26.92	0.0	33.33	100.0	54	-7.41	28.72	-83.3	0.00	66.7
	Cycle 5 Day 22	37	44.14	30.23	0.0	33.33	100.0	36	-8.80	24.07	-66.7	0.00	50.0
	Cycle 6 Day 1	50	46.00	26.63	0.0	33.33	100.0	49	-10.88	28.58	-66.7	0.00	66.7
	Cycle 6 Day 22	33	44.44	25.57	0.0	33.33	100.0	32	-14.58	28.00	-66.7	0.00	50.0
	Cycle 7 Day 1	38	41.67	23.17	0.0	33.33	100.0	38	-17.11	26.13	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.25.2: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Anxiety by Sex - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 7 Day 22	29	41.95	20.23	0.0	33.33	100.0	29	-16.67	33.03	-83.3	0.00	66.7
	Cycle 8 Day 1	33	45.96	28.57	0.0	33.33	100.0	33	-13.64	31.58	-66.7	0.00	83.3
	Cycle 8 Day 22	28	44.64	27.24	0.0	33.33	100.0	28	-13.10	34.35	-83.3	0.00	50.0
	Cycle 9 Day 1	26	46.15	22.26	0.0	33.33	100.0	26	-14.10	33.89	-100.0	0.00	66.7
	Cycle 9 Day 22	23	37.68	24.21	0.0	33.33	100.0	23	-22.46	28.70	-83.3	-16.67	33.3
	Cycle 10 Day 1	27	43.21	28.22	0.0	33.33	100.0	27	-16.67	35.20	-66.7	-16.67	66.7
	Cycle 10 Day 22	17	46.08	27.97	0.0	33.33	100.0	17	-9.80	33.88	-66.7	0.00	66.7
	Cycle 11 Day 1	20	52.50	26.09	16.7	33.33	100.0	20	-3.33	28.41	-66.7	0.00	33.3
	Cycle 11 Day 22	13	47.44	36.54	0.0	33.33	100.0	13	-8.97	34.44	-83.3	0.00	33.3
	Cycle 12 Day 1	20	50.00	28.10	0.0	33.33	100.0	20	-8.33	23.26	-66.7	0.00	16.7
	Cycle 12 Day 22	12	44.44	30.43	0.0	33.33	100.0	12	-15.28	33.68	-100.0	0.00	33.3
	Cycle 13 Day 1	16	44.79	36.88	0.0	33.33	100.0	16	-12.50	28.22	-100.0	0.00	16.7
	Cycle 13 Day 22	11	43.94	30.07	0.0	33.33	100.0	11	-6.06	22.70	-33.3	0.00	33.3
	Cycle 14 Day 1	17	44.12	33.82	0.0	33.33	100.0	17	-12.75	23.22	-83.3	0.00	16.7
	Cycle 14 Day 22	10	43.33	35.31	0.0	50.00	100.0	10	-8.33	19.64	-33.3	0.00	16.7
	Cycle 15 Day 1	13	39.74	37.60	0.0	33.33	100.0	13	-19.23	31.07	-100.0	-16.67	16.7
	Study Disc 1	59	54.80	31.87	0.0	50.00	100.0	57	-6.43	31.46	-66.7	0.00	66.7
	30 D SFU Z/P	28	57.74	28.86	0.0	66.67	100.0	27	-4.94	31.29	-66.7	0.00	66.7
	90 D SFU Z/P	27	63.58	29.61	16.7	66.67	100.0	27	1.23	35.18	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	14.66	25.11	0.0	0.00	100.0						
Cycle 1 Day 22	186	11.83	21.72	0.0	0.00	100.0	176	-1.14	25.42	-100.0	0.00	66.7
Cycle 2 Day 1	216	12.50	23.25	0.0	0.00	100.0	206	-1.46	25.57	-100.0	0.00	100.0
Cycle 2 Day 22	157	10.83	22.40	0.0	0.00	100.0	150	-2.00	28.96	-100.0	0.00	100.0
Cycle 3 Day 1	200	7.33	17.42	0.0	0.00	100.0	190	-5.79	25.11	-100.0	0.00	100.0
Cycle 3 Day 22	161	11.59	21.81	0.0	0.00	100.0	152	-2.19	26.21	-100.0	0.00	100.0
Cycle 4 Day 1	177	9.04	19.62	0.0	0.00	100.0	169	-4.93	27.13	-100.0	0.00	100.0
Cycle 4 Day 22	127	11.55	22.37	0.0	0.00	100.0	122	-0.82	25.16	-100.0	0.00	66.7
Cycle 5 Day 1	156	10.04	20.88	0.0	0.00	100.0	148	-3.83	25.94	-100.0	0.00	66.7
Cycle 5 Day 22	117	13.11	26.25	0.0	0.00	100.0	110	-2.42	26.22	-100.0	0.00	100.0
Cycle 6 Day 1	131	7.89	19.76	0.0	0.00	100.0	122	-5.74	22.14	-66.7	0.00	66.7
Cycle 6 Day 22	108	8.33	19.40	0.0	0.00	100.0	103	-2.27	21.52	-66.7	0.00	66.7
Cycle 7 Day 1	119	9.24	21.23	0.0	0.00	100.0	113	-2.36	26.99	-100.0	0.00	100.0
Cycle 7 Day 22	87	9.58	20.27	0.0	0.00	100.0	81	-2.88	20.55	-66.7	0.00	66.7
Cycle 8 Day 1	88	9.47	20.18	0.0	0.00	100.0	80	-1.25	23.98	-66.7	0.00	100.0
Cycle 8 Day 22	77	8.23	18.85	0.0	0.00	100.0	71	-3.29	21.93	-66.7	0.00	66.7
Cycle 9 Day 1	82	6.10	16.67	0.0	0.00	100.0	75	-6.67	19.76	-66.7	0.00	66.7
Cycle 9 Day 22	65	9.74	19.30	0.0	0.00	100.0	60	-2.22	22.85	-66.7	0.00	66.7
Cycle 10 Day 1	72	6.02	16.14	0.0	0.00	100.0	66	-6.06	26.09	-100.0	0.00	66.7
Cycle 10 Day 22	61	7.10	18.37	0.0	0.00	100.0	57	-3.51	21.53	-66.7	0.00	66.7
Cycle 11 Day 1	68	6.37	16.55	0.0	0.00	100.0	63	-6.35	23.84	-100.0	0.00	66.7
Cycle 11 Day 22	48	6.25	14.84	0.0	0.00	66.7	44	-8.33	22.87	-66.7	0.00	33.3
Cycle 12 Day 1	58	6.32	19.20	0.0	0.00	100.0	53	-5.03	20.04	-66.7	0.00	66.7
Cycle 12 Day 22	40	6.67	20.25	0.0	0.00	100.0	37	-9.91	27.06	-100.0	0.00	66.7
Cycle 13 Day 1	51	10.46	23.56	0.0	0.00	100.0	48	-4.17	27.18	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	10.08	19.97	0.0	0.00	66.7	40	-3.33	21.08	-66.7	0.00	33.3
Cycle 14 Day 1	41	7.32	20.43	0.0	0.00	100.0	39	-4.27	20.49	-33.3	0.00	66.7
Cycle 14 Day 22	33	11.11	23.07	0.0	0.00	100.0	32	-2.08	22.30	-33.3	0.00	66.7
Cycle 15 Day 1	36	10.19	22.28	0.0	0.00	100.0	35	-0.95	18.94	-33.3	0.00	66.7
Cycle 15 Day 22	29	13.79	26.00	0.0	0.00	100.0	29	1.15	25.95	-33.3	0.00	66.7
Cycle 16 Day 1	35	7.62	16.34	0.0	0.00	66.7	35	-2.86	18.74	-33.3	0.00	33.3
Cycle 16 Day 22	29	9.20	17.59	0.0	0.00	66.7	29	-2.30	17.66	-33.3	0.00	33.3
Cycle 17 Day 1	30	7.78	18.94	0.0	0.00	66.7	30	-2.22	21.32	-33.3	0.00	66.7
Cycle 17 Day 22	23	8.70	20.64	0.0	0.00	66.7	23	-1.45	23.52	-33.3	0.00	66.7
Cycle 18 Day 1	27	6.17	16.11	0.0	0.00	66.7	27	-3.70	16.88	-33.3	0.00	33.3
Cycle 18 Day 22	20	5.00	12.21	0.0	0.00	33.3	20	-3.33	18.42	-33.3	0.00	33.3
Cycle 19 Day 1	23	1.45	6.95	0.0	0.00	33.3	23	-5.80	16.37	-33.3	0.00	33.3
Cycle 19 Day 22	20	1.67	7.45	0.0	0.00	33.3	20	-6.67	17.44	-33.3	0.00	33.3
Cycle 20 Day 1	23	2.90	9.60	0.0	0.00	33.3	23	-4.35	15.26	-33.3	0.00	33.3
Cycle 20 Day 22	18	5.56	12.78	0.0	0.00	33.3	18	-3.70	19.43	-33.3	0.00	33.3
Cycle 21 Day 1	20	3.33	10.26	0.0	0.00	33.3	20	-3.33	14.91	-33.3	0.00	33.3
Cycle 21 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
Cycle 22 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 22 Day 22	10	13.33	17.21	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 23 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 23 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 24 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
Cycle 25 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
Cycle 25 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 26 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-7.69	19.97	-33.3	0.00	33.3
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	20.10	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Study Disc 1	144	17.13	28.96	0.0	0.00	100.0	136	4.41	30.31	-100.0	0.00	100.0
30 D SFU Z/P	77	14.72	26.76	0.0	0.00	100.0	72	3.24	24.49	-66.7	0.00	100.0
90 D SFU Z/P	89	12.36	23.24	0.0	0.00	100.0	86	1.94	25.23	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	15.95	26.85	0.0	0.00	100.0						
Cycle 1 Day 22	211	13.74	23.58	0.0	0.00	100.0	208	-0.64	23.16	-100.0	0.00	100.0
Cycle 2 Day 1	230	10.58	21.11	0.0	0.00	100.0	223	-4.04	23.86	-100.0	0.00	100.0
Cycle 2 Day 22	185	10.99	20.98	0.0	0.00	100.0	180	-3.52	25.28	-100.0	0.00	100.0
Cycle 3 Day 1	203	9.85	20.21	0.0	0.00	100.0	196	-5.27	27.23	-100.0	0.00	100.0
Cycle 3 Day 22	156	9.62	19.31	0.0	0.00	100.0	148	-6.08	26.38	-100.0	0.00	100.0
Cycle 4 Day 1	170	7.84	17.12	0.0	0.00	100.0	161	-7.45	23.86	-100.0	0.00	66.7
Cycle 4 Day 22	133	9.27	18.51	0.0	0.00	100.0	127	-4.99	26.25	-100.0	0.00	100.0
Cycle 5 Day 1	149	8.28	16.40	0.0	0.00	66.7	144	-4.63	25.43	-100.0	0.00	66.7
Cycle 5 Day 22	122	7.65	16.48	0.0	0.00	66.7	115	-4.06	22.14	-100.0	0.00	66.7
Cycle 6 Day 1	126	9.79	19.81	0.0	0.00	100.0	121	-1.93	24.83	-66.7	0.00	100.0
Cycle 6 Day 22	96	7.64	14.89	0.0	0.00	66.7	92	-4.71	23.48	-66.7	0.00	66.7
Cycle 7 Day 1	101	6.60	15.65	0.0	0.00	66.7	98	-4.76	23.93	-66.7	0.00	66.7
Cycle 7 Day 22	75	5.78	14.88	0.0	0.00	66.7	73	-3.65	22.61	-66.7	0.00	66.7
Cycle 8 Day 1	82	4.88	11.85	0.0	0.00	33.3	81	-4.94	18.34	-66.7	0.00	33.3
Cycle 8 Day 22	67	5.47	12.44	0.0	0.00	33.3	65	-3.59	20.52	-66.7	0.00	33.3
Cycle 9 Day 1	64	5.21	13.57	0.0	0.00	66.7	62	-4.84	23.26	-100.0	0.00	66.7
Cycle 9 Day 22	57	8.77	20.44	0.0	0.00	100.0	55	-0.61	27.59	-66.7	0.00	100.0
Cycle 10 Day 1	58	5.75	15.47	0.0	0.00	66.7	56	-2.98	22.27	-66.7	0.00	66.7
Cycle 10 Day 22	44	6.06	16.51	0.0	0.00	66.7	43	-2.33	21.08	-33.3	0.00	66.7
Cycle 11 Day 1	48	6.94	19.40	0.0	0.00	100.0	46	-1.45	22.17	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.26: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Eating in Front of Others - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	5.05	12.14	0.0	0.00	33.3	31	-2.15	17.07	-33.3	0.00	33.3
Cycle 12 Day 1	43	6.20	16.68	0.0	0.00	66.7	41	-2.44	18.84	-33.3	0.00	66.7
Cycle 12 Day 22	27	4.94	12.07	0.0	0.00	33.3	25	-5.33	18.46	-33.3	0.00	33.3
Cycle 13 Day 1	37	5.41	12.46	0.0	0.00	33.3	35	-3.81	17.66	-33.3	0.00	33.3
Cycle 13 Day 22	22	6.06	19.62	0.0	0.00	66.7	21	0.00	25.82	-33.3	0.00	66.7
Cycle 14 Day 1	31	5.38	15.15	0.0	0.00	66.7	30	-2.22	21.32	-33.3	0.00	66.7
Cycle 14 Day 22	20	5.00	12.21	0.0	0.00	33.3	19	-3.51	18.90	-33.3	0.00	33.3
Cycle 15 Day 1	27	4.94	12.07	0.0	0.00	33.3	27	-2.47	15.81	-33.3	0.00	33.3
Cycle 15 Day 22	17	7.84	18.74	0.0	0.00	66.7	17	-1.96	21.96	-33.3	0.00	66.7
Cycle 16 Day 1	22	6.06	16.70	0.0	0.00	66.7	22	-1.52	21.77	-33.3	0.00	66.7
Cycle 16 Day 22	14	7.14	14.19	0.0	0.00	33.3	14	-4.76	17.82	-33.3	0.00	33.3
Cycle 17 Day 1	18	3.70	10.78	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	-4.17	16.67	-33.3	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
Cycle 19 Day 1	16	6.25	13.44	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 19 Day 22	12	8.33	15.08	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 20 Day 1	16	6.25	13.44	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 20 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-6.67	21.08	-33.3	0.00	33.3
Cycle 21 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-7.14	19.30	-33.3	0.00	33.3
Cycle 22 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-5.56	19.25	-33.3	0.00	33.3
Cycle 23 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
Study Disc 1	153	17.65	29.63	0.0	0.00	100.0	149	1.79	30.70	-100.0	0.00	100.0
Study Disc 2	12	13.89	33.21	0.0	0.00	100.0	11	3.03	37.87	-66.7	0.00	66.7
30 D SFU Z/P	93	15.77	25.82	0.0	0.00	100.0	90	0.37	33.70	-100.0	0.00	100.0
90 D SFU Z/P	84	13.49	25.41	0.0	0.00	100.0	82	0.81	34.34	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	21.92	26.99	0.0	0.00	100.0						
Cycle 1 Day 22	186	26.34	26.03	0.0	33.33	100.0	176	5.68	27.01	-100.0	0.00	66.7
Cycle 2 Day 1	216	23.92	27.45	0.0	33.33	100.0	206	1.78	31.10	-100.0	0.00	100.0
Cycle 2 Day 22	157	24.42	27.58	0.0	33.33	100.0	150	3.56	26.80	-66.7	0.00	100.0
Cycle 3 Day 1	200	21.33	25.46	0.0	0.00	100.0	190	1.05	31.03	-100.0	0.00	66.7
Cycle 3 Day 22	161	24.64	24.87	0.0	33.33	100.0	152	4.39	30.85	-100.0	0.00	100.0
Cycle 4 Day 1	177	19.77	24.45	0.0	0.00	100.0	169	-0.39	30.43	-66.7	0.00	100.0
Cycle 4 Day 22	127	20.21	24.18	0.0	0.00	100.0	122	1.09	29.36	-100.0	0.00	100.0
Cycle 5 Day 1	156	22.86	25.63	0.0	33.33	100.0	148	3.15	32.14	-100.0	0.00	100.0
Cycle 5 Day 22	117	18.52	22.51	0.0	0.00	100.0	110	-0.30	28.38	-100.0	0.00	66.7
Cycle 6 Day 1	131	17.56	23.14	0.0	0.00	100.0	122	-1.91	26.87	-100.0	0.00	66.7
Cycle 6 Day 22	108	16.05	21.61	0.0	0.00	100.0	103	-3.56	27.97	-100.0	0.00	33.3
Cycle 7 Day 1	119	17.37	20.74	0.0	0.00	100.0	113	-2.06	25.31	-66.7	0.00	66.7
Cycle 7 Day 22	87	17.62	22.64	0.0	0.00	100.0	81	-0.82	29.33	-100.0	0.00	100.0
Cycle 8 Day 1	88	17.80	20.18	0.0	0.00	100.0	80	-0.83	28.05	-66.7	0.00	100.0
Cycle 8 Day 22	77	18.61	23.87	0.0	0.00	100.0	71	-0.94	28.16	-66.7	0.00	66.7
Cycle 9 Day 1	82	17.89	22.34	0.0	0.00	100.0	75	-0.44	27.67	-66.7	0.00	66.7
Cycle 9 Day 22	65	19.49	21.16	0.0	33.33	66.7	60	2.22	29.98	-66.7	0.00	66.7
Cycle 10 Day 1	72	15.74	21.65	0.0	0.00	66.7	66	-0.51	30.66	-66.7	0.00	66.7
Cycle 10 Day 22	61	15.30	19.79	0.0	0.00	66.7	57	-0.58	25.58	-66.7	0.00	66.7
Cycle 11 Day 1	68	15.20	21.11	0.0	0.00	66.7	63	1.59	27.06	-66.7	0.00	66.7
Cycle 11 Day 22	48	15.97	19.44	0.0	0.00	66.7	44	2.27	24.27	-33.3	0.00	66.7
Cycle 12 Day 1	58	16.67	19.99	0.0	0.00	66.7	53	2.52	29.12	-66.7	0.00	66.7
Cycle 12 Day 22	40	13.33	16.54	0.0	0.00	33.3	37	0.90	25.44	-66.7	0.00	33.3
Cycle 13 Day 1	51	16.99	21.47	0.0	0.00	100.0	48	2.08	26.10	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	17.05	21.05	0.0	0.00	66.7	40	4.17	25.25	-33.3	0.00	66.7
Cycle 14 Day 1	41	17.89	23.68	0.0	0.00	100.0	39	0.00	26.49	-66.7	0.00	66.7
Cycle 14 Day 22	33	16.16	20.62	0.0	0.00	66.7	32	0.00	26.77	-33.3	0.00	66.7
Cycle 15 Day 1	36	15.74	21.80	0.0	0.00	66.7	35	0.00	29.15	-66.7	0.00	66.7
Cycle 15 Day 22	29	16.09	21.12	0.0	0.00	66.7	29	0.00	26.73	-33.3	0.00	66.7
Cycle 16 Day 1	35	15.24	20.36	0.0	0.00	66.7	35	-1.90	27.94	-66.7	0.00	66.7
Cycle 16 Day 22	29	17.24	21.12	0.0	0.00	66.7	29	2.30	26.62	-33.3	0.00	66.7
Cycle 17 Day 1	30	22.22	25.27	0.0	33.33	100.0	30	5.56	30.43	-66.7	0.00	66.7
Cycle 17 Day 22	23	15.94	22.18	0.0	0.00	66.7	23	1.45	27.48	-33.3	0.00	66.7
Cycle 18 Day 1	27	12.35	18.83	0.0	0.00	66.7	27	-3.70	23.27	-66.7	0.00	33.3
Cycle 18 Day 22	20	11.67	19.57	0.0	0.00	66.7	20	-1.67	22.88	-33.3	0.00	66.7
Cycle 19 Day 1	23	13.04	19.43	0.0	0.00	66.7	23	-2.90	26.43	-66.7	0.00	66.7
Cycle 19 Day 22	20	10.00	15.67	0.0	0.00	33.3	20	-3.33	18.42	-33.3	0.00	33.3
Cycle 20 Day 1	23	10.14	15.68	0.0	0.00	33.3	23	-5.80	25.92	-66.7	0.00	33.3
Cycle 20 Day 22	18	9.26	15.36	0.0	0.00	33.3	18	-5.56	23.57	-66.7	0.00	33.3
Cycle 21 Day 1	20	8.33	14.81	0.0	0.00	33.3	20	-10.00	24.42	-66.7	0.00	33.3
Cycle 21 Day 22	14	9.52	15.63	0.0	0.00	33.3	14	-4.76	22.10	-66.7	0.00	33.3
Cycle 22 Day 1	15	11.11	16.27	0.0	0.00	33.3	15	-11.11	24.12	-66.7	0.00	0.0
Cycle 22 Day 22	10	13.33	17.21	0.0	0.00	33.3	10	-10.00	22.50	-66.7	0.00	0.0
Cycle 23 Day 1	15	11.11	16.27	0.0	0.00	33.3	15	-13.33	27.60	-66.7	0.00	33.3
Cycle 23 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-12.12	22.47	-66.7	0.00	0.0
Cycle 24 Day 1	14	9.52	15.63	0.0	0.00	33.3	14	-14.29	25.20	-66.7	0.00	0.0
Cycle 25 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-11.11	21.71	-66.7	0.00	0.0
Cycle 25 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-12.12	22.47	-66.7	0.00	0.0
Cycle 26 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	-17.95	25.88	-66.7	0.00	0.0
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-21.21	26.97	-66.7	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	5.56	12.97	0.0	0.00	33.3	12	-19.44	26.43	-66.7	0.00	0.0
Study Disc 1	144	29.40	30.66	0.0	33.33	100.0	136	4.41	34.62	-100.0	0.00	100.0
30 D SFU Z/P	77	26.41	26.68	0.0	33.33	100.0	72	5.09	28.89	-100.0	0.00	66.7
90 D SFU Z/P	89	22.85	24.92	0.0	33.33	100.0	86	1.94	30.83	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	22.70	26.83	0.0	33.33	100.0						
Cycle 1 Day 22	211	27.17	26.00	0.0	33.33	100.0	208	4.33	27.17	-100.0	0.00	100.0
Cycle 2 Day 1	230	23.48	25.87	0.0	33.33	100.0	223	0.45	28.03	-100.0	0.00	100.0
Cycle 2 Day 22	185	25.41	25.95	0.0	33.33	100.0	180	1.11	29.67	-100.0	0.00	100.0
Cycle 3 Day 1	203	21.67	24.39	0.0	33.33	100.0	196	-1.53	29.68	-100.0	0.00	66.7
Cycle 3 Day 22	156	23.93	25.90	0.0	33.33	100.0	148	1.13	29.46	-100.0	0.00	66.7
Cycle 4 Day 1	170	22.16	25.88	0.0	33.33	100.0	161	-0.62	29.22	-100.0	0.00	100.0
Cycle 4 Day 22	133	22.06	23.88	0.0	33.33	100.0	127	1.57	29.05	-100.0	0.00	66.7
Cycle 5 Day 1	149	21.03	25.51	0.0	0.00	100.0	144	1.16	27.43	-100.0	0.00	66.7
Cycle 5 Day 22	122	18.58	23.49	0.0	0.00	100.0	115	-0.58	25.74	-100.0	0.00	66.7
Cycle 6 Day 1	126	19.05	26.14	0.0	0.00	100.0	121	0.28	29.66	-100.0	0.00	66.7
Cycle 6 Day 22	96	15.62	20.49	0.0	0.00	66.7	92	-3.99	25.60	-100.0	0.00	33.3
Cycle 7 Day 1	101	15.84	22.90	0.0	0.00	100.0	98	-2.38	29.21	-100.0	0.00	66.7
Cycle 7 Day 22	75	15.56	20.01	0.0	0.00	66.7	73	-3.65	31.21	-100.0	0.00	33.3
Cycle 8 Day 1	82	17.48	24.69	0.0	0.00	100.0	81	-3.29	29.16	-100.0	0.00	100.0
Cycle 8 Day 22	67	19.40	21.04	0.0	33.33	66.7	65	0.51	30.33	-100.0	0.00	66.7
Cycle 9 Day 1	64	17.19	23.00	0.0	0.00	100.0	62	-0.54	30.47	-100.0	0.00	66.7
Cycle 9 Day 22	57	16.37	21.93	0.0	0.00	100.0	55	-1.21	31.40	-100.0	0.00	33.3
Cycle 10 Day 1	58	14.94	20.87	0.0	0.00	100.0	56	-2.38	28.33	-100.0	0.00	33.3
Cycle 10 Day 22	44	20.45	26.13	0.0	0.00	100.0	43	-0.78	31.28	-100.0	0.00	66.7
Cycle 11 Day 1	48	17.36	25.72	0.0	0.00	100.0	46	-2.17	27.58	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.27: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Dry Mouth - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	16.16	22.24	0.0	0.00	66.7	31	-1.08	21.92	-66.7	0.00	33.3
Cycle 12 Day 1	43	20.16	26.37	0.0	0.00	100.0	41	-0.81	29.33	-100.0	0.00	66.7
Cycle 12 Day 22	27	25.93	28.24	0.0	33.33	100.0	25	2.67	27.08	-66.7	0.00	33.3
Cycle 13 Day 1	37	20.72	27.61	0.0	0.00	100.0	35	-1.90	29.09	-100.0	0.00	33.3
Cycle 13 Day 22	22	25.76	32.42	0.0	0.00	100.0	21	-1.59	34.12	-100.0	0.00	33.3
Cycle 14 Day 1	31	18.28	25.59	0.0	0.00	100.0	30	-4.44	29.99	-100.0	0.00	33.3
Cycle 14 Day 22	20	25.00	28.36	0.0	33.33	100.0	19	-5.26	31.94	-100.0	0.00	33.3
Cycle 15 Day 1	27	12.35	24.72	0.0	0.00	100.0	27	-9.88	28.96	-100.0	0.00	33.3
Cycle 15 Day 22	17	17.65	29.15	0.0	0.00	100.0	17	-13.73	33.46	-100.0	0.00	33.3
Cycle 16 Day 1	22	13.64	28.47	0.0	0.00	100.0	22	-12.12	30.07	-100.0	0.00	33.3
Cycle 16 Day 22	14	21.43	38.36	0.0	0.00	100.0	14	-7.14	41.71	-100.0	0.00	66.7
Cycle 17 Day 1	18	9.26	22.30	0.0	0.00	66.7	18	-9.26	31.94	-100.0	0.00	33.3
Cycle 18 Day 1	16	14.58	29.74	0.0	0.00	100.0	16	-8.33	35.49	-100.0	0.00	33.3
Cycle 18 Day 22	11	18.18	34.52	0.0	0.00	100.0	10	-6.67	30.63	-66.7	0.00	33.3
Cycle 19 Day 1	16	14.58	29.74	0.0	0.00	100.0	15	-2.22	23.46	-66.7	0.00	33.3
Cycle 19 Day 22	12	22.22	32.82	0.0	0.00	100.0	11	0.00	29.81	-66.7	0.00	33.3
Cycle 20 Day 1	16	12.50	29.50	0.0	0.00	100.0	15	-4.44	24.77	-66.7	0.00	33.3
Cycle 20 Day 22	11	12.12	22.47	0.0	0.00	66.7	10	-6.67	30.63	-66.7	0.00	33.3
Cycle 21 Day 1	15	15.56	30.52	0.0	0.00	100.0	14	-2.38	27.62	-66.7	0.00	33.3
Cycle 22 Day 1	12	5.56	19.25	0.0	0.00	66.7	12	-11.11	21.71	-66.7	0.00	0.0
Cycle 23 Day 1	13	17.95	32.25	0.0	0.00	100.0	13	-2.56	28.74	-66.7	0.00	33.3
Study Disc 1	153	27.23	31.17	0.0	33.33	100.0	149	3.80	35.41	-100.0	0.00	100.0
Study Disc 2	12	33.33	42.64	0.0	16.67	100.0	11	21.21	26.97	0.0	0.00	66.7
30 D SFU Z/P	93	25.09	30.16	0.0	33.33	100.0	90	5.19	36.69	-100.0	0.00	100.0
90 D SFU Z/P	84	25.79	28.97	0.0	33.33	100.0	82	4.47	33.85	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	12.06	23.32	0.0	0.00	100.0						
Cycle 1 Day 22	186	20.97	25.63	0.0	0.00	100.0	176	10.80	29.66	-100.0	0.00	100.0
Cycle 2 Day 1	216	22.99	28.95	0.0	0.00	100.0	206	12.62	29.49	-66.7	0.00	100.0
Cycle 2 Day 22	157	25.05	30.11	0.0	33.33	100.0	150	15.78	33.60	-66.7	0.00	100.0
Cycle 3 Day 1	200	24.50	30.53	0.0	0.00	100.0	190	14.56	34.52	-100.0	0.00	100.0
Cycle 3 Day 22	161	31.26	31.55	0.0	33.33	100.0	152	21.93	31.66	-66.7	16.67	100.0
Cycle 4 Day 1	177	27.31	31.80	0.0	33.33	100.0	169	17.75	35.46	-66.7	0.00	100.0
Cycle 4 Day 22	127	28.87	31.53	0.0	33.33	100.0	122	20.49	32.48	-66.7	0.00	100.0
Cycle 5 Day 1	156	29.70	29.95	0.0	33.33	100.0	148	19.59	31.81	-66.7	0.00	100.0
Cycle 5 Day 22	117	28.21	30.52	0.0	33.33	100.0	110	20.00	28.98	-66.7	0.00	100.0
Cycle 6 Day 1	131	21.88	27.97	0.0	0.00	100.0	122	12.02	27.46	-33.3	0.00	100.0
Cycle 6 Day 22	108	20.06	28.07	0.0	0.00	100.0	103	9.71	29.38	-33.3	0.00	100.0
Cycle 7 Day 1	119	17.65	25.61	0.0	0.00	100.0	113	8.55	24.71	-33.3	0.00	100.0
Cycle 7 Day 22	87	21.07	28.35	0.0	0.00	100.0	81	10.70	26.78	-33.3	0.00	100.0
Cycle 8 Day 1	88	17.05	25.77	0.0	0.00	100.0	80	6.25	22.56	-33.3	0.00	100.0
Cycle 8 Day 22	77	16.02	26.27	0.0	0.00	100.0	71	3.76	22.22	-33.3	0.00	100.0
Cycle 9 Day 1	82	14.63	25.17	0.0	0.00	100.0	75	3.56	20.92	-33.3	0.00	100.0
Cycle 9 Day 22	65	22.05	29.63	0.0	0.00	100.0	60	12.78	28.85	-33.3	0.00	100.0
Cycle 10 Day 1	72	16.20	24.38	0.0	0.00	100.0	66	7.07	23.76	-33.3	0.00	100.0
Cycle 10 Day 22	61	15.30	24.02	0.0	0.00	100.0	57	7.02	22.48	-33.3	0.00	100.0
Cycle 11 Day 1	68	14.22	23.97	0.0	0.00	100.0	63	6.35	26.00	-66.7	0.00	100.0
Cycle 11 Day 22	48	15.28	23.78	0.0	0.00	100.0	44	4.55	18.46	-33.3	0.00	66.7
Cycle 12 Day 1	58	17.24	26.67	0.0	0.00	100.0	53	6.29	26.20	-66.7	0.00	100.0
Cycle 12 Day 22	40	21.67	26.74	0.0	0.00	100.0	37	11.71	25.11	-33.3	0.00	100.0
Cycle 13 Day 1	51	15.03	23.39	0.0	0.00	100.0	48	7.64	20.90	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	17.83	27.55	0.0	0.00	100.0	40	10.00	27.43	-33.3	0.00	100.0
Cycle 14 Day 1	41	13.82	24.69	0.0	0.00	100.0	39	4.27	24.40	-33.3	0.00	100.0
Cycle 14 Day 22	33	16.16	20.62	0.0	0.00	66.7	32	9.37	22.77	-33.3	0.00	66.7
Cycle 15 Day 1	36	12.04	21.31	0.0	0.00	100.0	35	3.81	26.53	-66.7	0.00	100.0
Cycle 15 Day 22	29	19.54	27.48	0.0	0.00	100.0	29	11.49	28.56	-33.3	0.00	100.0
Cycle 16 Day 1	35	14.29	20.27	0.0	0.00	66.7	35	7.62	21.52	-33.3	0.00	66.7
Cycle 16 Day 22	29	16.09	22.92	0.0	0.00	66.7	29	6.90	24.20	-66.7	0.00	66.7
Cycle 17 Day 1	30	12.22	20.50	0.0	0.00	66.7	30	4.44	24.34	-66.7	0.00	33.3
Cycle 17 Day 22	23	21.74	25.84	0.0	0.00	66.7	23	11.59	29.49	-66.7	0.00	66.7
Cycle 18 Day 1	27	9.88	15.51	0.0	0.00	33.3	27	1.23	19.57	-33.3	0.00	33.3
Cycle 18 Day 22	20	8.33	14.81	0.0	0.00	33.3	20	3.33	18.42	-33.3	0.00	33.3
Cycle 19 Day 1	23	10.14	15.68	0.0	0.00	33.3	23	2.90	17.15	-33.3	0.00	33.3
Cycle 19 Day 22	20	13.33	19.94	0.0	0.00	66.7	20	5.00	22.36	-33.3	0.00	66.7
Cycle 20 Day 1	23	8.70	14.97	0.0	0.00	33.3	23	1.45	15.82	-33.3	0.00	33.3
Cycle 20 Day 22	18	12.96	20.26	0.0	0.00	66.7	18	3.70	15.71	-33.3	0.00	33.3
Cycle 21 Day 1	20	15.00	25.31	0.0	0.00	100.0	20	6.67	17.44	-33.3	0.00	33.3
Cycle 21 Day 22	14	9.52	15.63	0.0	0.00	33.3	14	-2.38	20.52	-33.3	0.00	33.3
Cycle 22 Day 1	15	8.89	15.26	0.0	0.00	33.3	15	2.22	15.26	-33.3	0.00	33.3
Cycle 22 Day 22	10	10.00	16.10	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 23 Day 1	15	11.11	16.27	0.0	0.00	33.3	15	2.22	15.26	-33.3	0.00	33.3
Cycle 23 Day 22	11	12.12	16.82	0.0	0.00	33.3	11	6.06	13.48	0.0	0.00	33.3
Cycle 24 Day 1	14	9.52	15.63	0.0	0.00	33.3	14	2.38	15.82	-33.3	0.00	33.3
Cycle 25 Day 1	12	11.11	21.71	0.0	0.00	66.7	12	0.00	20.10	-33.3	0.00	33.3
Cycle 25 Day 22	11	15.15	22.92	0.0	0.00	66.7	11	3.03	17.98	-33.3	0.00	33.3
Cycle 26 Day 1	13	12.82	16.88	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
Cycle 27 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	11.11	16.41	0.0	0.00	33.3	12	2.78	22.29	-33.3	0.00	33.3
Study Disc 1	144	31.48	34.77	0.0	33.33	100.0	136	19.36	33.84	-100.0	0.00	100.0
30 D SFU Z/P	77	20.78	29.14	0.0	0.00	100.0	72	12.96	27.15	-33.3	0.00	100.0
90 D SFU Z/P	89	24.72	28.66	0.0	33.33	100.0	86	14.73	28.29	-33.3	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	11.54	22.07	0.0	0.00	100.0						
Cycle 1 Day 22	211	19.27	27.16	0.0	0.00	100.0	208	8.17	27.46	-100.0	0.00	100.0
Cycle 2 Day 1	230	15.80	24.06	0.0	0.00	100.0	223	4.19	28.69	-100.0	0.00	100.0
Cycle 2 Day 22	185	22.16	27.28	0.0	0.00	100.0	180	10.56	31.01	-100.0	0.00	100.0
Cycle 3 Day 1	203	19.70	25.59	0.0	0.00	100.0	196	9.35	30.53	-100.0	0.00	100.0
Cycle 3 Day 22	156	24.57	28.11	0.0	33.33	100.0	148	13.51	31.31	-100.0	0.00	100.0
Cycle 4 Day 1	170	25.10	28.51	0.0	33.33	100.0	161	15.94	34.78	-100.0	0.00	100.0
Cycle 4 Day 22	133	27.57	30.29	0.0	33.33	100.0	127	16.01	35.10	-100.0	0.00	100.0
Cycle 5 Day 1	149	23.71	27.21	0.0	33.33	100.0	144	15.05	29.98	-100.0	0.00	100.0
Cycle 5 Day 22	122	24.32	28.44	0.0	16.67	100.0	115	16.52	30.71	-100.0	0.00	100.0
Cycle 6 Day 1	126	22.75	26.88	0.0	16.67	100.0	121	15.70	26.90	-33.3	0.00	100.0
Cycle 6 Day 22	96	19.44	25.44	0.0	0.00	100.0	92	10.87	28.86	-100.0	0.00	100.0
Cycle 7 Day 1	101	15.51	23.83	0.0	0.00	100.0	98	9.18	23.83	-66.7	0.00	66.7
Cycle 7 Day 22	75	16.44	22.17	0.0	0.00	100.0	73	10.50	24.77	-33.3	0.00	66.7
Cycle 8 Day 1	82	16.26	23.57	0.0	0.00	100.0	81	10.70	22.25	-33.3	0.00	66.7
Cycle 8 Day 22	67	16.42	21.22	0.0	0.00	100.0	65	11.28	22.26	-33.3	0.00	66.7
Cycle 9 Day 1	64	17.71	28.46	0.0	0.00	100.0	62	12.37	28.46	-33.3	0.00	100.0
Cycle 9 Day 22	57	17.54	28.94	0.0	0.00	100.0	55	11.52	27.38	-33.3	0.00	100.0
Cycle 10 Day 1	58	12.64	21.47	0.0	0.00	66.7	56	8.33	21.32	-33.3	0.00	66.7
Cycle 10 Day 22	44	13.64	23.09	0.0	0.00	66.7	43	9.30	23.37	-33.3	0.00	66.7
Cycle 11 Day 1	48	11.11	21.01	0.0	0.00	66.7	46	7.25	20.98	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.28: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Taste - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	12.12	23.30	0.0	0.00	100.0	31	8.60	24.29	-33.3	0.00	100.0
Cycle 12 Day 1	43	11.63	21.68	0.0	0.00	66.7	41	8.13	17.92	-33.3	0.00	66.7
Cycle 12 Day 22	27	19.75	26.57	0.0	0.00	66.7	25	16.00	27.42	-33.3	0.00	66.7
Cycle 13 Day 1	37	13.51	26.60	0.0	0.00	100.0	35	10.48	25.27	-33.3	0.00	100.0
Cycle 13 Day 22	22	25.76	30.74	0.0	16.67	100.0	21	22.22	30.43	0.0	0.00	100.0
Cycle 14 Day 1	31	18.28	28.33	0.0	0.00	100.0	30	14.44	27.24	-33.3	0.00	100.0
Cycle 14 Day 22	20	15.00	22.88	0.0	0.00	66.7	19	12.28	22.80	0.0	0.00	66.7
Cycle 15 Day 1	27	8.64	19.81	0.0	0.00	66.7	27	6.17	18.58	-33.3	0.00	66.7
Cycle 15 Day 22	17	7.84	22.14	0.0	0.00	66.7	17	3.92	20.01	-33.3	0.00	66.7
Cycle 16 Day 1	22	7.58	17.61	0.0	0.00	66.7	22	4.55	18.67	-33.3	0.00	66.7
Cycle 16 Day 22	14	9.52	20.37	0.0	0.00	66.7	14	4.76	22.10	-33.3	0.00	66.7
Cycle 17 Day 1	18	7.41	18.28	0.0	0.00	66.7	18	5.56	20.61	-33.3	0.00	66.7
Cycle 18 Day 1	16	8.33	19.25	0.0	0.00	66.7	16	4.17	20.64	-33.3	0.00	66.7
Cycle 18 Day 22	11	12.12	26.97	0.0	0.00	66.7	10	6.67	26.29	-33.3	0.00	66.7
Cycle 19 Day 1	16	8.33	19.25	0.0	0.00	66.7	15	4.44	17.21	-33.3	0.00	33.3
Cycle 19 Day 22	12	11.11	25.95	0.0	0.00	66.7	11	6.06	25.03	-33.3	0.00	66.7
Cycle 20 Day 1	16	10.42	23.47	0.0	0.00	66.7	15	6.67	22.54	-33.3	0.00	66.7
Cycle 20 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 21 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
Cycle 22 Day 1	12	8.33	20.72	0.0	0.00	66.7	12	5.56	23.92	-33.3	0.00	66.7
Cycle 23 Day 1	13	10.26	21.01	0.0	0.00	66.7	13	5.13	22.96	-33.3	0.00	66.7
Study Disc 1	153	25.71	31.18	0.0	33.33	100.0	149	14.32	33.84	-100.0	0.00	100.0
Study Disc 2	12	16.67	33.33	0.0	0.00	100.0	11	18.18	34.52	0.0	0.00	100.0
30 D SFU Z/P	93	23.66	26.27	0.0	33.33	100.0	90	15.93	32.08	-100.0	0.00	100.0
90 D SFU Z/P	84	22.22	28.96	0.0	0.00	100.0	82	13.82	32.69	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	22.57	29.62	0.0	0.00	100.0						
Cycle 1 Day 22	186	26.70	28.54	0.0	33.33	100.0	176	3.60	25.06	-100.0	0.00	66.7
Cycle 2 Day 1	216	25.31	29.94	0.0	33.33	100.0	206	3.56	26.91	-66.7	0.00	100.0
Cycle 2 Day 22	157	26.11	29.07	0.0	33.33	100.0	150	5.11	26.96	-100.0	0.00	100.0
Cycle 3 Day 1	200	24.33	26.25	0.0	33.33	100.0	190	4.21	25.54	-100.0	0.00	66.7
Cycle 3 Day 22	161	29.61	29.11	0.0	33.33	100.0	152	7.46	25.21	-66.7	0.00	100.0
Cycle 4 Day 1	177	23.16	27.70	0.0	33.33	100.0	169	1.58	24.07	-66.7	0.00	66.7
Cycle 4 Day 22	127	28.61	29.61	0.0	33.33	100.0	122	9.29	27.53	-66.7	0.00	100.0
Cycle 5 Day 1	156	27.14	28.54	0.0	33.33	100.0	148	5.63	28.67	-66.7	0.00	100.0
Cycle 5 Day 22	117	29.63	28.96	0.0	33.33	100.0	110	5.76	30.91	-100.0	0.00	100.0
Cycle 6 Day 1	131	25.45	29.19	0.0	33.33	100.0	122	4.64	31.00	-100.0	0.00	100.0
Cycle 6 Day 22	108	22.22	25.37	0.0	33.33	100.0	103	1.62	27.76	-100.0	0.00	100.0
Cycle 7 Day 1	119	20.45	26.79	0.0	0.00	100.0	113	-0.29	29.04	-66.7	0.00	100.0
Cycle 7 Day 22	87	24.90	26.03	0.0	33.33	100.0	81	3.70	30.28	-66.7	0.00	100.0
Cycle 8 Day 1	88	20.83	24.92	0.0	16.67	100.0	80	-1.25	28.29	-100.0	0.00	100.0
Cycle 8 Day 22	77	23.81	27.50	0.0	33.33	100.0	71	-0.47	31.11	-100.0	0.00	66.7
Cycle 9 Day 1	82	19.92	22.14	0.0	33.33	100.0	75	-4.44	30.67	-100.0	0.00	66.7
Cycle 9 Day 22	65	22.05	27.18	0.0	0.00	100.0	60	-1.11	32.46	-100.0	0.00	100.0
Cycle 10 Day 1	72	20.37	25.97	0.0	0.00	100.0	66	-1.01	32.54	-100.0	0.00	100.0
Cycle 10 Day 22	61	21.31	29.21	0.0	0.00	100.0	57	-0.58	31.80	-100.0	0.00	100.0
Cycle 11 Day 1	68	20.10	29.44	0.0	0.00	100.0	63	-2.65	31.28	-100.0	0.00	100.0
Cycle 11 Day 22	48	18.75	26.55	0.0	0.00	100.0	44	-7.58	27.72	-100.0	0.00	33.3
Cycle 12 Day 1	58	21.26	27.00	0.0	0.00	100.0	53	-0.63	28.86	-100.0	0.00	66.7
Cycle 12 Day 22	40	24.17	29.22	0.0	16.67	100.0	37	0.00	33.33	-100.0	0.00	66.7
Cycle 13 Day 1	51	20.26	25.01	0.0	0.00	100.0	48	-2.08	31.81	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	17.83	24.50	0.0	0.00	100.0	40	-5.00	28.79	-100.0	0.00	33.3
Cycle 14 Day 1	41	17.07	24.86	0.0	0.00	100.0	39	-4.27	30.76	-100.0	0.00	66.7
Cycle 14 Day 22	33	20.20	26.27	0.0	0.00	100.0	32	-1.04	31.09	-100.0	0.00	66.7
Cycle 15 Day 1	36	15.74	25.80	0.0	0.00	100.0	35	-3.81	27.74	-100.0	0.00	66.7
Cycle 15 Day 22	29	13.79	20.93	0.0	0.00	66.7	29	-8.05	29.08	-100.0	0.00	33.3
Cycle 16 Day 1	35	12.38	19.94	0.0	0.00	66.7	35	-5.71	28.57	-100.0	0.00	66.7
Cycle 16 Day 22	29	12.64	18.72	0.0	0.00	66.7	29	-8.05	26.21	-100.0	0.00	33.3
Cycle 17 Day 1	30	17.78	29.99	0.0	0.00	100.0	30	0.00	36.09	-100.0	0.00	66.7
Cycle 17 Day 22	23	13.04	26.09	0.0	0.00	100.0	23	-2.90	30.01	-33.3	0.00	66.7
Cycle 18 Day 1	27	8.64	17.52	0.0	0.00	66.7	27	-7.41	21.35	-33.3	0.00	33.3
Cycle 18 Day 22	20	11.67	24.84	0.0	0.00	100.0	20	-5.00	27.09	-33.3	0.00	66.7
Cycle 19 Day 1	23	13.04	24.08	0.0	0.00	100.0	23	-1.45	25.58	-33.3	0.00	66.7
Cycle 19 Day 22	20	11.67	24.84	0.0	0.00	100.0	20	-5.00	24.84	-33.3	0.00	66.7
Cycle 20 Day 1	23	11.59	25.84	0.0	0.00	100.0	23	-2.90	28.27	-33.3	0.00	66.7
Cycle 20 Day 22	18	12.96	25.92	0.0	0.00	100.0	18	-3.70	27.75	-33.3	0.00	66.7
Cycle 21 Day 1	20	6.67	17.44	0.0	0.00	66.7	20	-6.67	17.44	-33.3	0.00	33.3
Cycle 21 Day 22	14	11.90	21.11	0.0	0.00	66.7	14	-4.76	22.10	-33.3	0.00	33.3
Cycle 22 Day 1	15	15.56	27.79	0.0	0.00	100.0	15	0.00	28.17	-33.3	0.00	66.7
Cycle 22 Day 22	10	16.67	32.39	0.0	0.00	100.0	10	-6.67	30.63	-33.3	0.00	66.7
Cycle 23 Day 1	15	11.11	20.57	0.0	0.00	66.7	15	-6.67	22.54	-33.3	0.00	33.3
Cycle 23 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	-6.06	20.10	-33.3	0.00	33.3
Cycle 24 Day 1	14	11.90	21.11	0.0	0.00	66.7	14	-4.76	22.10	-33.3	0.00	33.3
Cycle 25 Day 1	12	13.89	30.01	0.0	0.00	100.0	12	-8.33	28.87	-33.3	0.00	66.7
Cycle 25 Day 22	11	15.15	31.14	0.0	0.00	100.0	11	-9.09	30.15	-33.3	0.00	66.7
Cycle 26 Day 1	13	15.38	29.24	0.0	0.00	100.0	13	-5.13	26.69	-33.3	0.00	66.7
Cycle 27 Day 1	11	9.09	15.57	0.0	0.00	33.3	11	-12.12	16.82	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-11.11	16.41	-33.3	0.00	0.0
Study Disc 1	144	33.33	32.03	0.0	33.33	100.0	136	11.76	31.04	-100.0	0.00	100.0
30 D SFU Z/P	77	29.00	30.28	0.0	33.33	100.0	72	9.72	28.77	-100.0	0.00	100.0
90 D SFU Z/P	89	28.46	29.11	0.0	33.33	100.0	86	6.98	32.39	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	24.90	30.80	0.0	0.00	100.0						
Cycle 1 Day 22	211	24.17	28.73	0.0	33.33	100.0	208	-0.96	26.60	-100.0	0.00	100.0
Cycle 2 Day 1	230	24.78	29.21	0.0	33.33	100.0	223	0.00	31.00	-100.0	0.00	100.0
Cycle 2 Day 22	185	25.41	27.75	0.0	33.33	100.0	180	2.78	30.08	-66.7	0.00	100.0
Cycle 3 Day 1	203	23.15	27.26	0.0	33.33	100.0	196	-0.51	29.33	-100.0	0.00	100.0
Cycle 3 Day 22	156	22.44	25.16	0.0	33.33	100.0	148	-0.90	28.02	-100.0	0.00	100.0
Cycle 4 Day 1	170	20.78	25.37	0.0	0.00	100.0	161	-4.35	28.90	-100.0	0.00	100.0
Cycle 4 Day 22	133	21.30	24.73	0.0	0.00	100.0	127	-3.41	26.84	-100.0	0.00	66.7
Cycle 5 Day 1	149	21.48	25.72	0.0	0.00	100.0	144	-3.01	26.42	-100.0	0.00	66.7
Cycle 5 Day 22	122	22.40	27.25	0.0	0.00	100.0	115	-2.32	34.69	-100.0	0.00	66.7
Cycle 6 Day 1	126	23.81	26.62	0.0	33.33	100.0	121	-1.93	28.32	-100.0	0.00	66.7
Cycle 6 Day 22	96	21.87	26.41	0.0	0.00	100.0	92	-4.71	29.06	-66.7	0.00	66.7
Cycle 7 Day 1	101	22.44	26.71	0.0	0.00	100.0	98	-2.72	31.27	-100.0	0.00	66.7
Cycle 7 Day 22	75	20.44	25.05	0.0	0.00	100.0	73	-5.48	34.25	-100.0	0.00	100.0
Cycle 8 Day 1	82	22.76	28.15	0.0	0.00	100.0	81	-2.88	30.82	-100.0	0.00	66.7
Cycle 8 Day 22	67	19.40	24.72	0.0	0.00	100.0	65	-6.15	29.98	-100.0	0.00	33.3
Cycle 9 Day 1	64	16.15	25.19	0.0	0.00	100.0	62	-8.06	32.33	-100.0	0.00	66.7
Cycle 9 Day 22	57	16.96	24.50	0.0	0.00	100.0	55	-8.48	32.21	-100.0	0.00	66.7
Cycle 10 Day 1	58	20.11	27.17	0.0	0.00	100.0	56	-4.17	33.67	-100.0	0.00	66.7
Cycle 10 Day 22	44	15.91	23.28	0.0	0.00	100.0	43	-10.08	31.32	-100.0	0.00	33.3
Cycle 11 Day 1	48	18.06	25.69	0.0	0.00	100.0	46	-5.07	31.40	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	15.15	20.57	0.0	0.00	66.7	31	-7.53	33.01	-100.0	0.00	33.3
Cycle 12 Day 1	43	18.60	26.53	0.0	0.00	100.0	41	-7.32	30.29	-100.0	0.00	33.3
Cycle 12 Day 22	27	24.69	28.63	0.0	33.33	100.0	25	-4.00	26.03	-66.7	0.00	33.3
Cycle 13 Day 1	37	21.62	29.62	0.0	0.00	100.0	35	-5.71	27.40	-66.7	0.00	33.3
Cycle 13 Day 22	22	18.18	24.62	0.0	0.00	66.7	21	-12.70	32.45	-100.0	0.00	33.3
Cycle 14 Day 1	31	17.20	24.15	0.0	0.00	100.0	30	-11.11	33.14	-100.0	0.00	33.3
Cycle 14 Day 22	20	21.67	27.09	0.0	16.67	100.0	19	-12.28	33.72	-100.0	0.00	33.3
Cycle 15 Day 1	27	14.81	25.04	0.0	0.00	100.0	27	-12.35	33.52	-100.0	0.00	33.3
Cycle 15 Day 22	17	13.73	20.61	0.0	0.00	66.7	17	-17.65	33.58	-100.0	0.00	33.3
Cycle 16 Day 1	22	15.15	22.37	0.0	0.00	66.7	22	-10.61	37.64	-100.0	0.00	33.3
Cycle 16 Day 22	14	14.29	28.39	0.0	0.00	100.0	14	-14.29	33.88	-66.7	0.00	33.3
Cycle 17 Day 1	18	12.96	20.26	0.0	0.00	66.7	18	-7.41	26.95	-66.7	0.00	33.3
Cycle 18 Day 1	16	16.67	21.08	0.0	0.00	66.7	16	-4.17	31.91	-66.7	0.00	33.3
Cycle 18 Day 22	11	9.09	15.57	0.0	0.00	33.3	10	-20.00	28.11	-66.7	0.00	0.0
Cycle 19 Day 1	16	14.58	17.08	0.0	0.00	33.3	15	-4.44	30.52	-66.7	0.00	33.3
Cycle 19 Day 22	12	13.89	22.29	0.0	0.00	66.7	11	-12.12	34.23	-66.7	0.00	33.3
Cycle 20 Day 1	16	10.42	20.07	0.0	0.00	66.7	15	-8.89	29.46	-66.7	0.00	33.3
Cycle 20 Day 22	11	9.09	15.57	0.0	0.00	33.3	10	-16.67	32.39	-66.7	0.00	33.3
Cycle 21 Day 1	15	22.22	32.53	0.0	0.00	66.7	14	2.38	40.22	-66.7	0.00	66.7
Cycle 22 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-13.89	36.12	-66.7	0.00	33.3
Cycle 23 Day 1	13	17.95	22.01	0.0	0.00	66.7	13	-5.13	35.61	-66.7	0.00	33.3
Study Disc 1	153	26.14	31.75	0.0	33.33	100.0	149	2.01	34.27	-100.0	0.00	100.0
Study Disc 2	12	27.78	39.78	0.0	0.00	100.0	11	-6.06	35.96	-66.7	0.00	66.7
30 D SFU Z/P	93	30.47	30.16	0.0	33.33	100.0	90	5.56	31.70	-66.7	0.00	100.0
90 D SFU Z/P	84	35.32	33.27	0.0	33.33	100.0	82	8.94	29.65	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	23.29	27.09	0.0	33.33	100.0						
	Cycle 1 Day 22	123	29.00	28.93	0.0	33.33	100.0	117	4.84	25.24	-100.0	0.00	66.7
	Cycle 2 Day 1	137	27.49	29.95	0.0	33.33	100.0	132	2.78	26.39	-66.7	0.00	100.0
	Cycle 2 Day 22	104	28.53	30.25	0.0	33.33	100.0	100	4.67	26.39	-100.0	0.00	100.0
	Cycle 3 Day 1	133	25.31	26.32	0.0	33.33	100.0	127	3.15	24.64	-100.0	0.00	66.7
	Cycle 3 Day 22	107	31.15	28.33	0.0	33.33	100.0	102	6.86	23.14	-33.3	0.00	100.0
	Cycle 4 Day 1	112	26.19	29.49	0.0	33.33	100.0	108	2.16	24.23	-66.7	0.00	66.7
	Cycle 4 Day 22	84	32.14	31.24	0.0	33.33	100.0	80	9.58	27.66	-66.7	0.00	100.0
	Cycle 5 Day 1	104	30.13	30.29	0.0	33.33	100.0	99	7.07	30.59	-66.7	0.00	100.0
	Cycle 5 Day 22	78	33.33	30.39	0.0	33.33	100.0	73	9.13	29.01	-66.7	0.00	100.0
	Cycle 6 Day 1	88	26.52	31.22	0.0	33.33	100.0	83	4.82	29.05	-66.7	0.00	100.0
	Cycle 6 Day 22	67	23.88	27.10	0.0	33.33	100.0	64	2.60	27.41	-66.7	0.00	100.0
	Cycle 7 Day 1	77	23.38	28.65	0.0	33.33	100.0	74	0.45	30.47	-66.7	0.00	100.0
	Cycle 7 Day 22	62	26.34	27.75	0.0	33.33	100.0	57	3.51	30.66	-66.7	0.00	100.0
	Cycle 8 Day 1	57	19.30	25.16	0.0	0.00	100.0	52	-2.56	27.89	-100.0	0.00	100.0
	Cycle 8 Day 22	47	23.40	25.93	0.0	33.33	100.0	43	-0.78	31.28	-100.0	0.00	66.7
	Cycle 9 Day 1	49	19.73	22.48	0.0	33.33	100.0	44	-6.06	30.73	-100.0	0.00	66.7
	Cycle 9 Day 22	43	25.58	29.85	0.0	33.33	100.0	39	1.71	32.40	-66.7	0.00	100.0
	Cycle 10 Day 1	47	22.70	27.89	0.0	0.00	100.0	43	-1.55	33.30	-100.0	0.00	100.0
	Cycle 10 Day 22	42	25.40	31.93	0.0	16.67	100.0	39	0.00	35.87	-100.0	0.00	100.0
	Cycle 11 Day 1	44	24.24	31.63	0.0	0.00	100.0	41	-4.07	34.31	-100.0	0.00	100.0
	Cycle 11 Day 22	31	20.43	29.41	0.0	0.00	100.0	28	-10.71	31.50	-100.0	0.00	33.3
	Cycle 12 Day 1	35	23.81	27.50	0.0	33.33	100.0	32	-1.04	33.32	-100.0	0.00	66.7
	Cycle 12 Day 22	28	25.00	30.93	0.0	16.67	100.0	25	-4.00	36.41	-100.0	0.00	66.7
	Cycle 13 Day 1	32	22.92	27.35	0.0	33.33	100.0	31	-4.30	36.25	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	28	21.43	26.00	0.0	16.67	100.0	26	-6.41	32.69	-100.0	0.00	33.3
	Cycle 14 Day 1	24	19.44	27.66	0.0	0.00	100.0	23	-7.25	37.55	-100.0	0.00	66.7
	Cycle 14 Day 22	17	25.49	30.11	0.0	33.33	100.0	17	-1.96	38.13	-100.0	0.00	66.7
	Cycle 15 Day 1	21	19.05	27.02	0.0	0.00	100.0	21	-3.17	33.17	-100.0	0.00	66.7
	Cycle 15 Day 22	18	16.67	20.61	0.0	0.00	66.7	18	-9.26	31.94	-100.0	0.00	33.3
	Cycle 16 Day 1	21	14.29	19.92	0.0	0.00	66.7	21	-7.94	33.17	-100.0	0.00	66.7
	Cycle 16 Day 22	18	14.81	17.04	0.0	0.00	33.3	18	-11.11	30.25	-100.0	0.00	33.3
	Cycle 17 Day 1	17	13.73	20.61	0.0	0.00	66.7	17	-7.84	36.38	-100.0	0.00	66.7
	Cycle 17 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	-13.33	23.31	-33.3	-16.67	33.3
	Cycle 18 Day 1	14	9.52	15.63	0.0	0.00	33.3	14	-9.52	24.21	-33.3	0.00	33.3
	Cycle 18 Day 22	11	9.09	15.57	0.0	0.00	33.3	11	-9.09	26.21	-33.3	0.00	33.3
	Cycle 19 Day 1	13	10.26	16.01	0.0	0.00	33.3	13	-5.13	22.96	-33.3	0.00	33.3
	Cycle 19 Day 22	12	8.33	15.08	0.0	0.00	33.3	12	-8.33	20.72	-33.3	0.00	33.3
	Cycle 20 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-10.26	21.01	-33.3	0.00	33.3
	Cycle 20 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	-10.00	22.50	-33.3	0.00	33.3
	Cycle 21 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-10.00	16.10	-33.3	0.00	0.0
	Study Disc 1	97	36.43	32.30	0.0	33.33	100.0	93	13.62	29.17	-100.0	0.00	100.0
	30 D SFU Z/P	50	31.33	31.16	0.0	33.33	100.0	47	10.64	26.10	-33.3	0.00	100.0
	90 D SFU Z/P	56	33.33	29.13	0.0	33.33	100.0	55	11.52	24.19	-33.3	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	26.02	31.99	0.0	16.67	100.0						
	Cycle 1 Day 22	133	24.56	29.56	0.0	33.33	100.0	131	-1.78	25.26	-100.0	0.00	100.0
	Cycle 2 Day 1	147	25.62	31.95	0.0	0.00	100.0	143	-0.70	31.27	-100.0	0.00	100.0
	Cycle 2 Day 22	117	23.65	28.05	0.0	33.33	100.0	113	1.47	28.66	-66.7	0.00	100.0
	Cycle 3 Day 1	128	22.92	27.35	0.0	16.67	100.0	125	-1.07	28.69	-100.0	0.00	66.7
	Cycle 3 Day 22	102	22.88	25.68	0.0	33.33	100.0	98	-2.04	26.57	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	107	21.81	26.74	0.0	0.00	100.0	102	-4.90	26.70	-66.7	0.00	66.7
	Cycle 4 Day 22	87	20.31	24.04	0.0	0.00	100.0	84	-3.57	24.82	-100.0	0.00	33.3
	Cycle 5 Day 1	97	22.68	27.02	0.0	0.00	100.0	95	-2.46	23.94	-100.0	0.00	33.3
	Cycle 5 Day 22	80	17.50	23.10	0.0	0.00	100.0	76	-7.89	29.25	-100.0	0.00	66.7
	Cycle 6 Day 1	83	23.69	26.81	0.0	33.33	100.0	81	-2.47	27.27	-100.0	0.00	66.7
	Cycle 6 Day 22	63	20.63	26.39	0.0	0.00	100.0	61	-4.37	26.86	-66.7	0.00	66.7
	Cycle 7 Day 1	68	21.08	26.95	0.0	0.00	100.0	65	-3.59	30.69	-100.0	0.00	66.7
	Cycle 7 Day 22	48	18.06	23.78	0.0	0.00	66.7	46	-7.25	33.64	-100.0	0.00	66.7
	Cycle 8 Day 1	55	22.42	28.73	0.0	0.00	100.0	54	-3.70	31.50	-100.0	0.00	66.7
	Cycle 8 Day 22	43	15.50	25.56	0.0	0.00	100.0	41	-8.94	29.84	-100.0	0.00	33.3
	Cycle 9 Day 1	40	15.83	27.20	0.0	0.00	100.0	38	-7.89	33.27	-100.0	0.00	66.7
	Cycle 9 Day 22	35	14.29	24.64	0.0	0.00	100.0	33	-10.10	29.44	-66.7	0.00	66.7
	Cycle 10 Day 1	37	18.92	27.82	0.0	0.00	100.0	35	-4.76	33.47	-100.0	0.00	66.7
	Cycle 10 Day 22	28	13.10	22.84	0.0	0.00	100.0	27	-9.88	27.45	-100.0	0.00	33.3
	Cycle 11 Day 1	29	17.24	26.16	0.0	0.00	100.0	27	-3.70	28.24	-66.7	0.00	66.7
	Cycle 11 Day 22	21	11.11	19.25	0.0	0.00	66.7	19	-3.51	31.22	-100.0	0.00	33.3
	Cycle 12 Day 1	27	14.81	25.04	0.0	0.00	100.0	25	-8.00	27.69	-100.0	0.00	33.3
	Cycle 12 Day 22	17	19.61	26.51	0.0	0.00	100.0	15	0.00	17.82	-33.3	0.00	33.3
	Cycle 13 Day 1	22	15.15	24.62	0.0	0.00	100.0	20	-8.33	26.21	-66.7	0.00	33.3
	Cycle 13 Day 22	13	10.26	16.01	0.0	0.00	33.3	12	-13.89	36.12	-100.0	0.00	33.3
	Cycle 14 Day 1	18	20.37	25.92	0.0	16.67	100.0	17	-5.88	29.43	-66.7	0.00	33.3
	Cycle 14 Day 22	15	13.33	16.90	0.0	0.00	33.3	14	-11.90	36.06	-100.0	0.00	33.3
	Cycle 15 Day 1	16	14.58	27.13	0.0	0.00	100.0	16	-12.50	36.26	-100.0	0.00	33.3
	Cycle 15 Day 22	12	8.33	15.08	0.0	0.00	33.3	12	-13.89	33.21	-100.0	0.00	33.3
	Cycle 16 Day 1	12	11.11	21.71	0.0	0.00	66.7	12	-11.11	41.03	-100.0	0.00	33.3
	Study Disc 1	100	26.33	31.89	0.0	33.33	100.0	97	0.69	34.35	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	30 D SFU Z/P	55	29.09	31.46	0.0	33.33	100.0	53	1.89	26.49	-66.7	0.00	100.0
	90 D SFU Z/P	51	30.72	31.16	0.0	33.33	100.0	50	6.00	23.99	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	21.25	33.89	0.0	0.00	100.0						
	Cycle 1 Day 22	63	22.22	27.44	0.0	0.00	100.0	59	1.13	24.73	-66.7	0.00	66.7
	Cycle 2 Day 1	79	21.52	29.74	0.0	0.00	100.0	74	4.95	27.96	-66.7	0.00	100.0
	Cycle 2 Day 22	53	21.38	26.23	0.0	0.00	100.0	50	6.00	28.32	-66.7	0.00	66.7
	Cycle 3 Day 1	67	22.39	26.20	0.0	33.33	100.0	63	6.35	27.34	-66.7	0.00	66.7
	Cycle 3 Day 22	54	26.54	30.63	0.0	33.33	100.0	50	8.67	29.21	-66.7	0.00	66.7
	Cycle 4 Day 1	65	17.95	23.63	0.0	0.00	100.0	61	0.55	23.95	-66.7	0.00	33.3
	Cycle 4 Day 22	43	21.71	25.08	0.0	0.00	66.7	42	8.73	27.60	-66.7	0.00	66.7
	Cycle 5 Day 1	52	21.15	23.83	0.0	16.67	66.7	49	2.72	24.38	-66.7	0.00	66.7
	Cycle 5 Day 22	39	22.22	24.58	0.0	33.33	66.7	37	-0.90	33.78	-100.0	0.00	66.7
	Cycle 6 Day 1	43	23.26	24.70	0.0	33.33	100.0	39	4.27	35.19	-100.0	0.00	100.0
	Cycle 6 Day 22	41	19.51	22.33	0.0	0.00	66.7	39	0.00	28.61	-100.0	0.00	33.3
	Cycle 7 Day 1	42	15.08	22.33	0.0	0.00	100.0	39	-1.71	26.43	-66.7	0.00	66.7
	Cycle 7 Day 22	25	21.33	21.26	0.0	33.33	66.7	24	4.17	30.00	-66.7	0.00	66.7
	Cycle 8 Day 1	31	23.66	24.64	0.0	33.33	100.0	28	1.19	29.37	-66.7	0.00	33.3
	Cycle 8 Day 22	30	24.44	30.24	0.0	16.67	100.0	28	0.00	31.43	-100.0	0.00	33.3
	Cycle 9 Day 1	33	20.20	21.95	0.0	33.33	66.7	31	-2.15	30.95	-66.7	0.00	66.7
	Cycle 9 Day 22	22	15.15	19.86	0.0	0.00	66.7	21	-6.35	32.69	-100.0	0.00	33.3
	Cycle 10 Day 1	25	16.00	21.77	0.0	0.00	66.7	23	0.00	31.78	-100.0	0.00	66.7
	Cycle 10 Day 22	19	12.28	19.91	0.0	0.00	66.7	18	-1.85	21.30	-33.3	0.00	33.3
	Cycle 11 Day 1	24	12.50	23.70	0.0	0.00	100.0	22	0.00	25.20	-33.3	0.00	66.7
	Cycle 11 Day 22	17	15.69	20.81	0.0	0.00	66.7	16	-2.08	19.12	-33.3	0.00	33.3
	Cycle 12 Day 1	23	17.39	26.34	0.0	0.00	100.0	21	0.00	21.08	-33.3	0.00	33.3
	Cycle 12 Day 22	12	22.22	25.95	0.0	16.67	66.7	12	8.33	25.13	-33.3	0.00	66.7
	Cycle 13 Day 1	19	15.79	20.39	0.0	0.00	66.7	17	1.96	21.96	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	15	11.11	20.57	0.0	0.00	66.7	14	-2.38	20.52	-33.3	0.00	33.3
	Cycle 14 Day 1	17	13.73	20.61	0.0	0.00	66.7	16	0.00	17.21	-33.3	0.00	33.3
	Cycle 14 Day 22	16	14.58	20.97	0.0	0.00	66.7	15	0.00	21.82	-33.3	0.00	33.3
	Cycle 15 Day 1	15	11.11	24.12	0.0	0.00	66.7	14	-4.76	17.82	-33.3	0.00	33.3
	Cycle 15 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	-6.06	25.03	-33.3	0.00	33.3
	Cycle 16 Day 1	14	9.52	20.37	0.0	0.00	66.7	14	-2.38	20.52	-33.3	0.00	33.3
	Cycle 16 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	-3.03	17.98	-33.3	0.00	33.3
	Cycle 17 Day 1	13	23.08	39.40	0.0	0.00	100.0	13	10.26	34.39	-33.3	0.00	66.7
	Cycle 17 Day 22	13	17.95	32.25	0.0	0.00	100.0	13	5.13	32.90	-33.3	0.00	66.7
	Cycle 18 Day 1	13	7.69	19.97	0.0	0.00	66.7	13	-5.13	18.49	-33.3	0.00	33.3
	Cycle 19 Day 1	10	16.67	32.39	0.0	0.00	100.0	10	3.33	29.19	-33.3	0.00	66.7
	Cycle 20 Day 1	10	20.00	35.83	0.0	0.00	100.0	10	6.67	34.43	-33.3	0.00	66.7
	Cycle 21 Day 1	10	10.00	22.50	0.0	0.00	66.7	10	-3.33	18.92	-33.3	0.00	33.3
	Study Disc 1	47	26.95	30.80	0.0	33.33	100.0	43	7.75	34.76	-66.7	0.00	100.0
	30 D SFU Z/P	27	24.69	28.63	0.0	33.33	100.0	25	8.00	33.72	-100.0	0.00	66.7
	90 D SFU Z/P	33	20.20	27.56	0.0	0.00	100.0	31	-1.08	42.59	-100.0	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	22.94	28.65	0.0	0.00	100.0						
	Cycle 1 Day 22	78	23.50	27.45	0.0	16.67	100.0	77	0.43	28.86	-100.0	0.00	66.7
	Cycle 2 Day 1	83	23.29	23.70	0.0	33.33	100.0	80	1.25	30.67	-66.7	0.00	66.7
	Cycle 2 Day 22	68	28.43	27.17	0.0	33.33	100.0	67	4.98	32.44	-66.7	0.00	100.0
	Cycle 3 Day 1	75	23.56	27.28	0.0	33.33	100.0	71	0.47	30.60	-66.7	0.00	100.0
	Cycle 3 Day 22	54	21.60	24.36	0.0	33.33	100.0	50	1.33	30.83	-100.0	0.00	100.0
	Cycle 4 Day 1	63	19.05	22.97	0.0	0.00	100.0	59	-3.39	32.57	-100.0	0.00	100.0
	Cycle 4 Day 22	46	23.19	26.17	0.0	16.67	66.7	43	-3.10	30.70	-100.0	0.00	66.7
	Cycle 5 Day 1	52	19.23	23.19	0.0	0.00	66.7	49	-4.08	30.91	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.29.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	42	31.75	32.05	0.0	33.33	100.0	39	8.55	41.69	-100.0	0.00	66.7
	Cycle 6 Day 1	43	24.03	26.55	0.0	33.33	100.0	40	-0.83	30.65	-66.7	0.00	66.7
	Cycle 6 Day 22	33	24.24	26.71	0.0	33.33	100.0	31	-5.38	33.44	-66.7	0.00	66.7
	Cycle 7 Day 1	33	25.25	26.39	0.0	33.33	66.7	33	-1.01	32.79	-66.7	0.00	66.7
	Cycle 7 Day 22	27	24.69	27.10	0.0	33.33	100.0	27	-2.47	35.72	-66.7	0.00	100.0
	Cycle 8 Day 1	27	23.46	27.45	0.0	33.33	100.0	27	-1.23	29.93	-100.0	0.00	33.3
	Cycle 8 Day 22	24	26.39	21.93	0.0	33.33	66.7	24	-1.39	30.26	-66.7	0.00	33.3
	Cycle 9 Day 1	24	16.67	21.98	0.0	0.00	66.7	24	-8.33	31.47	-100.0	0.00	33.3
	Cycle 9 Day 22	22	21.21	24.22	0.0	16.67	66.7	22	-6.06	36.57	-100.0	0.00	33.3
	Cycle 10 Day 1	21	22.22	26.53	0.0	0.00	66.7	21	-3.17	34.81	-100.0	0.00	33.3
	Cycle 10 Day 22	16	20.83	23.96	0.0	16.67	66.7	16	-10.42	37.94	-100.0	0.00	33.3
	Cycle 11 Day 1	19	19.30	25.62	0.0	0.00	66.7	19	-7.02	36.14	-100.0	0.00	33.3
	Cycle 11 Day 22	12	22.22	21.71	0.0	33.33	66.7	12	-13.89	36.12	-66.7	0.00	33.3
	Cycle 12 Day 1	16	25.00	28.54	0.0	16.67	66.7	16	-6.25	34.89	-66.7	0.00	33.3
	Cycle 12 Day 22	10	33.33	31.43	0.0	33.33	66.7	10	-10.00	35.31	-66.7	0.00	33.3
	Cycle 13 Day 1	15	31.11	34.43	0.0	33.33	100.0	15	-2.22	29.46	-66.7	0.00	33.3
	Cycle 14 Day 1	13	12.82	21.68	0.0	0.00	66.7	13	-17.95	37.55	-100.0	0.00	33.3
	Cycle 15 Day 1	11	15.15	22.92	0.0	0.00	66.7	11	-12.12	30.81	-66.7	0.00	33.3
	Cycle 16 Day 1	10	20.00	23.31	0.0	16.67	66.7	10	-10.00	35.31	-66.7	0.00	33.3
	Study Disc 1	53	25.79	31.79	0.0	33.33	100.0	52	4.49	34.32	-66.7	0.00	100.0
	30 D SFU Z/P	38	32.46	28.46	0.0	33.33	100.0	37	10.81	37.72	-66.7	0.00	100.0
	90 D SFU Z/P	33	42.42	35.62	0.0	33.33	100.0	32	13.54	36.77	-66.7	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.65	17.36	0.0	0.00	100.0						
Cycle 1 Day 22	186	8.42	16.46	0.0	0.00	100.0	176	0.95	21.51	-100.0	0.00	66.7
Cycle 2 Day 1	216	9.10	17.74	0.0	0.00	66.7	206	1.46	21.91	-100.0	0.00	66.7
Cycle 2 Day 22	157	8.49	18.45	0.0	0.00	100.0	150	1.56	19.44	-66.7	0.00	100.0
Cycle 3 Day 1	200	7.33	16.08	0.0	0.00	100.0	190	-0.18	20.72	-100.0	0.00	66.7
Cycle 3 Day 22	161	11.18	20.73	0.0	0.00	100.0	152	3.73	25.02	-66.7	0.00	100.0
Cycle 4 Day 1	177	6.97	14.92	0.0	0.00	66.7	169	-0.59	21.66	-100.0	0.00	66.7
Cycle 4 Day 22	127	8.40	18.29	0.0	0.00	100.0	122	1.64	23.41	-100.0	0.00	100.0
Cycle 5 Day 1	156	10.26	19.90	0.0	0.00	100.0	148	3.60	24.01	-66.7	0.00	100.0
Cycle 5 Day 22	117	9.12	19.39	0.0	0.00	100.0	110	2.12	21.31	-66.7	0.00	66.7
Cycle 6 Day 1	131	6.62	14.57	0.0	0.00	66.7	122	-0.82	18.41	-66.7	0.00	66.7
Cycle 6 Day 22	108	6.79	16.90	0.0	0.00	100.0	103	-1.29	18.03	-66.7	0.00	33.3
Cycle 7 Day 1	119	4.76	13.22	0.0	0.00	66.7	113	-1.77	19.33	-100.0	0.00	33.3
Cycle 7 Day 22	87	6.90	14.50	0.0	0.00	66.7	81	-0.41	20.75	-66.7	0.00	66.7
Cycle 8 Day 1	88	6.82	16.11	0.0	0.00	100.0	80	0.00	19.12	-100.0	0.00	33.3
Cycle 8 Day 22	77	6.49	15.33	0.0	0.00	66.7	71	-0.47	17.36	-66.7	0.00	66.7
Cycle 9 Day 1	82	5.69	13.66	0.0	0.00	66.7	75	-0.44	17.75	-66.7	0.00	66.7
Cycle 9 Day 22	65	6.67	14.67	0.0	0.00	66.7	60	0.56	19.88	-66.7	0.00	66.7
Cycle 10 Day 1	72	4.17	12.43	0.0	0.00	66.7	66	-1.52	21.43	-100.0	0.00	66.7
Cycle 10 Day 22	61	3.83	12.32	0.0	0.00	66.7	57	-1.17	20.86	-100.0	0.00	66.7
Cycle 11 Day 1	68	4.41	12.75	0.0	0.00	66.7	63	0.00	19.86	-100.0	0.00	66.7
Cycle 11 Day 22	48	3.47	12.38	0.0	0.00	66.7	44	-4.55	21.07	-100.0	0.00	33.3
Cycle 12 Day 1	58	2.87	11.32	0.0	0.00	66.7	53	0.00	14.62	-33.3	0.00	66.7
Cycle 12 Day 22	40	3.33	10.13	0.0	0.00	33.3	37	-3.60	21.92	-100.0	0.00	33.3
Cycle 13 Day 1	51	3.92	12.73	0.0	0.00	66.7	48	-1.39	22.76	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	6.98	18.63	0.0	0.00	100.0	40	0.00	23.87	-66.7	0.00	100.0
Cycle 14 Day 1	41	5.69	12.70	0.0	0.00	33.3	39	1.71	17.01	-33.3	0.00	33.3
Cycle 14 Day 22	33	6.06	19.46	0.0	0.00	100.0	32	-2.08	14.51	-33.3	0.00	33.3
Cycle 15 Day 1	36	4.63	11.69	0.0	0.00	33.3	35	-0.95	15.09	-33.3	0.00	33.3
Cycle 15 Day 22	29	3.45	10.33	0.0	0.00	33.3	29	-2.30	12.38	-33.3	0.00	33.3
Cycle 16 Day 1	35	5.71	12.75	0.0	0.00	33.3	35	0.95	15.09	-33.3	0.00	33.3
Cycle 16 Day 22	29	4.60	11.70	0.0	0.00	33.3	29	-1.15	14.04	-33.3	0.00	33.3
Cycle 17 Day 1	30	5.56	12.63	0.0	0.00	33.3	30	1.11	16.34	-33.3	0.00	33.3
Cycle 17 Day 22	23	5.80	12.92	0.0	0.00	33.3	23	0.00	17.41	-33.3	0.00	33.3
Cycle 18 Day 1	27	3.70	10.68	0.0	0.00	33.3	27	-1.23	17.25	-33.3	0.00	33.3
Cycle 18 Day 22	20	1.67	7.45	0.0	0.00	33.3	20	-1.67	13.13	-33.3	0.00	33.3
Cycle 19 Day 1	23	1.45	6.95	0.0	0.00	33.3	23	-1.45	12.22	-33.3	0.00	33.3
Cycle 19 Day 22	20	3.33	10.26	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 20 Day 1	23	2.90	9.60	0.0	0.00	33.3	23	0.00	10.05	-33.3	0.00	33.3
Cycle 20 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
Cycle 21 Day 1	20	5.00	12.21	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
Cycle 21 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
Cycle 22 Day 1	15	2.22	8.61	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 22 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	-6.67	21.08	-33.3	0.00	33.3
Cycle 23 Day 1	15	2.22	8.61	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 23 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	15.57	-33.3	0.00	0.0
Cycle 24 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
Cycle 25 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-8.33	15.08	-33.3	0.00	0.0
Cycle 25 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 26 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	-2.56	21.35	-33.3	0.00	33.3
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Study Disc 1	144	15.74	28.41	0.0	0.00	100.0	136	8.09	27.37	-33.3	0.00	100.0
30 D SFU Z/P	77	13.85	24.99	0.0	0.00	100.0	72	6.94	24.35	-33.3	0.00	100.0
90 D SFU Z/P	89	9.74	20.84	0.0	0.00	100.0	86	2.33	24.94	-66.7	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	9.08	20.93	0.0	0.00	100.0						
Cycle 1 Day 22	211	7.27	19.24	0.0	0.00	100.0	208	-2.40	19.65	-100.0	0.00	66.7
Cycle 2 Day 1	230	6.09	16.53	0.0	0.00	100.0	223	-3.44	24.57	-100.0	0.00	100.0
Cycle 2 Day 22	185	7.21	17.26	0.0	0.00	100.0	180	-2.41	24.16	-100.0	0.00	100.0
Cycle 3 Day 1	203	5.25	15.01	0.0	0.00	100.0	196	-2.89	22.59	-100.0	0.00	100.0
Cycle 3 Day 22	156	6.20	15.52	0.0	0.00	100.0	148	-2.25	21.88	-100.0	0.00	66.7
Cycle 4 Day 1	170	5.10	14.05	0.0	0.00	66.7	161	-3.11	21.34	-100.0	0.00	66.7
Cycle 4 Day 22	133	6.77	16.80	0.0	0.00	100.0	127	0.26	21.62	-100.0	0.00	66.7
Cycle 5 Day 1	149	4.47	12.65	0.0	0.00	66.7	144	-2.78	19.51	-100.0	0.00	33.3
Cycle 5 Day 22	122	5.74	14.65	0.0	0.00	66.7	115	-1.45	21.81	-100.0	0.00	66.7
Cycle 6 Day 1	126	6.08	16.00	0.0	0.00	100.0	121	-0.55	20.63	-100.0	0.00	66.7
Cycle 6 Day 22	96	3.82	11.72	0.0	0.00	66.7	92	-1.45	20.32	-100.0	0.00	66.7
Cycle 7 Day 1	101	3.30	11.06	0.0	0.00	66.7	98	-1.70	18.77	-100.0	0.00	66.7
Cycle 7 Day 22	75	4.44	13.79	0.0	0.00	66.7	73	-0.91	20.77	-100.0	0.00	66.7
Cycle 8 Day 1	82	3.66	10.48	0.0	0.00	33.3	81	-2.47	18.09	-100.0	0.00	33.3
Cycle 8 Day 22	67	2.99	9.59	0.0	0.00	33.3	65	-3.59	22.14	-100.0	0.00	33.3
Cycle 9 Day 1	64	4.17	11.11	0.0	0.00	33.3	62	-2.15	19.90	-100.0	0.00	33.3
Cycle 9 Day 22	57	4.09	11.04	0.0	0.00	33.3	55	-2.42	20.14	-100.0	0.00	33.3
Cycle 10 Day 1	58	2.87	11.32	0.0	0.00	66.7	56	-2.38	19.96	-100.0	0.00	66.7
Cycle 10 Day 22	44	3.79	12.89	0.0	0.00	66.7	43	-0.78	21.19	-100.0	0.00	66.7
Cycle 11 Day 1	48	5.56	15.88	0.0	0.00	66.7	46	1.45	23.26	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	4.04	11.05	0.0	0.00	33.3	31	4.30	11.36	0.0	0.00	33.3
Cycle 12 Day 1	43	3.88	13.03	0.0	0.00	66.7	41	0.00	21.08	-100.0	0.00	66.7
Cycle 12 Day 22	27	4.94	15.20	0.0	0.00	66.7	25	2.67	16.44	-33.3	0.00	66.7
Cycle 13 Day 1	37	4.50	13.97	0.0	0.00	66.7	35	0.00	22.87	-100.0	0.00	66.7
Cycle 13 Day 22	22	6.06	13.16	0.0	0.00	33.3	21	0.00	25.82	-100.0	0.00	33.3
Cycle 14 Day 1	31	2.15	8.32	0.0	0.00	33.3	30	-3.33	20.25	-100.0	0.00	33.3
Cycle 14 Day 22	20	3.33	10.26	0.0	0.00	33.3	19	-3.51	24.58	-100.0	0.00	33.3
Cycle 15 Day 1	27	0.00	0.00	0.0	0.00	0.0	27	-6.17	20.75	-100.0	0.00	0.0
Cycle 15 Day 22	17	1.96	8.08	0.0	0.00	33.3	17	-5.88	24.25	-100.0	0.00	0.0
Cycle 16 Day 1	22	3.03	9.81	0.0	0.00	33.3	22	-3.03	22.79	-100.0	0.00	33.3
Cycle 16 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	-7.14	26.73	-100.0	0.00	0.0
Cycle 17 Day 1	18	0.00	0.00	0.0	0.00	0.0	18	-5.56	23.57	-100.0	0.00	0.0
Cycle 18 Day 1	16	2.08	8.33	0.0	0.00	33.3	16	-6.25	25.00	-100.0	0.00	0.0
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 19 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	0.00	0.00	0.0	0.00	0.0
Cycle 19 Day 22	12	2.78	9.62	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
Cycle 20 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	0.00	0.00	0.0	0.00	0.0
Cycle 20 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
Cycle 21 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	0.00	0.00	0.0	0.00	0.0
Cycle 22 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
Cycle 23 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	0.00	0.0	0.00	0.0
Study Disc 1	153	10.89	23.83	0.0	0.00	100.0	149	1.34	26.53	-100.0	0.00	100.0
Study Disc 2	12	16.67	38.92	0.0	0.00	100.0	11	15.15	34.52	0.0	0.00	100.0
30 D SFU Z/P	93	8.24	20.06	0.0	0.00	100.0	90	-0.37	24.73	-100.0	0.00	66.7
90 D SFU Z/P	84	5.95	16.49	0.0	0.00	100.0	82	-1.63	24.51	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	7.63	17.08	0.0	0.00	100.0						
	Cycle 1 Day 22	123	8.67	15.88	0.0	0.00	66.7	117	2.56	20.60	-100.0	0.00	66.7
	Cycle 2 Day 1	137	8.76	17.28	0.0	0.00	66.7	132	0.51	22.93	-100.0	0.00	66.7
	Cycle 2 Day 22	104	8.01	16.42	0.0	0.00	66.7	100	0.00	17.73	-66.7	0.00	66.7
	Cycle 3 Day 1	133	7.02	16.44	0.0	0.00	100.0	127	-0.79	21.19	-100.0	0.00	66.7
	Cycle 3 Day 22	107	11.21	19.93	0.0	0.00	66.7	102	3.92	26.66	-66.7	0.00	66.7
	Cycle 4 Day 1	112	7.14	15.13	0.0	0.00	66.7	108	-0.93	24.73	-100.0	0.00	66.7
	Cycle 4 Day 22	84	8.73	18.74	0.0	0.00	100.0	80	1.25	25.68	-100.0	0.00	100.0
	Cycle 5 Day 1	104	10.90	21.00	0.0	0.00	100.0	99	4.71	26.52	-66.7	0.00	100.0
	Cycle 5 Day 22	78	8.12	18.75	0.0	0.00	100.0	73	2.28	18.70	-33.3	0.00	66.7
	Cycle 6 Day 1	88	5.68	13.58	0.0	0.00	66.7	83	0.00	18.77	-66.7	0.00	66.7
	Cycle 6 Day 22	67	4.48	11.45	0.0	0.00	33.3	64	-0.52	16.26	-33.3	0.00	33.3
	Cycle 7 Day 1	77	3.03	9.65	0.0	0.00	33.3	74	-3.60	21.06	-100.0	0.00	33.3
	Cycle 7 Day 22	62	6.45	14.58	0.0	0.00	66.7	57	-0.58	22.26	-66.7	0.00	66.7
	Cycle 8 Day 1	57	6.43	17.18	0.0	0.00	100.0	52	0.00	20.87	-100.0	0.00	33.3
	Cycle 8 Day 22	47	4.26	13.22	0.0	0.00	66.7	43	0.00	17.82	-33.3	0.00	66.7
	Cycle 9 Day 1	49	5.44	14.19	0.0	0.00	66.7	44	0.76	18.31	-33.3	0.00	66.7
	Cycle 9 Day 22	43	6.98	15.53	0.0	0.00	66.7	39	0.85	20.92	-66.7	0.00	66.7
	Cycle 10 Day 1	47	4.26	13.22	0.0	0.00	66.7	43	-1.55	22.95	-100.0	0.00	66.7
	Cycle 10 Day 22	42	3.97	13.17	0.0	0.00	66.7	39	-1.71	24.12	-100.0	0.00	66.7
	Cycle 11 Day 1	44	6.06	14.86	0.0	0.00	66.7	41	0.81	24.14	-100.0	0.00	66.7
	Cycle 11 Day 22	31	2.15	8.32	0.0	0.00	33.3	28	-5.95	24.09	-100.0	0.00	33.3
	Cycle 12 Day 1	35	2.86	12.45	0.0	0.00	66.7	32	0.00	16.93	-33.3	0.00	66.7
	Cycle 12 Day 22	28	2.38	8.74	0.0	0.00	33.3	25	-5.33	24.87	-100.0	0.00	33.3
	Cycle 13 Day 1	32	6.25	15.70	0.0	0.00	66.7	31	0.00	27.22	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	28	9.52	21.96	0.0	0.00	100.0	26	1.28	27.46	-66.7	0.00	100.0
	Cycle 14 Day 1	24	6.94	13.83	0.0	0.00	33.3	23	2.90	19.88	-33.3	0.00	33.3
	Cycle 14 Day 22	17	3.92	11.07	0.0	0.00	33.3	17	-1.96	18.52	-33.3	0.00	33.3
	Cycle 15 Day 1	21	4.76	11.95	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
	Cycle 15 Day 22	18	1.85	7.86	0.0	0.00	33.3	18	-3.70	15.71	-33.3	0.00	33.3
	Cycle 16 Day 1	21	4.76	11.95	0.0	0.00	33.3	21	0.00	18.26	-33.3	0.00	33.3
	Cycle 16 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	-1.85	17.98	-33.3	0.00	33.3
	Cycle 17 Day 1	17	5.88	13.10	0.0	0.00	33.3	17	1.96	18.52	-33.3	0.00	33.3
	Cycle 17 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	0.00	22.22	-33.3	0.00	33.3
	Cycle 18 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	0.00	18.49	-33.3	0.00	33.3
	Cycle 18 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Cycle 19 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 19 Day 22	12	2.78	9.62	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 20 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Cycle 21 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Study Disc 1	97	15.81	27.26	0.0	0.00	100.0	93	7.89	25.25	-33.3	0.00	66.7
	30 D SFU Z/P	50	12.00	24.06	0.0	0.00	100.0	47	4.26	21.55	-33.3	0.00	100.0
	90 D SFU Z/P	56	10.71	21.18	0.0	0.00	100.0	55	3.64	23.72	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	9.76	23.35	0.0	0.00	100.0						
	Cycle 1 Day 22	133	5.01	16.66	0.0	0.00	100.0	131	-5.09	18.71	-100.0	0.00	33.3
	Cycle 2 Day 1	147	4.76	15.11	0.0	0.00	100.0	143	-6.06	25.53	-100.0	0.00	100.0
	Cycle 2 Day 22	117	5.41	15.76	0.0	0.00	100.0	113	-4.42	26.17	-100.0	0.00	100.0
	Cycle 3 Day 1	128	4.43	12.81	0.0	0.00	66.7	125	-4.80	23.07	-100.0	0.00	66.7
	Cycle 3 Day 22	102	3.92	10.79	0.0	0.00	33.3	98	-5.44	20.69	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	107	2.80	9.30	0.0	0.00	33.3	102	-6.54	22.51	-100.0	0.00	33.3
	Cycle 4 Day 22	87	4.60	11.56	0.0	0.00	33.3	84	-2.38	20.56	-100.0	0.00	33.3
	Cycle 5 Day 1	97	2.06	9.40	0.0	0.00	66.7	95	-5.96	20.62	-100.0	0.00	33.3
	Cycle 5 Day 22	80	3.33	11.38	0.0	0.00	66.7	76	-4.39	21.32	-100.0	0.00	33.3
	Cycle 6 Day 1	83	2.41	10.13	0.0	0.00	66.7	81	-4.12	20.67	-100.0	0.00	66.7
	Cycle 6 Day 22	63	2.65	9.08	0.0	0.00	33.3	61	-3.83	21.17	-100.0	0.00	33.3
	Cycle 7 Day 1	68	0.49	4.04	0.0	0.00	33.3	65	-5.13	17.90	-100.0	0.00	0.0
	Cycle 7 Day 22	48	2.08	8.15	0.0	0.00	33.3	46	-4.35	20.62	-100.0	0.00	33.3
	Cycle 8 Day 1	55	1.82	7.64	0.0	0.00	33.3	54	-4.94	18.78	-100.0	0.00	33.3
	Cycle 8 Day 22	43	2.33	8.59	0.0	0.00	33.3	41	-5.69	24.61	-100.0	0.00	33.3
	Cycle 9 Day 1	40	1.67	7.36	0.0	0.00	33.3	38	-6.14	21.72	-100.0	0.00	33.3
	Cycle 9 Day 22	35	1.90	7.85	0.0	0.00	33.3	33	-6.06	22.75	-100.0	0.00	33.3
	Cycle 10 Day 1	37	0.00	0.00	0.0	0.00	0.0	35	-6.67	21.08	-100.0	0.00	0.0
	Cycle 10 Day 22	28	0.00	0.00	0.0	0.00	0.0	27	-6.17	20.75	-100.0	0.00	0.0
	Cycle 11 Day 1	29	0.00	0.00	0.0	0.00	0.0	27	-6.17	20.75	-100.0	0.00	0.0
	Cycle 11 Day 22	21	0.00	0.00	0.0	0.00	0.0	19	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	27	1.23	6.42	0.0	0.00	33.3	25	-4.00	22.19	-100.0	0.00	33.3
	Cycle 12 Day 22	17	1.96	8.08	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
	Cycle 13 Day 1	22	0.00	0.00	0.0	0.00	0.0	20	-6.67	23.20	-100.0	0.00	0.0
	Cycle 13 Day 22	13	2.56	9.25	0.0	0.00	33.3	12	-5.56	31.25	-100.0	0.00	33.3
	Cycle 14 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	-5.88	26.97	-100.0	0.00	33.3
	Cycle 14 Day 22	15	0.00	0.00	0.0	0.00	0.0	14	-7.14	26.73	-100.0	0.00	0.0
	Cycle 15 Day 1	16	0.00	0.00	0.0	0.00	0.0	16	-8.33	25.82	-100.0	0.00	0.0
	Cycle 15 Day 22	12	0.00	0.00	0.0	0.00	0.0	12	-8.33	28.87	-100.0	0.00	0.0
	Cycle 16 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-5.56	31.25	-100.0	0.00	33.3
	Study Disc 1	100	7.67	19.45	0.0	0.00	100.0	97	-2.41	24.18	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	30 D SFU Z/P	55	6.67	18.59	0.0	0.00	100.0	53	-3.77	25.03	-100.0	0.00	66.7
	90 D SFU Z/P	51	3.92	10.85	0.0	0.00	33.3	50	-5.33	23.68	-100.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	7.69	17.97	0.0	0.00	100.0						
	Cycle 1 Day 22	63	7.94	17.67	0.0	0.00	100.0	59	-2.26	23.05	-100.0	0.00	66.7
	Cycle 2 Day 1	79	9.70	18.61	0.0	0.00	66.7	74	3.15	20.02	-66.7	0.00	66.7
	Cycle 2 Day 22	53	9.43	22.05	0.0	0.00	100.0	50	4.67	22.35	-33.3	0.00	100.0
	Cycle 3 Day 1	67	7.96	15.45	0.0	0.00	66.7	63	1.06	19.83	-66.7	0.00	66.7
	Cycle 3 Day 22	54	11.11	22.43	0.0	0.00	100.0	50	3.33	21.56	-33.3	0.00	100.0
	Cycle 4 Day 1	65	6.67	14.67	0.0	0.00	66.7	61	0.00	14.91	-33.3	0.00	33.3
	Cycle 4 Day 22	43	7.75	17.57	0.0	0.00	66.7	42	2.38	18.61	-33.3	0.00	66.7
	Cycle 5 Day 1	52	8.97	17.61	0.0	0.00	66.7	49	1.36	17.95	-33.3	0.00	66.7
	Cycle 5 Day 22	39	11.11	20.71	0.0	0.00	66.7	37	1.80	25.99	-66.7	0.00	66.7
	Cycle 6 Day 1	43	8.53	16.42	0.0	0.00	66.7	39	-2.56	17.75	-66.7	0.00	33.3
	Cycle 6 Day 22	41	10.57	22.90	0.0	0.00	100.0	39	-2.56	20.78	-66.7	0.00	33.3
	Cycle 7 Day 1	42	7.94	17.74	0.0	0.00	66.7	39	1.71	15.20	-33.3	0.00	33.3
	Cycle 7 Day 22	25	8.00	14.53	0.0	0.00	33.3	24	0.00	17.03	-33.3	0.00	33.3
	Cycle 8 Day 1	31	7.53	14.17	0.0	0.00	33.3	28	0.00	15.71	-33.3	0.00	33.3
	Cycle 8 Day 22	30	10.00	17.83	0.0	0.00	66.7	28	-1.19	16.93	-66.7	0.00	33.3
	Cycle 9 Day 1	33	6.06	13.06	0.0	0.00	33.3	31	-2.15	17.07	-66.7	0.00	33.3
	Cycle 9 Day 22	22	6.06	13.16	0.0	0.00	33.3	21	0.00	18.26	-66.7	0.00	33.3
	Cycle 10 Day 1	25	4.00	11.06	0.0	0.00	33.3	23	-1.45	18.74	-66.7	0.00	33.3
	Cycle 10 Day 22	19	3.51	10.51	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
	Cycle 11 Day 1	24	1.39	6.80	0.0	0.00	33.3	22	-1.52	7.11	-33.3	0.00	0.0
	Cycle 11 Day 22	17	5.88	17.62	0.0	0.00	66.7	16	-2.08	14.75	-33.3	0.00	33.3
	Cycle 12 Day 1	23	2.90	9.60	0.0	0.00	33.3	21	0.00	10.54	-33.3	0.00	33.3
	Cycle 12 Day 22	12	5.56	12.97	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
	Cycle 13 Day 1	19	0.00	0.00	0.0	0.00	0.0	17	-3.92	11.07	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	15	2.22	8.61	0.0	0.00	33.3	14	-2.38	15.82	-33.3	0.00	33.3
	Cycle 14 Day 1	17	3.92	11.07	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
	Cycle 14 Day 22	16	8.33	25.82	0.0	0.00	100.0	15	-2.22	8.61	-33.3	0.00	0.0
	Cycle 15 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	-2.38	8.91	-33.3	0.00	0.0
	Cycle 15 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
	Cycle 16 Day 1	14	7.14	14.19	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
	Cycle 16 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	0.00	0.00	0.0	0.00	0.0
	Cycle 17 Day 1	13	5.13	12.52	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 17 Day 22	13	5.13	12.52	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 18 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-2.56	16.45	-33.3	0.00	33.3
	Cycle 19 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 20 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
	Cycle 21 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Study Disc 1	47	15.60	30.97	0.0	0.00	100.0	43	8.53	31.78	-33.3	0.00	100.0
	30 D SFU Z/P	27	17.28	26.75	0.0	0.00	66.7	25	12.00	28.67	-33.3	0.00	66.7
	90 D SFU Z/P	33	8.08	20.46	0.0	0.00	100.0	31	0.00	27.22	-66.7	0.00	100.0
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	7.89	15.85	0.0	0.00	66.7						
	Cycle 1 Day 22	78	11.11	22.58	0.0	0.00	100.0	77	2.16	20.48	-33.3	0.00	66.7
	Cycle 2 Day 1	83	8.43	18.66	0.0	0.00	100.0	80	1.25	22.15	-66.7	0.00	66.7
	Cycle 2 Day 22	68	10.29	19.32	0.0	0.00	100.0	67	1.00	20.08	-33.3	0.00	66.7
	Cycle 3 Day 1	75	6.67	18.17	0.0	0.00	100.0	71	0.47	21.45	-33.3	0.00	100.0
	Cycle 3 Day 22	54	10.49	21.30	0.0	0.00	100.0	50	4.00	22.98	-33.3	0.00	66.7
	Cycle 4 Day 1	63	8.99	19.13	0.0	0.00	66.7	59	2.82	17.82	-33.3	0.00	66.7
	Cycle 4 Day 22	46	10.87	23.36	0.0	0.00	100.0	43	5.43	22.92	-33.3	0.00	66.7
	Cycle 5 Day 1	52	8.97	16.32	0.0	0.00	66.7	49	3.40	15.58	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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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: 08SEP23

Table 301.3.3002.30.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	42	10.32	18.75	0.0	0.00	66.7	39	4.27	21.87	-33.3	0.00	66.7
	Cycle 6 Day 1	43	13.18	21.99	0.0	0.00	100.0	40	6.67	18.80	-33.3	0.00	66.7
	Cycle 6 Day 22	33	6.06	15.49	0.0	0.00	66.7	31	3.23	17.96	-33.3	0.00	66.7
	Cycle 7 Day 1	33	9.09	17.23	0.0	0.00	66.7	33	5.05	18.86	-33.3	0.00	66.7
	Cycle 7 Day 22	27	8.64	19.81	0.0	0.00	66.7	27	4.94	20.05	-33.3	0.00	66.7
	Cycle 8 Day 1	27	7.41	14.12	0.0	0.00	33.3	27	2.47	15.81	-33.3	0.00	33.3
	Cycle 8 Day 22	24	4.17	11.26	0.0	0.00	33.3	24	0.00	17.03	-33.3	0.00	33.3
	Cycle 9 Day 1	24	8.33	14.74	0.0	0.00	33.3	24	4.17	14.95	-33.3	0.00	33.3
	Cycle 9 Day 22	22	7.58	14.30	0.0	0.00	33.3	22	3.03	14.21	-33.3	0.00	33.3
	Cycle 10 Day 1	21	7.94	17.97	0.0	0.00	66.7	21	4.76	15.94	0.0	0.00	66.7
	Cycle 10 Day 22	16	10.42	20.07	0.0	0.00	66.7	16	8.33	19.25	0.0	0.00	66.7
	Cycle 11 Day 1	19	14.04	23.08	0.0	0.00	66.7	19	12.28	22.80	0.0	0.00	66.7
	Cycle 11 Day 22	12	11.11	16.41	0.0	0.00	33.3	12	11.11	16.41	0.0	0.00	33.3
	Cycle 12 Day 1	16	8.33	19.25	0.0	0.00	66.7	16	6.25	18.13	0.0	0.00	66.7
	Cycle 12 Day 22	10	10.00	22.50	0.0	0.00	66.7	10	6.67	21.08	0.0	0.00	66.7
	Cycle 13 Day 1	15	11.11	20.57	0.0	0.00	66.7	15	8.89	19.79	0.0	0.00	66.7
	Cycle 14 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Cycle 16 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	53	16.98	29.69	0.0	0.00	100.0	52	8.33	29.43	-33.3	0.00	100.0
	30 D SFU Z/P	38	10.53	22.06	0.0	0.00	100.0	37	4.50	23.78	-33.3	0.00	66.7
	90 D SFU Z/P	33	9.09	22.47	0.0	0.00	100.0	32	4.17	25.04	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	7.00	18.24	0.0	0.00	100.0						
Cycle 1 Day 22	186	8.24	17.78	0.0	0.00	100.0	176	1.52	17.75	-66.7	0.00	66.7
Cycle 2 Day 1	216	6.33	14.94	0.0	0.00	100.0	206	-0.49	17.26	-100.0	0.00	66.7
Cycle 2 Day 22	157	4.67	13.85	0.0	0.00	100.0	150	-2.67	19.12	-100.0	0.00	66.7
Cycle 3 Day 1	200	5.17	14.98	0.0	0.00	100.0	190	-1.23	18.90	-100.0	0.00	100.0
Cycle 3 Day 22	161	8.90	16.57	0.0	0.00	66.7	152	2.19	19.81	-66.7	0.00	66.7
Cycle 4 Day 1	177	5.46	13.82	0.0	0.00	66.7	169	-0.99	17.22	-66.7	0.00	66.7
Cycle 4 Day 22	127	6.56	14.57	0.0	0.00	66.7	122	1.09	18.15	-66.7	0.00	66.7
Cycle 5 Day 1	156	7.26	16.20	0.0	0.00	66.7	148	0.45	18.64	-66.7	0.00	66.7
Cycle 5 Day 22	117	8.26	18.52	0.0	0.00	100.0	110	0.91	18.87	-66.7	0.00	100.0
Cycle 6 Day 1	131	6.62	15.70	0.0	0.00	66.7	122	-1.37	17.87	-66.7	0.00	33.3
Cycle 6 Day 22	108	5.25	15.23	0.0	0.00	100.0	103	-1.62	16.42	-66.7	0.00	66.7
Cycle 7 Day 1	119	3.64	12.11	0.0	0.00	66.7	113	-2.95	17.00	-66.7	0.00	33.3
Cycle 7 Day 22	87	7.28	14.75	0.0	0.00	66.7	81	0.41	17.07	-66.7	0.00	33.3
Cycle 8 Day 1	88	6.82	13.52	0.0	0.00	33.3	80	-0.83	18.35	-66.7	0.00	33.3
Cycle 8 Day 22	77	5.63	13.68	0.0	0.00	66.7	71	-1.88	16.80	-66.7	0.00	33.3
Cycle 9 Day 1	82	4.88	11.85	0.0	0.00	33.3	75	-2.22	14.84	-33.3	0.00	33.3
Cycle 9 Day 22	65	5.64	13.91	0.0	0.00	66.7	60	-0.56	17.88	-66.7	0.00	33.3
Cycle 10 Day 1	72	4.17	12.43	0.0	0.00	66.7	66	-0.51	17.04	-66.7	0.00	66.7
Cycle 10 Day 22	61	2.73	9.22	0.0	0.00	33.3	57	-1.17	16.62	-66.7	0.00	33.3
Cycle 11 Day 1	68	3.92	10.82	0.0	0.00	33.3	63	0.53	15.25	-66.7	0.00	33.3
Cycle 11 Day 22	48	4.17	11.14	0.0	0.00	33.3	44	-1.52	18.96	-66.7	0.00	33.3
Cycle 12 Day 1	58	4.60	11.59	0.0	0.00	33.3	53	0.00	16.01	-66.7	0.00	33.3
Cycle 12 Day 22	40	3.33	10.13	0.0	0.00	33.3	37	-1.80	17.47	-66.7	0.00	33.3
Cycle 13 Day 1	51	3.92	10.85	0.0	0.00	33.3	48	-0.69	16.11	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	5.43	12.45	0.0	0.00	33.3	40	0.83	19.23	-66.7	0.00	33.3
Cycle 14 Day 1	41	2.44	8.79	0.0	0.00	33.3	39	-2.56	16.01	-66.7	0.00	33.3
Cycle 14 Day 22	33	0.00	0.00	0.0	0.00	0.0	32	-6.25	15.70	-66.7	0.00	0.0
Cycle 15 Day 1	36	3.70	10.62	0.0	0.00	33.3	35	-0.95	12.75	-33.3	0.00	33.3
Cycle 15 Day 22	29	1.15	6.19	0.0	0.00	33.3	29	-4.60	11.70	-33.3	0.00	0.0
Cycle 16 Day 1	35	3.81	10.76	0.0	0.00	33.3	35	-1.90	13.87	-33.3	0.00	33.3
Cycle 16 Day 22	29	3.45	10.33	0.0	0.00	33.3	29	-2.30	12.38	-33.3	0.00	33.3
Cycle 17 Day 1	30	3.33	10.17	0.0	0.00	33.3	30	-2.22	17.36	-66.7	0.00	33.3
Cycle 17 Day 22	23	5.80	12.92	0.0	0.00	33.3	23	-1.45	21.27	-66.7	0.00	33.3
Cycle 18 Day 1	27	2.47	8.90	0.0	0.00	33.3	27	-2.47	18.32	-66.7	0.00	33.3
Cycle 18 Day 22	20	5.00	12.21	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
Cycle 19 Day 1	23	2.90	9.60	0.0	0.00	33.3	23	0.00	17.41	-66.7	0.00	33.3
Cycle 19 Day 22	20	3.33	10.26	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 20 Day 1	23	2.90	9.60	0.0	0.00	33.3	23	0.00	10.05	-33.3	0.00	33.3
Cycle 20 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
Cycle 21 Day 1	20	1.67	7.45	0.0	0.00	33.3	20	-1.67	17.01	-66.7	0.00	33.3
Cycle 21 Day 22	14	0.00	0.00	0.0	0.00	0.0	14	-4.76	17.82	-66.7	0.00	0.0
Cycle 22 Day 1	15	4.44	11.73	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 22 Day 22	10	0.00	0.00	0.0	0.00	0.0	10	-10.00	22.50	-66.7	0.00	0.0
Cycle 23 Day 1	15	2.22	8.61	0.0	0.00	33.3	15	-4.44	21.33	-66.7	0.00	33.3
Cycle 23 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-9.09	21.56	-66.7	0.00	0.0
Cycle 24 Day 1	14	2.38	8.91	0.0	0.00	33.3	14	-4.76	22.10	-66.7	0.00	33.3
Cycle 25 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-8.33	20.72	-66.7	0.00	0.0
Cycle 25 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	25.03	-66.7	0.00	33.3
Cycle 26 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-5.13	22.96	-66.7	0.00	33.3
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Study Disc 1	144	10.88	23.26	0.0	0.00	100.0	136	2.94	23.12	-66.7	0.00	100.0
30 D SFU Z/P	77	9.52	21.53	0.0	0.00	100.0	72	1.39	20.51	-33.3	0.00	66.7
90 D SFU Z/P	89	11.24	19.43	0.0	0.00	100.0	86	2.71	19.28	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	6.10	15.65	0.0	0.00	100.0						
Cycle 1 Day 22	211	5.37	15.35	0.0	0.00	100.0	208	-1.28	16.98	-66.7	0.00	100.0
Cycle 2 Day 1	230	4.49	13.00	0.0	0.00	66.7	223	-1.05	13.93	-66.7	0.00	66.7
Cycle 2 Day 22	185	5.23	15.63	0.0	0.00	100.0	180	-1.30	16.29	-66.7	0.00	100.0
Cycle 3 Day 1	203	5.75	14.64	0.0	0.00	66.7	196	-0.34	15.47	-66.7	0.00	66.7
Cycle 3 Day 22	156	4.27	12.40	0.0	0.00	66.7	148	-2.93	16.46	-66.7	0.00	33.3
Cycle 4 Day 1	170	4.90	12.90	0.0	0.00	66.7	161	-1.86	16.77	-66.7	0.00	33.3
Cycle 4 Day 22	133	5.76	13.30	0.0	0.00	66.7	127	-0.26	17.57	-66.7	0.00	33.3
Cycle 5 Day 1	149	4.70	11.64	0.0	0.00	33.3	144	-2.08	15.88	-66.7	0.00	33.3
Cycle 5 Day 22	122	6.83	14.81	0.0	0.00	66.7	115	0.29	18.47	-66.7	0.00	66.7
Cycle 6 Day 1	126	6.61	14.62	0.0	0.00	66.7	121	0.83	17.98	-66.7	0.00	66.7
Cycle 6 Day 22	96	2.43	8.71	0.0	0.00	33.3	92	-2.90	14.54	-66.7	0.00	33.3
Cycle 7 Day 1	101	3.30	10.01	0.0	0.00	33.3	98	-2.04	15.00	-66.7	0.00	33.3
Cycle 7 Day 22	75	3.11	9.76	0.0	0.00	33.3	73	-1.37	16.14	-66.7	0.00	33.3
Cycle 8 Day 1	82	4.47	12.57	0.0	0.00	66.7	81	0.00	14.91	-66.7	0.00	33.3
Cycle 8 Day 22	67	4.48	11.45	0.0	0.00	33.3	65	-0.51	15.01	-66.7	0.00	33.3
Cycle 9 Day 1	64	3.12	9.79	0.0	0.00	33.3	62	-1.61	16.45	-66.7	0.00	33.3
Cycle 9 Day 22	57	3.51	10.32	0.0	0.00	33.3	55	-0.61	17.56	-66.7	0.00	33.3
Cycle 10 Day 1	58	2.87	9.44	0.0	0.00	33.3	56	-2.38	17.82	-66.7	0.00	33.3
Cycle 10 Day 22	44	3.03	9.69	0.0	0.00	33.3	43	-2.33	18.40	-66.7	0.00	33.3
Cycle 11 Day 1	48	3.47	12.38	0.0	0.00	66.7	46	-1.45	19.82	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	5.05	12.14	0.0	0.00	33.3	31	2.15	14.75	-33.3	0.00	33.3
Cycle 12 Day 1	43	2.33	11.26	0.0	0.00	66.7	41	-0.81	13.92	-33.3	0.00	66.7
Cycle 12 Day 22	27	3.70	10.68	0.0	0.00	33.3	25	-1.33	15.15	-33.3	0.00	33.3
Cycle 13 Day 1	37	4.50	17.85	0.0	0.00	100.0	35	0.95	22.12	-33.3	0.00	100.0
Cycle 13 Day 22	22	4.55	11.71	0.0	0.00	33.3	21	1.59	16.59	-33.3	0.00	33.3
Cycle 14 Day 1	31	3.23	13.21	0.0	0.00	66.7	30	0.00	15.16	-33.3	0.00	66.7
Cycle 14 Day 22	20	1.67	7.45	0.0	0.00	33.3	19	-1.75	13.49	-33.3	0.00	33.3
Cycle 15 Day 1	27	1.23	6.42	0.0	0.00	33.3	27	-2.47	12.83	-33.3	0.00	33.3
Cycle 15 Day 22	17	0.00	0.00	0.0	0.00	0.0	17	-3.92	11.07	-33.3	0.00	0.0
Cycle 16 Day 1	22	3.03	9.81	0.0	0.00	33.3	22	0.00	10.29	-33.3	0.00	33.3
Cycle 16 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	-2.38	8.91	-33.3	0.00	0.0
Cycle 17 Day 1	18	0.00	0.00	0.0	0.00	0.0	18	-3.70	10.78	-33.3	0.00	0.0
Cycle 18 Day 1	16	4.17	11.39	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	0.00	22.22	-33.3	0.00	33.3
Cycle 19 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 19 Day 22	12	2.78	9.62	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
Cycle 20 Day 1	16	0.00	0.00	0.0	0.00	0.0	15	-4.44	11.73	-33.3	0.00	0.0
Cycle 20 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	-3.33	18.92	-33.3	0.00	33.3
Cycle 21 Day 1	15	0.00	0.00	0.0	0.00	0.0	14	-4.76	12.10	-33.3	0.00	0.0
Cycle 22 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	17.16	-33.3	0.00	33.3
Cycle 23 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	2.56	16.45	-33.3	0.00	33.3
Study Disc 1	153	8.71	19.41	0.0	0.00	100.0	149	2.01	21.65	-66.7	0.00	100.0
Study Disc 2	12	16.67	30.15	0.0	0.00	100.0	11	12.12	34.23	-33.3	0.00	100.0
30 D SFU Z/P	93	6.45	14.12	0.0	0.00	66.7	90	0.00	17.31	-66.7	0.00	66.7
90 D SFU Z/P	84	6.75	16.99	0.0	0.00	66.7	82	1.63	22.77	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	5.82	15.56	0.0	0.00	100.0						
	Cycle 1 Day 22	123	7.05	16.11	0.0	0.00	100.0	117	1.71	17.42	-66.7	0.00	66.7
	Cycle 2 Day 1	137	5.84	14.52	0.0	0.00	100.0	132	-0.51	18.41	-100.0	0.00	33.3
	Cycle 2 Day 22	104	4.49	13.98	0.0	0.00	100.0	100	-2.67	17.52	-66.7	0.00	33.3
	Cycle 3 Day 1	133	5.26	16.33	0.0	0.00	100.0	127	-1.31	19.43	-100.0	0.00	100.0
	Cycle 3 Day 22	107	9.35	17.01	0.0	0.00	66.7	102	2.94	21.55	-66.7	0.00	66.7
	Cycle 4 Day 1	112	5.95	14.30	0.0	0.00	66.7	108	-0.62	17.64	-66.7	0.00	66.7
	Cycle 4 Day 22	84	6.35	15.06	0.0	0.00	66.7	80	0.42	18.75	-66.7	0.00	66.7
	Cycle 5 Day 1	104	7.05	16.54	0.0	0.00	66.7	99	0.67	19.62	-66.7	0.00	66.7
	Cycle 5 Day 22	78	6.41	17.86	0.0	0.00	100.0	73	0.00	19.25	-66.7	0.00	100.0
	Cycle 6 Day 1	88	6.06	15.61	0.0	0.00	66.7	83	-1.20	17.61	-66.7	0.00	33.3
	Cycle 6 Day 22	67	4.98	15.63	0.0	0.00	100.0	64	-1.04	17.79	-66.7	0.00	66.7
	Cycle 7 Day 1	77	1.73	7.45	0.0	0.00	33.3	74	-3.60	16.15	-66.7	0.00	33.3
	Cycle 7 Day 22	62	5.91	12.84	0.0	0.00	33.3	57	0.00	16.67	-66.7	0.00	33.3
	Cycle 8 Day 1	57	5.26	12.26	0.0	0.00	33.3	52	-0.64	18.07	-66.7	0.00	33.3
	Cycle 8 Day 22	47	3.55	10.39	0.0	0.00	33.3	43	-1.55	14.46	-33.3	0.00	33.3
	Cycle 9 Day 1	49	4.76	11.79	0.0	0.00	33.3	44	0.00	12.45	-33.3	0.00	33.3
	Cycle 9 Day 22	43	6.20	15.01	0.0	0.00	66.7	39	2.56	14.07	-33.3	0.00	33.3
	Cycle 10 Day 1	47	4.96	13.86	0.0	0.00	66.7	43	2.33	15.25	-33.3	0.00	66.7
	Cycle 10 Day 22	42	2.38	8.69	0.0	0.00	33.3	39	0.00	13.25	-33.3	0.00	33.3
	Cycle 11 Day 1	44	4.55	11.57	0.0	0.00	33.3	41	2.44	13.72	-33.3	0.00	33.3
	Cycle 11 Day 22	31	5.38	12.46	0.0	0.00	33.3	28	1.19	16.93	-33.3	0.00	33.3
	Cycle 12 Day 1	35	6.67	13.53	0.0	0.00	33.3	32	3.12	13.01	-33.3	0.00	33.3
	Cycle 12 Day 22	28	3.57	10.50	0.0	0.00	33.3	25	1.33	11.71	-33.3	0.00	33.3
	Cycle 13 Day 1	32	5.21	12.30	0.0	0.00	33.3	31	2.15	11.97	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	28	5.95	13.00	0.0	0.00	33.3	26	3.85	14.38	-33.3	0.00	33.3
	Cycle 14 Day 1	24	2.78	9.41	0.0	0.00	33.3	23	0.00	10.05	-33.3	0.00	33.3
	Cycle 14 Day 22	17	0.00	0.00	0.0	0.00	0.0	17	-3.92	11.07	-33.3	0.00	0.0
	Cycle 15 Day 1	21	4.76	11.95	0.0	0.00	33.3	21	1.59	12.81	-33.3	0.00	33.3
	Cycle 15 Day 22	18	0.00	0.00	0.0	0.00	0.0	18	-3.70	10.78	-33.3	0.00	0.0
	Cycle 16 Day 1	21	3.17	10.03	0.0	0.00	33.3	21	0.00	14.91	-33.3	0.00	33.3
	Cycle 16 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
	Cycle 17 Day 1	17	3.92	11.07	0.0	0.00	33.3	17	1.96	14.29	-33.3	0.00	33.3
	Cycle 17 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	3.33	18.92	-33.3	0.00	33.3
	Cycle 18 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	2.38	15.82	-33.3	0.00	33.3
	Cycle 18 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Cycle 19 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	2.56	9.25	0.0	0.00	33.3
	Cycle 19 Day 22	12	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 20 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	2.56	9.25	0.0	0.00	33.3
	Cycle 20 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Cycle 21 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	97	9.97	21.06	0.0	0.00	100.0	93	2.15	22.95	-66.7	0.00	100.0
	30 D SFU Z/P	50	7.33	20.53	0.0	0.00	100.0	47	-1.42	16.96	-33.3	0.00	66.7
	90 D SFU Z/P	56	11.31	18.29	0.0	0.00	66.7	55	3.64	19.95	-66.7	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	4.47	13.07	0.0	0.00	66.7						
	Cycle 1 Day 22	133	3.26	10.75	0.0	0.00	66.7	131	-1.78	12.62	-66.7	0.00	33.3
	Cycle 2 Day 1	147	3.40	11.53	0.0	0.00	66.7	143	-1.17	11.47	-66.7	0.00	33.3
	Cycle 2 Day 22	117	4.84	14.69	0.0	0.00	100.0	113	-0.29	16.36	-66.7	0.00	100.0
	Cycle 3 Day 1	128	5.47	13.73	0.0	0.00	66.7	125	0.53	15.25	-66.7	0.00	66.7
	Cycle 3 Day 22	102	1.63	7.23	0.0	0.00	33.3	98	-3.74	16.50	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	107	3.12	10.77	0.0	0.00	66.7	102	-1.96	15.43	-66.7	0.00	33.3
	Cycle 4 Day 22	87	4.21	11.14	0.0	0.00	33.3	84	0.00	17.16	-66.7	0.00	33.3
	Cycle 5 Day 1	97	2.41	8.67	0.0	0.00	33.3	95	-2.46	13.96	-66.7	0.00	33.3
	Cycle 5 Day 22	80	5.00	11.98	0.0	0.00	33.3	76	0.44	17.63	-66.7	0.00	33.3
	Cycle 6 Day 1	83	3.61	10.43	0.0	0.00	33.3	81	-1.23	15.32	-66.7	0.00	33.3
	Cycle 6 Day 22	63	2.12	8.19	0.0	0.00	33.3	61	-3.28	13.20	-66.7	0.00	33.3
	Cycle 7 Day 1	68	1.96	7.90	0.0	0.00	33.3	65	-3.59	13.34	-66.7	0.00	33.3
	Cycle 7 Day 22	48	0.69	4.81	0.0	0.00	33.3	46	-3.62	14.45	-66.7	0.00	0.0
	Cycle 8 Day 1	55	3.03	11.61	0.0	0.00	66.7	54	-1.85	13.61	-66.7	0.00	33.3
	Cycle 8 Day 22	43	1.55	7.10	0.0	0.00	33.3	41	-3.25	12.48	-66.7	0.00	0.0
	Cycle 9 Day 1	40	3.33	10.13	0.0	0.00	33.3	38	-1.75	17.24	-66.7	0.00	33.3
	Cycle 9 Day 22	35	1.90	7.85	0.0	0.00	33.3	33	-2.02	16.54	-66.7	0.00	33.3
	Cycle 10 Day 1	37	0.90	5.48	0.0	0.00	33.3	35	-4.76	16.46	-66.7	0.00	33.3
	Cycle 10 Day 22	28	1.19	6.30	0.0	0.00	33.3	27	-4.94	17.79	-66.7	0.00	33.3
	Cycle 11 Day 1	29	1.15	6.19	0.0	0.00	33.3	27	-4.94	17.79	-66.7	0.00	33.3
	Cycle 11 Day 22	21	1.59	7.27	0.0	0.00	33.3	19	0.00	11.11	-33.3	0.00	33.3
	Cycle 12 Day 1	27	1.23	6.42	0.0	0.00	33.3	25	-1.33	6.67	-33.3	0.00	0.0
	Cycle 12 Day 22	17	1.96	8.08	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
	Cycle 13 Day 1	22	0.00	0.00	0.0	0.00	0.0	20	-3.33	10.26	-33.3	0.00	0.0
	Cycle 13 Day 22	13	2.56	9.25	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Cycle 14 Day 1	18	0.00	0.00	0.0	0.00	0.0	17	-1.96	8.08	-33.3	0.00	0.0
	Cycle 14 Day 22	15	0.00	0.00	0.0	0.00	0.0	14	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	16	0.00	0.00	0.0	0.00	0.0	16	-2.08	8.33	-33.3	0.00	0.0
	Cycle 15 Day 22	12	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 16 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	100	4.67	13.42	0.0	0.00	66.7	97	-0.69	17.99	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	30 D SFU Z/P	55	4.24	11.21	0.0	0.00	33.3	53	-0.63	13.85	-66.7	0.00	33.3
	90 D SFU Z/P	51	5.23	15.45	0.0	0.00	66.7	50	1.33	20.16	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	9.16	22.26	0.0	0.00	100.0						
	Cycle 1 Day 22	63	10.58	20.59	0.0	0.00	100.0	59	1.13	18.53	-33.3	0.00	66.7
	Cycle 2 Day 1	79	7.17	15.72	0.0	0.00	66.7	74	-0.45	15.10	-33.3	0.00	66.7
	Cycle 2 Day 22	53	5.03	13.71	0.0	0.00	66.7	50	-2.67	22.17	-100.0	0.00	66.7
	Cycle 3 Day 1	67	4.98	11.97	0.0	0.00	33.3	63	-1.06	17.93	-66.7	0.00	33.3
	Cycle 3 Day 22	54	8.02	15.78	0.0	0.00	66.7	50	0.67	15.78	-33.3	0.00	33.3
	Cycle 4 Day 1	65	4.62	13.01	0.0	0.00	66.7	61	-1.64	16.58	-66.7	0.00	66.7
	Cycle 4 Day 22	43	6.98	13.72	0.0	0.00	33.3	42	2.38	17.10	-33.3	0.00	33.3
	Cycle 5 Day 1	52	7.69	15.64	0.0	0.00	66.7	49	0.00	16.67	-66.7	0.00	33.3
	Cycle 5 Day 22	39	11.97	19.48	0.0	0.00	66.7	37	2.70	18.22	-33.3	0.00	66.7
	Cycle 6 Day 1	43	7.75	16.00	0.0	0.00	66.7	39	-1.71	18.65	-66.7	0.00	33.3
	Cycle 6 Day 22	41	5.69	14.72	0.0	0.00	66.7	39	-2.56	14.07	-33.3	0.00	33.3
	Cycle 7 Day 1	42	7.14	17.32	0.0	0.00	66.7	39	-1.71	18.65	-66.7	0.00	33.3
	Cycle 7 Day 22	25	10.67	18.56	0.0	0.00	66.7	24	1.39	18.33	-33.3	0.00	33.3
	Cycle 8 Day 1	31	9.68	15.38	0.0	0.00	33.3	28	-1.19	19.21	-66.7	0.00	33.3
	Cycle 8 Day 22	30	8.89	17.36	0.0	0.00	66.7	28	-2.38	20.14	-66.7	0.00	33.3
	Cycle 9 Day 1	33	5.05	12.14	0.0	0.00	33.3	31	-5.38	17.42	-33.3	0.00	33.3
	Cycle 9 Day 22	22	4.55	11.71	0.0	0.00	33.3	21	-6.35	22.65	-66.7	0.00	33.3
	Cycle 10 Day 1	25	2.67	9.23	0.0	0.00	33.3	23	-5.80	19.21	-66.7	0.00	33.3
	Cycle 10 Day 22	19	3.51	10.51	0.0	0.00	33.3	18	-3.70	22.55	-66.7	0.00	33.3
	Cycle 11 Day 1	24	2.78	9.41	0.0	0.00	33.3	22	-3.03	17.55	-66.7	0.00	33.3
	Cycle 11 Day 22	17	1.96	8.08	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
	Cycle 12 Day 1	23	1.45	6.95	0.0	0.00	33.3	21	-4.76	19.11	-66.7	0.00	33.3
	Cycle 12 Day 22	12	2.78	9.62	0.0	0.00	33.3	12	-8.33	25.13	-66.7	0.00	33.3
	Cycle 13 Day 1	19	1.75	7.65	0.0	0.00	33.3	17	-5.88	21.20	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	15	4.44	11.73	0.0	0.00	33.3	14	-4.76	25.68	-66.7	0.00	33.3
	Cycle 14 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	-6.25	21.84	-66.7	0.00	33.3
	Cycle 14 Day 22	16	0.00	0.00	0.0	0.00	0.0	15	-8.89	19.79	-66.7	0.00	0.0
	Cycle 15 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
	Cycle 15 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Cycle 16 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
	Cycle 16 Day 22	11	3.03	10.05	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0
	Cycle 17 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-7.69	19.97	-66.7	0.00	0.0
	Cycle 17 Day 22	13	5.13	12.52	0.0	0.00	33.3	13	-5.13	22.96	-66.7	0.00	33.3
	Cycle 18 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-7.69	19.97	-66.7	0.00	0.0
	Cycle 19 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	24.60	-66.7	0.00	33.3
	Cycle 20 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 21 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	24.60	-66.7	0.00	33.3
	Study Disc 1	47	12.77	27.41	0.0	0.00	100.0	43	4.65	23.66	-33.3	0.00	100.0
	30 D SFU Z/P	27	13.58	23.13	0.0	0.00	66.7	25	6.67	25.46	-33.3	0.00	66.7
	90 D SFU Z/P	33	11.11	21.52	0.0	0.00	100.0	31	1.08	18.22	-66.7	0.00	33.3
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	8.96	19.12	0.0	0.00	100.0						
	Cycle 1 Day 22	78	8.97	20.58	0.0	0.00	100.0	77	-0.43	22.62	-66.7	0.00	100.0
	Cycle 2 Day 1	83	6.43	15.14	0.0	0.00	66.7	80	-0.83	17.57	-33.3	0.00	66.7
	Cycle 2 Day 22	68	5.88	17.22	0.0	0.00	100.0	67	-2.99	16.13	-33.3	0.00	33.3
	Cycle 3 Day 1	75	6.22	16.16	0.0	0.00	66.7	71	-1.88	15.82	-33.3	0.00	33.3
	Cycle 3 Day 22	54	9.26	17.63	0.0	0.00	66.7	50	-1.33	16.44	-33.3	0.00	33.3
	Cycle 4 Day 1	63	7.94	15.51	0.0	0.00	66.7	59	-1.69	19.00	-33.3	0.00	33.3
	Cycle 4 Day 22	46	8.70	16.38	0.0	0.00	66.7	43	-0.78	18.53	-33.3	0.00	33.3
	Cycle 5 Day 1	52	8.97	14.93	0.0	0.00	33.3	49	-1.36	19.20	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.31.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	42	10.32	18.75	0.0	0.00	66.7	39	0.00	20.23	-33.3	0.00	66.7
	Cycle 6 Day 1	43	12.40	19.28	0.0	0.00	66.7	40	5.00	22.07	-33.3	0.00	66.7
	Cycle 6 Day 22	33	3.03	9.73	0.0	0.00	33.3	31	-2.15	17.07	-33.3	0.00	33.3
	Cycle 7 Day 1	33	6.06	13.06	0.0	0.00	33.3	33	1.01	17.65	-33.3	0.00	33.3
	Cycle 7 Day 22	27	7.41	14.12	0.0	0.00	33.3	27	2.47	18.32	-33.3	0.00	33.3
	Cycle 8 Day 1	27	7.41	14.12	0.0	0.00	33.3	27	3.70	16.88	-33.3	0.00	33.3
	Cycle 8 Day 22	24	9.72	15.48	0.0	0.00	33.3	24	4.17	17.89	-33.3	0.00	33.3
	Cycle 9 Day 1	24	2.78	9.41	0.0	0.00	33.3	24	-1.39	15.48	-33.3	0.00	33.3
	Cycle 9 Day 22	22	6.06	13.16	0.0	0.00	33.3	22	1.52	19.18	-33.3	0.00	33.3
	Cycle 10 Day 1	21	6.35	13.41	0.0	0.00	33.3	21	1.59	19.65	-33.3	0.00	33.3
	Cycle 10 Day 22	16	6.25	13.44	0.0	0.00	33.3	16	2.08	19.12	-33.3	0.00	33.3
	Cycle 11 Day 1	19	7.02	17.84	0.0	0.00	66.7	19	3.51	21.93	-33.3	0.00	66.7
	Cycle 11 Day 22	12	11.11	16.41	0.0	0.00	33.3	12	5.56	19.25	-33.3	0.00	33.3
	Cycle 12 Day 1	16	4.17	16.67	0.0	0.00	66.7	16	0.00	21.08	-33.3	0.00	66.7
	Cycle 12 Day 22	10	6.67	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Cycle 13 Day 1	15	11.11	27.22	0.0	0.00	100.0	15	6.67	31.37	-33.3	0.00	100.0
	Cycle 14 Day 1	13	7.69	19.97	0.0	0.00	66.7	13	2.56	21.35	-33.3	0.00	66.7
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	17.98	-33.3	0.00	33.3
	Cycle 16 Day 1	10	6.67	14.05	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Study Disc 1	53	16.35	25.84	0.0	0.00	100.0	52	7.05	26.68	-66.7	0.00	100.0
	30 D SFU Z/P	38	9.65	17.17	0.0	0.00	66.7	37	0.90	21.50	-66.7	0.00	66.7
	90 D SFU Z/P	33	9.09	19.14	0.0	0.00	66.7	32	2.08	26.69	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	12.06	19.69	0.0	0.00	100.0						
Cycle 1 Day 22	186	15.23	21.67	0.0	0.00	100.0	176	4.17	23.27	-66.7	0.00	100.0
Cycle 2 Day 1	216	13.89	21.39	0.0	0.00	100.0	206	2.75	23.47	-66.7	0.00	100.0
Cycle 2 Day 22	157	12.53	20.81	0.0	0.00	100.0	150	2.22	20.31	-33.3	0.00	100.0
Cycle 3 Day 1	200	15.50	22.88	0.0	0.00	100.0	190	4.74	26.24	-66.7	0.00	100.0
Cycle 3 Day 22	161	14.49	19.99	0.0	0.00	100.0	152	3.29	24.19	-66.7	0.00	66.7
Cycle 4 Day 1	177	13.18	20.15	0.0	0.00	100.0	169	1.97	23.77	-66.7	0.00	100.0
Cycle 4 Day 22	127	11.02	17.84	0.0	0.00	100.0	122	1.37	18.87	-66.7	0.00	66.7
Cycle 5 Day 1	156	11.54	19.91	0.0	0.00	100.0	148	1.80	20.86	-66.7	0.00	66.7
Cycle 5 Day 22	117	11.40	19.65	0.0	0.00	100.0	110	1.21	20.66	-66.7	0.00	66.7
Cycle 6 Day 1	131	10.43	18.53	0.0	0.00	100.0	122	-0.82	22.05	-66.7	0.00	66.7
Cycle 6 Day 22	108	10.19	17.33	0.0	0.00	66.7	103	-0.65	19.79	-33.3	0.00	66.7
Cycle 7 Day 1	119	11.48	19.13	0.0	0.00	100.0	113	0.29	20.65	-33.3	0.00	100.0
Cycle 7 Day 22	87	9.96	15.35	0.0	0.00	33.3	81	-1.65	18.18	-33.3	0.00	33.3
Cycle 8 Day 1	88	12.12	17.64	0.0	0.00	66.7	80	0.83	21.85	-66.7	0.00	66.7
Cycle 8 Day 22	77	11.69	17.74	0.0	0.00	66.7	71	2.35	18.96	-33.3	0.00	66.7
Cycle 9 Day 1	82	8.54	14.64	0.0	0.00	33.3	75	-2.22	17.62	-33.3	0.00	33.3
Cycle 9 Day 22	65	11.28	19.79	0.0	0.00	100.0	60	2.22	22.01	-33.3	0.00	100.0
Cycle 10 Day 1	72	8.80	15.82	0.0	0.00	66.7	66	-1.01	18.46	-33.3	0.00	66.7
Cycle 10 Day 22	61	9.29	15.07	0.0	0.00	33.3	57	0.58	17.24	-33.3	0.00	33.3
Cycle 11 Day 1	68	8.33	14.54	0.0	0.00	33.3	63	0.00	17.96	-33.3	0.00	33.3
Cycle 11 Day 22	48	7.64	15.74	0.0	0.00	66.7	44	-1.52	16.00	-33.3	0.00	33.3
Cycle 12 Day 1	58	9.20	18.52	0.0	0.00	100.0	53	-0.63	16.65	-33.3	0.00	33.3
Cycle 12 Day 22	40	6.67	15.47	0.0	0.00	66.7	37	0.90	12.39	-33.3	0.00	33.3
Cycle 13 Day 1	51	9.15	16.44	0.0	0.00	66.7	48	2.08	17.40	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	10.08	17.11	0.0	0.00	66.7	40	4.17	15.45	-33.3	0.00	33.3
Cycle 14 Day 1	41	8.94	14.95	0.0	0.00	33.3	39	2.56	16.01	-33.3	0.00	33.3
Cycle 14 Day 22	33	4.04	11.05	0.0	0.00	33.3	32	-3.12	13.01	-33.3	0.00	33.3
Cycle 15 Day 1	36	11.11	21.08	0.0	0.00	100.0	35	2.86	23.39	-33.3	0.00	100.0
Cycle 15 Day 22	29	8.05	14.52	0.0	0.00	33.3	29	0.00	15.43	-33.3	0.00	33.3
Cycle 16 Day 1	35	8.57	14.78	0.0	0.00	33.3	35	1.90	16.05	-33.3	0.00	33.3
Cycle 16 Day 22	29	11.49	20.46	0.0	0.00	66.7	29	4.60	19.36	-33.3	0.00	66.7
Cycle 17 Day 1	30	8.89	17.36	0.0	0.00	66.7	30	3.33	16.02	-33.3	0.00	33.3
Cycle 17 Day 22	23	4.35	11.48	0.0	0.00	33.3	23	-1.45	15.82	-33.3	0.00	33.3
Cycle 18 Day 1	27	6.17	13.19	0.0	0.00	33.3	27	0.00	16.01	-33.3	0.00	33.3
Cycle 18 Day 22	20	5.00	12.21	0.0	0.00	33.3	20	1.67	13.13	-33.3	0.00	33.3
Cycle 19 Day 1	23	2.90	9.60	0.0	0.00	33.3	23	-1.45	12.22	-33.3	0.00	33.3
Cycle 19 Day 22	20	6.67	13.68	0.0	0.00	33.3	20	3.33	14.91	-33.3	0.00	33.3
Cycle 20 Day 1	23	4.35	11.48	0.0	0.00	33.3	23	0.00	14.21	-33.3	0.00	33.3
Cycle 20 Day 22	18	5.56	12.78	0.0	0.00	33.3	18	1.85	13.87	-33.3	0.00	33.3
Cycle 21 Day 1	20	1.67	7.45	0.0	0.00	33.3	20	-3.33	10.26	-33.3	0.00	0.0
Cycle 21 Day 22	14	4.76	12.10	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
Cycle 22 Day 1	15	4.44	11.73	0.0	0.00	33.3	15	-4.44	11.73	-33.3	0.00	0.0
Cycle 22 Day 22	10	10.00	16.10	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
Cycle 23 Day 1	15	6.67	13.80	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 23 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-6.06	13.48	-33.3	0.00	0.0
Cycle 24 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-4.76	12.10	-33.3	0.00	0.0
Cycle 25 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-8.33	15.08	-33.3	0.00	0.0
Cycle 25 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 26 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-7.69	14.62	-33.3	0.00	0.0
Cycle 27 Day 1	11	6.06	13.48	0.0	0.00	33.3	11	-6.06	13.48	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-8.33	15.08	-33.3	0.00	0.0
Study Disc 1	144	17.13	23.97	0.0	0.00	100.0	136	3.19	26.26	-66.7	0.00	100.0
30 D SFU Z/P	77	15.15	23.91	0.0	0.00	100.0	72	-0.93	27.96	-66.7	0.00	66.7
90 D SFU Z/P	89	13.48	19.92	0.0	0.00	100.0	86	2.33	22.75	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	16.73	22.85	0.0	0.00	100.0						
Cycle 1 Day 22	211	14.06	21.76	0.0	0.00	100.0	208	-3.04	21.14	-66.7	0.00	100.0
Cycle 2 Day 1	230	13.19	19.82	0.0	0.00	100.0	223	-4.19	24.56	-100.0	0.00	66.7
Cycle 2 Day 22	185	13.51	20.94	0.0	0.00	100.0	180	-3.70	27.04	-100.0	0.00	100.0
Cycle 3 Day 1	203	12.32	19.52	0.0	0.00	100.0	196	-5.78	24.12	-100.0	0.00	66.7
Cycle 3 Day 22	156	13.68	21.38	0.0	0.00	100.0	148	-4.28	23.74	-66.7	0.00	66.7
Cycle 4 Day 1	170	11.76	18.99	0.0	0.00	66.7	161	-7.04	23.40	-100.0	0.00	66.7
Cycle 4 Day 22	133	13.53	22.86	0.0	0.00	100.0	127	-4.20	23.75	-66.7	0.00	66.7
Cycle 5 Day 1	149	10.74	18.69	0.0	0.00	66.7	144	-5.32	22.18	-66.7	0.00	33.3
Cycle 5 Day 22	122	13.11	20.35	0.0	0.00	100.0	115	-3.48	23.93	-66.7	0.00	66.7
Cycle 6 Day 1	126	12.43	20.10	0.0	0.00	100.0	121	-3.03	22.77	-66.7	0.00	66.7
Cycle 6 Day 22	96	10.76	19.64	0.0	0.00	100.0	92	-5.80	22.97	-66.7	0.00	66.7
Cycle 7 Day 1	101	9.24	17.07	0.0	0.00	66.7	98	-4.42	19.52	-66.7	0.00	33.3
Cycle 7 Day 22	75	5.78	13.83	0.0	0.00	66.7	73	-7.31	20.22	-66.7	0.00	33.3
Cycle 8 Day 1	82	8.54	16.41	0.0	0.00	66.7	81	-3.29	20.14	-66.7	0.00	33.3
Cycle 8 Day 22	67	7.96	16.50	0.0	0.00	66.7	65	-5.64	21.71	-66.7	0.00	33.3
Cycle 9 Day 1	64	11.46	18.99	0.0	0.00	66.7	62	-1.61	22.93	-66.7	0.00	33.3
Cycle 9 Day 22	57	9.36	16.37	0.0	0.00	66.7	55	-1.82	22.61	-66.7	0.00	33.3
Cycle 10 Day 1	58	9.77	19.75	0.0	0.00	66.7	56	-4.17	22.97	-66.7	0.00	33.3
Cycle 10 Day 22	44	11.36	20.26	0.0	0.00	66.7	43	-3.88	25.42	-66.7	0.00	66.7
Cycle 11 Day 1	48	11.81	20.03	0.0	0.00	66.7	46	-1.45	26.25	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.32: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble with Coughing - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	11.11	19.84	0.0	0.00	66.7	31	0.00	22.77	-33.3	0.00	33.3
Cycle 12 Day 1	43	9.30	20.99	0.0	0.00	100.0	41	-4.88	24.22	-66.7	0.00	33.3
Cycle 12 Day 22	27	11.11	18.49	0.0	0.00	66.7	25	-6.67	23.57	-33.3	0.00	33.3
Cycle 13 Day 1	37	7.21	15.98	0.0	0.00	66.7	35	-8.57	21.91	-66.7	0.00	33.3
Cycle 13 Day 22	22	13.64	24.47	0.0	0.00	100.0	21	-4.76	28.45	-66.7	0.00	33.3
Cycle 14 Day 1	31	11.83	16.21	0.0	0.00	33.3	30	-2.22	26.16	-66.7	0.00	33.3
Cycle 14 Day 22	20	10.00	19.04	0.0	0.00	66.7	19	-7.02	26.24	-66.7	0.00	33.3
Cycle 15 Day 1	27	12.35	20.98	0.0	0.00	66.7	27	-1.23	25.29	-66.7	0.00	33.3
Cycle 15 Day 22	17	9.80	15.66	0.0	0.00	33.3	17	-7.84	25.08	-66.7	0.00	33.3
Cycle 16 Day 1	22	6.06	13.16	0.0	0.00	33.3	22	-9.09	21.04	-66.7	0.00	33.3
Cycle 16 Day 22	14	11.90	16.57	0.0	0.00	33.3	14	-9.52	27.51	-66.7	0.00	33.3
Cycle 17 Day 1	18	11.11	16.17	0.0	0.00	33.3	18	-3.70	25.28	-66.7	0.00	33.3
Cycle 18 Day 1	16	10.42	15.96	0.0	0.00	33.3	16	-6.25	27.81	-66.7	0.00	33.3
Cycle 18 Day 22	11	6.06	20.10	0.0	0.00	66.7	10	-10.00	22.50	-33.3	0.00	33.3
Cycle 19 Day 1	16	8.33	14.91	0.0	0.00	33.3	15	-4.44	21.33	-33.3	0.00	33.3
Cycle 19 Day 22	12	11.11	16.41	0.0	0.00	33.3	11	-6.06	25.03	-33.3	0.00	33.3
Cycle 20 Day 1	16	8.33	14.91	0.0	0.00	33.3	15	-4.44	17.21	-33.3	0.00	33.3
Cycle 20 Day 22	11	9.09	15.57	0.0	0.00	33.3	10	-6.67	21.08	-33.3	0.00	33.3
Cycle 21 Day 1	15	15.56	21.33	0.0	0.00	66.7	14	0.00	26.15	-33.3	0.00	66.7
Cycle 22 Day 1	12	8.33	20.72	0.0	0.00	66.7	12	-2.78	26.43	-33.3	0.00	66.7
Cycle 23 Day 1	13	12.82	16.88	0.0	0.00	33.3	13	0.00	23.57	-33.3	0.00	33.3
Study Disc 1	153	16.56	24.22	0.0	0.00	100.0	149	-1.79	25.93	-66.7	0.00	66.7
Study Disc 2	12	19.44	30.01	0.0	0.00	100.0	11	3.03	27.71	-33.3	0.00	33.3
30 D SFU Z/P	93	12.90	20.28	0.0	0.00	66.7	90	-5.93	26.24	-66.7	0.00	66.7
90 D SFU Z/P	84	12.70	18.59	0.0	0.00	66.7	82	-2.85	21.72	-66.7	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	5.45	14.00	0.0	0.00	66.7						
Cycle 1 Day 22	186	8.06	16.64	0.0	0.00	66.7	176	3.03	19.93	-66.7	0.00	66.7
Cycle 2 Day 1	216	6.33	15.95	0.0	0.00	100.0	206	0.81	16.28	-66.7	0.00	66.7
Cycle 2 Day 22	157	6.58	15.76	0.0	0.00	100.0	150	0.89	16.81	-66.7	0.00	66.7
Cycle 3 Day 1	200	5.00	12.83	0.0	0.00	66.7	190	-0.18	15.52	-66.7	0.00	66.7
Cycle 3 Day 22	161	5.80	13.21	0.0	0.00	66.7	152	0.66	16.93	-66.7	0.00	66.7
Cycle 4 Day 1	177	6.03	13.81	0.0	0.00	66.7	169	0.59	16.05	-33.3	0.00	66.7
Cycle 4 Day 22	127	7.35	18.26	0.0	0.00	100.0	122	2.19	19.04	-33.3	0.00	100.0
Cycle 5 Day 1	156	4.49	12.03	0.0	0.00	66.7	148	-0.68	15.29	-33.3	0.00	66.7
Cycle 5 Day 22	117	7.12	17.41	0.0	0.00	100.0	110	1.21	16.23	-33.3	0.00	66.7
Cycle 6 Day 1	131	5.34	15.37	0.0	0.00	100.0	122	-0.27	15.74	-33.3	0.00	66.7
Cycle 6 Day 22	108	4.63	13.25	0.0	0.00	66.7	103	-1.62	16.42	-33.3	0.00	66.7
Cycle 7 Day 1	119	3.92	13.15	0.0	0.00	100.0	113	-1.47	17.47	-33.3	0.00	100.0
Cycle 7 Day 22	87	4.60	12.63	0.0	0.00	66.7	81	-1.65	15.72	-33.3	0.00	66.7
Cycle 8 Day 1	88	6.82	16.88	0.0	0.00	100.0	80	1.25	20.16	-33.3	0.00	100.0
Cycle 8 Day 22	77	4.33	11.28	0.0	0.00	33.3	71	-1.41	15.36	-33.3	0.00	33.3
Cycle 9 Day 1	82	2.44	8.73	0.0	0.00	33.3	75	-2.67	11.96	-33.3	0.00	33.3
Cycle 9 Day 22	65	4.62	11.60	0.0	0.00	33.3	60	-0.56	15.64	-33.3	0.00	33.3
Cycle 10 Day 1	72	4.63	11.61	0.0	0.00	33.3	66	-1.01	13.03	-33.3	0.00	33.3
Cycle 10 Day 22	61	4.37	11.35	0.0	0.00	33.3	57	0.58	13.35	-33.3	0.00	33.3
Cycle 11 Day 1	68	4.41	11.38	0.0	0.00	33.3	63	0.53	14.03	-33.3	0.00	33.3
Cycle 11 Day 22	48	2.08	8.15	0.0	0.00	33.3	44	-3.03	14.05	-33.3	0.00	33.3
Cycle 12 Day 1	58	4.02	10.95	0.0	0.00	33.3	53	-0.63	13.85	-33.3	0.00	33.3
Cycle 12 Day 22	40	2.50	8.89	0.0	0.00	33.3	37	-2.70	12.12	-33.3	0.00	33.3
Cycle 13 Day 1	51	3.92	10.85	0.0	0.00	33.3	48	-0.69	14.57	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	3.88	10.81	0.0	0.00	33.3	40	-0.83	14.10	-33.3	0.00	33.3
Cycle 14 Day 1	41	3.25	10.01	0.0	0.00	33.3	39	-0.85	14.28	-33.3	0.00	33.3
Cycle 14 Day 22	33	2.02	8.08	0.0	0.00	33.3	32	-2.08	11.79	-33.3	0.00	33.3
Cycle 15 Day 1	36	4.63	11.69	0.0	0.00	33.3	35	0.00	14.00	-33.3	0.00	33.3
Cycle 15 Day 22	29	4.60	11.70	0.0	0.00	33.3	29	0.00	12.60	-33.3	0.00	33.3
Cycle 16 Day 1	35	2.86	9.47	0.0	0.00	33.3	35	-1.90	13.87	-33.3	0.00	33.3
Cycle 16 Day 22	29	2.30	8.60	0.0	0.00	33.3	29	-3.45	13.64	-33.3	0.00	33.3
Cycle 17 Day 1	30	5.56	12.63	0.0	0.00	33.3	30	1.11	13.79	-33.3	0.00	33.3
Cycle 17 Day 22	23	1.45	6.95	0.0	0.00	33.3	23	-4.35	15.26	-33.3	0.00	33.3
Cycle 18 Day 1	27	2.47	8.90	0.0	0.00	33.3	27	-2.47	8.90	-33.3	0.00	0.0
Cycle 18 Day 22	20	1.67	7.45	0.0	0.00	33.3	20	0.00	10.81	-33.3	0.00	33.3
Cycle 19 Day 1	23	0.00	0.00	0.0	0.00	0.0	23	-1.45	6.95	-33.3	0.00	0.0
Cycle 19 Day 22	20	1.67	7.45	0.0	0.00	33.3	20	0.00	0.00	0.0	0.00	0.0
Cycle 20 Day 1	23	5.80	21.68	0.0	0.00	100.0	23	4.35	23.15	-33.3	0.00	100.0
Cycle 20 Day 22	18	0.00	0.00	0.0	0.00	0.0	18	-1.85	7.86	-33.3	0.00	0.0
Cycle 21 Day 1	20	0.00	0.00	0.0	0.00	0.0	20	-1.67	7.45	-33.3	0.00	0.0
Cycle 21 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	0.00	0.00	0.0	0.00	0.0
Cycle 22 Day 1	15	2.22	8.61	0.0	0.00	33.3	15	-2.22	15.26	-33.3	0.00	33.3
Cycle 22 Day 22	10	3.33	10.54	0.0	0.00	33.3	10	-3.33	10.54	-33.3	0.00	0.0
Cycle 23 Day 1	15	4.44	11.73	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
Cycle 23 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 24 Day 1	14	0.00	0.00	0.0	0.00	0.0	14	-4.76	12.10	-33.3	0.00	0.0
Cycle 25 Day 1	12	0.00	0.00	0.0	0.00	0.0	12	-5.56	12.97	-33.3	0.00	0.0
Cycle 25 Day 22	11	9.09	21.56	0.0	0.00	66.7	11	3.03	23.35	-33.3	0.00	66.7
Cycle 26 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	-2.56	9.25	-33.3	0.00	0.0
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-3.03	10.05	-33.3	0.00	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	-2.78	9.62	-33.3	0.00	0.0
Study Disc 1	144	12.04	22.85	0.0	0.00	100.0	136	5.88	23.96	-66.7	0.00	100.0
30 D SFU Z/P	77	9.09	19.97	0.0	0.00	100.0	72	1.85	21.59	-66.7	0.00	66.7
90 D SFU Z/P	89	7.12	15.47	0.0	0.00	66.7	86	1.16	18.75	-66.7	0.00	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	257	5.97	15.28	0.0	0.00	100.0						
Cycle 1 Day 22	211	7.27	17.21	0.0	0.00	100.0	208	1.60	14.56	-66.7	0.00	66.7
Cycle 2 Day 1	230	5.07	14.22	0.0	0.00	100.0	223	-0.75	15.96	-66.7	0.00	66.7
Cycle 2 Day 22	185	6.85	17.41	0.0	0.00	100.0	180	0.93	15.93	-33.3	0.00	66.7
Cycle 3 Day 1	203	4.27	12.11	0.0	0.00	66.7	196	-0.34	15.09	-33.3	0.00	66.7
Cycle 3 Day 22	156	4.91	13.01	0.0	0.00	66.7	148	0.23	15.31	-66.7	0.00	66.7
Cycle 4 Day 1	170	4.90	11.84	0.0	0.00	33.3	161	-0.21	14.67	-66.7	0.00	33.3
Cycle 4 Day 22	133	5.01	12.64	0.0	0.00	66.7	127	-0.52	17.81	-66.7	0.00	66.7
Cycle 5 Day 1	149	5.59	15.21	0.0	0.00	100.0	144	1.16	17.81	-66.7	0.00	100.0
Cycle 5 Day 22	122	6.83	17.11	0.0	0.00	100.0	115	1.45	19.94	-66.7	0.00	66.7
Cycle 6 Day 1	126	5.56	14.45	0.0	0.00	66.7	121	1.10	16.63	-66.7	0.00	66.7
Cycle 6 Day 22	96	5.56	14.24	0.0	0.00	66.7	92	1.09	16.72	-66.7	0.00	66.7
Cycle 7 Day 1	101	3.63	11.45	0.0	0.00	66.7	98	0.34	14.75	-66.7	0.00	66.7
Cycle 7 Day 22	75	4.00	12.20	0.0	0.00	66.7	73	0.46	15.21	-66.7	0.00	66.7
Cycle 8 Day 1	82	7.32	17.39	0.0	0.00	100.0	81	5.35	17.84	-33.3	0.00	100.0
Cycle 8 Day 22	67	5.97	17.34	0.0	0.00	100.0	65	3.59	18.75	-33.3	0.00	100.0
Cycle 9 Day 1	64	5.73	16.32	0.0	0.00	100.0	62	3.23	17.81	-33.3	0.00	100.0
Cycle 9 Day 22	57	4.09	11.04	0.0	0.00	33.3	55	1.82	13.48	-33.3	0.00	33.3
Cycle 10 Day 1	58	5.17	15.04	0.0	0.00	66.7	56	2.38	12.48	-33.3	0.00	66.7
Cycle 10 Day 22	44	7.58	20.16	0.0	0.00	100.0	43	4.65	18.66	-33.3	0.00	100.0
Cycle 11 Day 1	48	6.94	20.58	0.0	0.00	100.0	46	4.35	19.38	-33.3	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	8.08	20.46	0.0	0.00	100.0	31	4.30	22.35	-33.3	0.00	100.0
Cycle 12 Day 1	43	5.43	19.15	0.0	0.00	100.0	41	2.44	17.30	-33.3	0.00	100.0
Cycle 12 Day 22	27	9.88	22.29	0.0	0.00	100.0	25	8.00	24.11	-33.3	0.00	100.0
Cycle 13 Day 1	37	8.11	19.88	0.0	0.00	100.0	35	4.76	21.61	-33.3	0.00	100.0
Cycle 13 Day 22	22	7.58	22.84	0.0	0.00	100.0	21	6.35	22.65	0.0	0.00	100.0
Cycle 14 Day 1	31	4.30	11.36	0.0	0.00	33.3	30	3.33	13.42	-33.3	0.00	33.3
Cycle 14 Day 22	20	1.67	7.45	0.0	0.00	33.3	19	1.75	7.65	0.0	0.00	33.3
Cycle 15 Day 1	27	2.47	8.90	0.0	0.00	33.3	27	1.23	11.25	-33.3	0.00	33.3
Cycle 15 Day 22	17	0.00	0.00	0.0	0.00	0.0	17	-1.96	8.08	-33.3	0.00	0.0
Cycle 16 Day 1	22	3.03	9.81	0.0	0.00	33.3	22	1.52	12.50	-33.3	0.00	33.3
Cycle 16 Day 22	14	2.38	8.91	0.0	0.00	33.3	14	0.00	13.07	-33.3	0.00	33.3
Cycle 17 Day 1	18	1.85	7.86	0.0	0.00	33.3	18	0.00	11.43	-33.3	0.00	33.3
Cycle 18 Day 1	16	2.08	8.33	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
Cycle 18 Day 22	11	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
Cycle 19 Day 1	16	4.17	11.39	0.0	0.00	33.3	15	2.22	15.26	-33.3	0.00	33.3
Cycle 19 Day 22	12	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
Cycle 20 Day 1	16	2.08	8.33	0.0	0.00	33.3	15	0.00	12.60	-33.3	0.00	33.3
Cycle 20 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	0.00	0.00	0.0	0.00	0.0
Cycle 21 Day 1	15	0.00	0.00	0.0	0.00	0.0	14	-2.38	8.91	-33.3	0.00	0.0
Cycle 22 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	0.00	14.21	-33.3	0.00	33.3
Cycle 23 Day 1	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
Study Disc 1	153	8.06	17.11	0.0	0.00	66.7	149	2.68	20.33	-66.7	0.00	66.7
Study Disc 2	12	13.89	22.29	0.0	0.00	66.7	11	6.06	13.48	0.0	0.00	33.3
30 D SFU Z/P	93	6.09	15.50	0.0	0.00	66.7	90	2.59	15.98	-66.7	0.00	66.7
90 D SFU Z/P	84	6.75	15.33	0.0	0.00	66.7	82	4.88	14.93	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full 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 + mFOLFOX6 (N=181)												
	Baseline	166	4.62	12.66	0.0	0.00	66.7						
	Cycle 1 Day 22	123	9.49	17.35	0.0	0.00	66.7	117	5.70	18.20	-33.3	0.00	66.7
	Cycle 2 Day 1	137	6.08	16.28	0.0	0.00	100.0	132	1.77	16.64	-33.3	0.00	66.7
	Cycle 2 Day 22	104	6.09	15.93	0.0	0.00	100.0	100	1.00	15.32	-33.3	0.00	66.7
	Cycle 3 Day 1	133	5.26	13.51	0.0	0.00	66.7	127	0.79	15.41	-33.3	0.00	66.7
	Cycle 3 Day 22	107	6.23	13.84	0.0	0.00	66.7	102	1.96	17.44	-33.3	0.00	66.7
	Cycle 4 Day 1	112	5.65	12.57	0.0	0.00	33.3	108	0.62	15.10	-33.3	0.00	33.3
	Cycle 4 Day 22	84	6.75	16.99	0.0	0.00	100.0	80	1.67	19.05	-33.3	0.00	100.0
	Cycle 5 Day 1	104	4.17	11.08	0.0	0.00	33.3	99	-0.67	15.04	-33.3	0.00	33.3
	Cycle 5 Day 22	78	7.26	17.53	0.0	0.00	100.0	73	0.91	15.69	-33.3	0.00	33.3
	Cycle 6 Day 1	88	4.55	14.46	0.0	0.00	100.0	83	-1.20	15.13	-33.3	0.00	33.3
	Cycle 6 Day 22	67	2.99	11.21	0.0	0.00	66.7	64	-3.65	16.92	-33.3	0.00	66.7
	Cycle 7 Day 1	77	3.90	14.28	0.0	0.00	100.0	74	-1.35	19.46	-33.3	0.00	100.0
	Cycle 7 Day 22	62	4.84	13.29	0.0	0.00	66.7	57	-1.17	16.62	-33.3	0.00	66.7
	Cycle 8 Day 1	57	6.43	17.18	0.0	0.00	100.0	52	0.64	21.38	-33.3	0.00	100.0
	Cycle 8 Day 22	47	2.84	9.40	0.0	0.00	33.3	43	-3.88	14.92	-33.3	0.00	33.3
	Cycle 9 Day 1	49	2.04	8.07	0.0	0.00	33.3	44	-3.79	12.89	-33.3	0.00	33.3
	Cycle 9 Day 22	43	6.20	13.12	0.0	0.00	33.3	39	0.00	17.10	-33.3	0.00	33.3
	Cycle 10 Day 1	47	3.55	10.39	0.0	0.00	33.3	43	-2.33	15.25	-33.3	0.00	33.3
	Cycle 10 Day 22	42	5.56	12.57	0.0	0.00	33.3	39	0.85	16.20	-33.3	0.00	33.3
	Cycle 11 Day 1	44	4.55	11.57	0.0	0.00	33.3	41	0.00	16.67	-33.3	0.00	33.3
	Cycle 11 Day 22	31	2.15	8.32	0.0	0.00	33.3	28	-4.76	17.48	-33.3	0.00	33.3
	Cycle 12 Day 1	35	2.86	9.47	0.0	0.00	33.3	32	-1.04	15.80	-33.3	0.00	33.3
	Cycle 12 Day 22	28	3.57	10.50	0.0	0.00	33.3	25	-2.67	13.33	-33.3	0.00	33.3
	Cycle 13 Day 1	32	4.17	11.20	0.0	0.00	33.3	31	-1.08	16.06	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	28	3.57	10.50	0.0	0.00	33.3	26	-2.56	16.12	-33.3	0.00	33.3
	Cycle 14 Day 1	24	4.17	11.26	0.0	0.00	33.3	23	-1.45	15.82	-33.3	0.00	33.3
	Cycle 14 Day 22	17	1.96	8.08	0.0	0.00	33.3	17	-3.92	16.17	-33.3	0.00	33.3
	Cycle 15 Day 1	21	4.76	11.95	0.0	0.00	33.3	21	-1.59	16.59	-33.3	0.00	33.3
	Cycle 15 Day 22	18	3.70	10.78	0.0	0.00	33.3	18	-1.85	13.87	-33.3	0.00	33.3
	Cycle 16 Day 1	21	1.59	7.27	0.0	0.00	33.3	21	-4.76	15.94	-33.3	0.00	33.3
	Cycle 16 Day 22	18	0.00	0.00	0.0	0.00	0.0	18	-7.41	14.26	-33.3	0.00	0.0
	Cycle 17 Day 1	17	3.92	11.07	0.0	0.00	33.3	17	-1.96	14.29	-33.3	0.00	33.3
	Cycle 17 Day 22	10	0.00	0.00	0.0	0.00	0.0	10	-10.00	16.10	-33.3	0.00	0.0
	Cycle 18 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	-2.38	8.91	-33.3	0.00	0.0
	Cycle 18 Day 22	11	0.00	0.00	0.0	0.00	0.0	11	-3.03	10.05	-33.3	0.00	0.0
	Cycle 19 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.25	-33.3	0.00	0.0
	Cycle 19 Day 22	12	2.78	9.62	0.0	0.00	33.3	12	0.00	0.00	0.0	0.00	0.0
	Cycle 20 Day 1	13	7.69	27.74	0.0	0.00	100.0	13	5.13	29.96	-33.3	0.00	100.0
	Cycle 20 Day 22	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Cycle 21 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	-3.33	10.54	-33.3	0.00	0.0
	Study Disc 1	97	11.68	22.07	0.0	0.00	100.0	93	6.81	22.28	-33.3	0.00	100.0
	30 D SFU Z/P	50	9.33	20.25	0.0	0.00	100.0	47	3.55	21.12	-33.3	0.00	66.7
	90 D SFU Z/P	56	7.74	15.56	0.0	0.00	66.7	55	3.03	18.45	-33.3	0.00	66.7
	Placebo + mFOLFOX6 (N=181)												
	Baseline	164	4.88	13.94	0.0	0.00	100.0						
	Cycle 1 Day 22	133	6.27	15.43	0.0	0.00	66.7	131	1.53	14.83	-66.7	0.00	66.7
	Cycle 2 Day 1	147	3.85	12.04	0.0	0.00	66.7	143	-1.17	13.94	-66.7	0.00	66.7
	Cycle 2 Day 22	117	4.84	15.33	0.0	0.00	100.0	113	0.29	15.10	-33.3	0.00	66.7
	Cycle 3 Day 1	128	2.60	9.91	0.0	0.00	66.7	125	-0.80	13.02	-33.3	0.00	66.7
	Cycle 3 Day 22	102	4.90	13.59	0.0	0.00	66.7	98	1.02	13.92	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 4 Day 1	107	2.18	8.28	0.0	0.00	33.3	102	-0.98	9.90	-33.3	0.00	33.3
	Cycle 4 Day 22	87	3.07	9.69	0.0	0.00	33.3	84	0.40	13.19	-33.3	0.00	33.3
	Cycle 5 Day 1	97	3.44	13.16	0.0	0.00	100.0	95	0.70	13.73	-33.3	0.00	100.0
	Cycle 5 Day 22	80	3.75	14.03	0.0	0.00	100.0	76	0.44	12.76	-33.3	0.00	66.7
	Cycle 6 Day 1	83	3.21	12.34	0.0	0.00	66.7	81	1.23	11.11	-33.3	0.00	66.7
	Cycle 6 Day 22	63	2.12	8.19	0.0	0.00	33.3	61	0.55	7.43	-33.3	0.00	33.3
	Cycle 7 Day 1	68	1.47	6.90	0.0	0.00	33.3	65	1.03	8.27	-33.3	0.00	33.3
	Cycle 7 Day 22	48	0.69	4.81	0.0	0.00	33.3	46	0.00	7.03	-33.3	0.00	33.3
	Cycle 8 Day 1	55	2.42	8.74	0.0	0.00	33.3	54	1.85	10.07	-33.3	0.00	33.3
	Cycle 8 Day 22	43	0.78	5.08	0.0	0.00	33.3	41	0.00	7.45	-33.3	0.00	33.3
	Cycle 9 Day 1	40	2.50	8.89	0.0	0.00	33.3	38	2.63	9.11	0.0	0.00	33.3
	Cycle 9 Day 22	35	0.95	5.63	0.0	0.00	33.3	33	1.01	5.80	0.0	0.00	33.3
	Cycle 10 Day 1	37	0.00	0.00	0.0	0.00	0.0	35	0.00	0.00	0.0	0.00	0.0
	Cycle 10 Day 22	28	2.38	8.74	0.0	0.00	33.3	27	2.47	8.90	0.0	0.00	33.3
	Cycle 11 Day 1	29	0.00	0.00	0.0	0.00	0.0	27	0.00	0.00	0.0	0.00	0.0
	Cycle 11 Day 22	21	0.00	0.00	0.0	0.00	0.0	19	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	27	0.00	0.00	0.0	0.00	0.0	25	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 22	17	3.92	11.07	0.0	0.00	33.3	15	4.44	11.73	0.0	0.00	33.3
	Cycle 13 Day 1	22	3.03	9.81	0.0	0.00	33.3	20	3.33	10.26	0.0	0.00	33.3
	Cycle 13 Day 22	13	2.56	9.25	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Cycle 14 Day 1	18	1.85	7.86	0.0	0.00	33.3	17	1.96	8.08	0.0	0.00	33.3
	Cycle 14 Day 22	15	0.00	0.00	0.0	0.00	0.0	14	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	16	2.08	8.33	0.0	0.00	33.3	16	2.08	8.33	0.0	0.00	33.3
	Cycle 15 Day 22	12	0.00	0.00	0.0	0.00	0.0	12	0.00	0.00	0.0	0.00	0.0
	Cycle 16 Day 1	12	2.78	9.62	0.0	0.00	33.3	12	2.78	9.62	0.0	0.00	33.3
	Study Disc 1	100	6.00	14.51	0.0	0.00	66.7	97	1.03	17.65	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	30 D SFU Z/P	55	3.03	11.61	0.0	0.00	66.7	53	-1.89	12.08	-66.7	0.00	33.3
	90 D SFU Z/P	51	5.23	13.94	0.0	0.00	66.7	50	3.33	13.88	-33.3	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full 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 + mFOLFOX6 (N=102)												
	Baseline	91	6.96	16.11	0.0	0.00	66.7						
	Cycle 1 Day 22	63	5.29	14.91	0.0	0.00	66.7	59	-2.26	22.20	-66.7	0.00	66.7
	Cycle 2 Day 1	79	6.75	15.45	0.0	0.00	66.7	74	-0.90	15.58	-66.7	0.00	33.3
	Cycle 2 Day 22	53	7.55	15.53	0.0	0.00	66.7	50	0.67	19.62	-66.7	0.00	33.3
	Cycle 3 Day 1	67	4.48	11.45	0.0	0.00	33.3	63	-2.12	15.70	-66.7	0.00	33.3
	Cycle 3 Day 22	54	4.94	11.95	0.0	0.00	33.3	50	-2.00	15.66	-66.7	0.00	33.3
	Cycle 4 Day 1	65	6.67	15.81	0.0	0.00	66.7	61	0.55	17.73	-33.3	0.00	66.7
	Cycle 4 Day 22	43	8.53	20.69	0.0	0.00	100.0	42	3.17	19.21	-33.3	0.00	66.7
	Cycle 5 Day 1	52	5.13	13.82	0.0	0.00	66.7	49	-0.68	15.94	-33.3	0.00	66.7
	Cycle 5 Day 22	39	6.84	17.40	0.0	0.00	66.7	37	1.80	17.47	-33.3	0.00	66.7
	Cycle 6 Day 1	43	6.98	17.15	0.0	0.00	66.7	39	1.71	17.01	-33.3	0.00	66.7
	Cycle 6 Day 22	41	7.32	15.83	0.0	0.00	66.7	39	1.71	15.20	-33.3	0.00	33.3
	Cycle 7 Day 1	42	3.97	10.93	0.0	0.00	33.3	39	-1.71	13.13	-33.3	0.00	33.3
	Cycle 7 Day 22	25	4.00	11.06	0.0	0.00	33.3	24	-2.78	13.61	-33.3	0.00	33.3
	Cycle 8 Day 1	31	7.53	16.58	0.0	0.00	66.7	28	2.38	17.98	-33.3	0.00	66.7
	Cycle 8 Day 22	30	6.67	13.56	0.0	0.00	33.3	28	2.38	15.53	-33.3	0.00	33.3
	Cycle 9 Day 1	33	3.03	9.73	0.0	0.00	33.3	31	-1.08	10.48	-33.3	0.00	33.3
	Cycle 9 Day 22	22	1.52	7.11	0.0	0.00	33.3	21	-1.59	12.81	-33.3	0.00	33.3
	Cycle 10 Day 1	25	6.67	13.61	0.0	0.00	33.3	23	1.45	6.95	0.0	0.00	33.3
	Cycle 10 Day 22	19	1.75	7.65	0.0	0.00	33.3	18	0.00	0.00	0.0	0.00	0.0
	Cycle 11 Day 1	24	4.17	11.26	0.0	0.00	33.3	22	1.52	7.11	0.0	0.00	33.3
	Cycle 11 Day 22	17	1.96	8.08	0.0	0.00	33.3	16	0.00	0.00	0.0	0.00	0.0
	Cycle 12 Day 1	23	5.80	12.92	0.0	0.00	33.3	21	0.00	10.54	-33.3	0.00	33.3
	Cycle 12 Day 22	12	0.00	0.00	0.0	0.00	0.0	12	-2.78	9.62	-33.3	0.00	0.0
	Cycle 13 Day 1	19	3.51	10.51	0.0	0.00	33.3	17	0.00	11.79	-33.3	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 13 Day 22	15	4.44	11.73	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
	Cycle 14 Day 1	17	1.96	8.08	0.0	0.00	33.3	16	0.00	12.17	-33.3	0.00	33.3
	Cycle 14 Day 22	16	2.08	8.33	0.0	0.00	33.3	15	0.00	0.00	0.0	0.00	0.0
	Cycle 15 Day 1	15	4.44	11.73	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
	Cycle 15 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Cycle 16 Day 1	14	4.76	12.10	0.0	0.00	33.3	14	2.38	8.91	0.0	0.00	33.3
	Cycle 16 Day 22	11	6.06	13.48	0.0	0.00	33.3	11	3.03	10.05	0.0	0.00	33.3
	Cycle 17 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	5.13	12.52	0.0	0.00	33.3
	Cycle 17 Day 22	13	2.56	9.25	0.0	0.00	33.3	13	0.00	13.61	-33.3	0.00	33.3
	Cycle 18 Day 1	13	0.00	0.00	0.0	0.00	0.0	13	-2.56	9.25	-33.3	0.00	0.0
	Cycle 19 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Cycle 20 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	3.33	10.54	0.0	0.00	33.3
	Cycle 21 Day 1	10	0.00	0.00	0.0	0.00	0.0	10	0.00	0.00	0.0	0.00	0.0
	Study Disc 1	47	12.77	24.63	0.0	0.00	100.0	43	3.88	27.42	-66.7	0.00	100.0
	30 D SFU Z/P	27	8.64	19.81	0.0	0.00	66.7	25	-1.33	22.53	-66.7	0.00	33.3
	90 D SFU Z/P	33	6.06	15.49	0.0	0.00	66.7	31	-2.15	19.12	-66.7	0.00	33.3
	Placebo + mFOLFOX6 (N=101)												
	Baseline	93	7.89	17.31	0.0	0.00	66.7						
	Cycle 1 Day 22	78	8.97	19.86	0.0	0.00	100.0	77	1.73	14.20	-33.3	0.00	33.3
	Cycle 2 Day 1	83	7.23	17.30	0.0	0.00	100.0	80	0.00	19.12	-66.7	0.00	66.7
	Cycle 2 Day 22	68	10.29	20.16	0.0	0.00	100.0	67	1.99	17.29	-33.3	0.00	33.3
	Cycle 3 Day 1	75	7.11	14.80	0.0	0.00	66.7	71	0.47	18.25	-33.3	0.00	66.7
	Cycle 3 Day 22	54	4.94	11.95	0.0	0.00	33.3	50	-1.33	17.77	-66.7	0.00	33.3
	Cycle 4 Day 1	63	9.52	15.18	0.0	0.00	33.3	59	1.13	20.50	-66.7	0.00	33.3
	Cycle 4 Day 22	46	8.70	16.38	0.0	0.00	66.7	43	-2.33	24.55	-66.7	0.00	66.7
	Cycle 5 Day 1	52	9.62	17.88	0.0	0.00	66.7	49	2.04	23.97	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.33.1: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Category	Treatment Group Analysis Visit	Value						Change from Baseline					
		n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
	Cycle 5 Day 22	42	12.70	20.76	0.0	0.00	66.7	39	3.42	29.41	-66.7	0.00	66.7
	Cycle 6 Day 1	43	10.08	17.11	0.0	0.00	66.7	40	0.83	24.45	-66.7	0.00	66.7
	Cycle 6 Day 22	33	12.12	20.10	0.0	0.00	66.7	31	2.15	27.13	-66.7	0.00	66.7
	Cycle 7 Day 1	33	8.08	16.73	0.0	0.00	66.7	33	-1.01	22.80	-66.7	0.00	66.7
	Cycle 7 Day 22	27	9.88	18.06	0.0	0.00	66.7	27	1.23	23.54	-66.7	0.00	66.7
	Cycle 8 Day 1	27	17.28	25.10	0.0	0.00	100.0	27	12.35	26.39	-33.3	0.00	100.0
	Cycle 8 Day 22	24	15.28	25.97	0.0	0.00	100.0	24	9.72	28.62	-33.3	0.00	100.0
	Cycle 9 Day 1	24	11.11	23.40	0.0	0.00	100.0	24	4.17	26.58	-33.3	0.00	100.0
	Cycle 9 Day 22	22	9.09	15.19	0.0	0.00	33.3	22	3.03	20.34	-33.3	0.00	33.3
	Cycle 10 Day 1	21	14.29	22.54	0.0	0.00	66.7	21	6.35	20.05	-33.3	0.00	66.7
	Cycle 10 Day 22	16	16.67	29.81	0.0	0.00	100.0	16	8.33	28.54	-33.3	0.00	100.0
	Cycle 11 Day 1	19	17.54	30.16	0.0	0.00	100.0	19	10.53	29.51	-33.3	0.00	100.0
	Cycle 11 Day 22	12	22.22	29.59	0.0	16.67	100.0	12	11.11	35.77	-33.3	0.00	100.0
	Cycle 12 Day 1	16	14.58	29.74	0.0	0.00	100.0	16	6.25	27.81	-33.3	0.00	100.0
	Cycle 12 Day 22	10	20.00	32.20	0.0	0.00	100.0	10	13.33	35.83	-33.3	0.00	100.0
	Cycle 13 Day 1	15	15.56	27.79	0.0	0.00	100.0	15	6.67	31.37	-33.3	0.00	100.0
	Cycle 14 Day 1	13	7.69	14.62	0.0	0.00	33.3	13	5.13	18.49	-33.3	0.00	33.3
	Cycle 15 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	0.00	14.91	-33.3	0.00	33.3
	Cycle 16 Day 1	10	3.33	10.54	0.0	0.00	33.3	10	0.00	15.71	-33.3	0.00	33.3
	Study Disc 1	53	11.95	20.77	0.0	0.00	66.7	52	5.77	24.45	-66.7	0.00	66.7
	30 D SFU Z/P	38	10.53	19.15	0.0	0.00	66.7	37	9.01	18.67	0.0	0.00	66.7
	90 D SFU Z/P	33	9.09	17.23	0.0	0.00	66.7	32	7.29	16.36	0.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	29.70	32.47	0.0	33.33	100.0						
Cycle 1 Day 22	186	32.08	32.95	0.0	33.33	100.0	176	0.95	28.60	-66.7	0.00	100.0
Cycle 2 Day 1	216	29.94	31.97	0.0	33.33	100.0	206	-0.65	31.23	-100.0	0.00	100.0
Cycle 2 Day 22	157	29.51	31.12	0.0	33.33	100.0	150	0.00	30.41	-66.7	0.00	100.0
Cycle 3 Day 1	200	26.50	30.13	0.0	33.33	100.0	190	-2.46	31.14	-100.0	0.00	66.7
Cycle 3 Day 22	161	28.57	32.03	0.0	33.33	100.0	152	-1.75	31.59	-100.0	0.00	100.0
Cycle 4 Day 1	177	24.48	29.36	0.0	0.00	100.0	169	-5.72	29.32	-100.0	0.00	100.0
Cycle 4 Day 22	127	27.03	31.35	0.0	33.33	100.0	122	-2.19	32.84	-100.0	0.00	100.0
Cycle 5 Day 1	156	26.71	30.15	0.0	33.33	100.0	148	-3.15	35.49	-100.0	0.00	100.0
Cycle 5 Day 22	117	26.50	29.54	0.0	33.33	100.0	110	-5.76	33.44	-100.0	0.00	100.0
Cycle 6 Day 1	131	22.14	26.99	0.0	0.00	100.0	122	-6.01	31.79	-100.0	0.00	100.0
Cycle 6 Day 22	108	20.37	28.03	0.0	0.00	100.0	103	-9.39	34.11	-100.0	0.00	100.0
Cycle 7 Day 1	119	16.81	26.35	0.0	0.00	100.0	113	-11.80	31.79	-100.0	0.00	66.7
Cycle 7 Day 22	87	20.31	29.36	0.0	0.00	100.0	81	-8.64	34.47	-100.0	0.00	66.7
Cycle 8 Day 1	88	17.42	26.25	0.0	0.00	100.0	80	-10.83	31.28	-100.0	0.00	66.7
Cycle 8 Day 22	77	17.32	25.14	0.0	0.00	100.0	71	-11.27	33.78	-100.0	0.00	66.7
Cycle 9 Day 1	82	12.60	23.21	0.0	0.00	100.0	75	-15.56	32.11	-100.0	0.00	66.7
Cycle 9 Day 22	65	17.95	30.09	0.0	0.00	100.0	60	-9.44	34.77	-100.0	0.00	100.0
Cycle 10 Day 1	72	13.89	26.68	0.0	0.00	100.0	66	-10.61	33.67	-100.0	0.00	66.7
Cycle 10 Day 22	61	15.30	26.23	0.0	0.00	100.0	57	-11.11	30.43	-66.7	0.00	66.7
Cycle 11 Day 1	68	14.71	26.00	0.0	0.00	100.0	63	-12.17	34.03	-100.0	0.00	100.0
Cycle 11 Day 22	48	11.81	25.25	0.0	0.00	100.0	44	-17.42	29.19	-100.0	0.00	33.3
Cycle 12 Day 1	58	13.79	27.24	0.0	0.00	100.0	53	-10.06	33.71	-66.7	0.00	100.0
Cycle 12 Day 22	40	11.67	23.33	0.0	0.00	100.0	37	-11.71	27.46	-66.7	0.00	33.3
Cycle 13 Day 1	51	13.73	24.20	0.0	0.00	100.0	48	-10.42	29.30	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	13.95	29.31	0.0	0.00	100.0	40	-10.00	26.37	-66.7	0.00	66.7
Cycle 14 Day 1	41	13.01	26.75	0.0	0.00	100.0	39	-11.97	25.92	-66.7	0.00	66.7
Cycle 14 Day 22	33	14.14	23.61	0.0	0.00	100.0	32	-8.33	28.08	-66.7	0.00	66.7
Cycle 15 Day 1	36	13.89	24.40	0.0	0.00	100.0	35	-6.67	26.57	-66.7	0.00	66.7
Cycle 15 Day 22	29	13.79	26.00	0.0	0.00	100.0	29	-8.05	26.21	-66.7	0.00	33.3
Cycle 16 Day 1	35	8.57	21.91	0.0	0.00	100.0	35	-13.33	23.15	-66.7	0.00	33.3
Cycle 16 Day 22	29	16.09	29.03	0.0	0.00	100.0	29	-8.05	30.41	-66.7	0.00	66.7
Cycle 17 Day 1	30	11.11	26.74	0.0	0.00	100.0	30	-10.00	26.48	-66.7	0.00	66.7
Cycle 17 Day 22	23	10.14	25.49	0.0	0.00	100.0	23	-8.70	25.06	-33.3	0.00	66.7
Cycle 18 Day 1	27	7.41	21.35	0.0	0.00	100.0	27	-14.81	23.27	-66.7	0.00	33.3
Cycle 18 Day 22	20	6.67	23.20	0.0	0.00	100.0	20	-15.00	25.31	-66.7	-16.67	33.3
Cycle 19 Day 1	23	5.80	21.68	0.0	0.00	100.0	23	-17.39	22.18	-66.7	-33.33	33.3
Cycle 19 Day 22	20	11.67	27.09	0.0	0.00	100.0	20	-11.67	29.17	-66.7	0.00	66.7
Cycle 20 Day 1	23	7.25	22.38	0.0	0.00	100.0	23	-15.94	24.35	-66.7	-33.33	33.3
Cycle 20 Day 22	18	11.11	25.57	0.0	0.00	100.0	18	-14.81	26.13	-66.7	-16.67	33.3
Cycle 21 Day 1	20	8.33	23.88	0.0	0.00	100.0	20	-16.67	25.36	-66.7	-33.33	33.3
Cycle 21 Day 22	14	9.52	27.51	0.0	0.00	100.0	14	-16.67	28.50	-66.7	-33.33	33.3
Cycle 22 Day 1	15	11.11	27.22	0.0	0.00	100.0	15	-15.56	27.79	-66.7	-33.33	33.3
Cycle 22 Day 22	10	13.33	32.20	0.0	0.00	100.0	10	-20.00	28.11	-66.7	-33.33	33.3
Cycle 23 Day 1	15	13.33	27.60	0.0	0.00	100.0	15	-15.56	24.77	-66.7	0.00	33.3
Cycle 23 Day 22	11	15.15	31.14	0.0	0.00	100.0	11	-9.09	30.15	-66.7	0.00	33.3
Cycle 24 Day 1	14	11.90	28.06	0.0	0.00	100.0	14	-16.67	28.50	-66.7	-33.33	33.3
Cycle 25 Day 1	12	16.67	30.15	0.0	0.00	100.0	12	-11.11	25.95	-33.3	-16.67	33.3
Cycle 25 Day 22	11	15.15	31.14	0.0	0.00	100.0	11	-12.12	22.47	-33.3	0.00	33.3
Cycle 26 Day 1	13	10.26	28.50	0.0	0.00	100.0	13	-17.95	22.01	-33.3	-33.33	33.3
Cycle 27 Day 1	11	3.03	10.05	0.0	0.00	33.3	11	-24.24	15.57	-33.3	-33.33	0.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-16.67	22.47	-33.3	-33.33	33.3
Study Disc 1	144	34.72	33.42	0.0	33.33	100.0	136	4.41	35.79	-100.0	0.00	66.7
30 D SFU Z/P	77	31.60	33.29	0.0	33.33	100.0	72	3.24	34.10	-100.0	0.00	100.0
90 D SFU Z/P	89	23.60	28.96	0.0	0.00	100.0	86	-2.71	37.99	-100.0	0.00	100.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	34.24	31.38	0.0	33.33	100.0						
Cycle 1 Day 22	211	31.12	32.45	0.0	33.33	100.0	208	-2.72	28.34	-100.0	0.00	100.0
Cycle 2 Day 1	230	26.23	27.74	0.0	33.33	100.0	223	-7.92	28.33	-100.0	0.00	66.7
Cycle 2 Day 22	185	28.29	30.67	0.0	33.33	100.0	180	-6.11	30.41	-100.0	0.00	66.7
Cycle 3 Day 1	203	23.97	28.63	0.0	33.33	100.0	196	-9.35	30.34	-100.0	0.00	66.7
Cycle 3 Day 22	156	24.57	30.79	0.0	0.00	100.0	148	-9.46	29.62	-100.0	0.00	66.7
Cycle 4 Day 1	170	20.00	27.71	0.0	0.00	100.0	161	-13.87	29.71	-100.0	0.00	66.7
Cycle 4 Day 22	133	20.30	27.47	0.0	0.00	100.0	127	-12.34	29.04	-100.0	0.00	66.7
Cycle 5 Day 1	149	21.03	28.83	0.0	0.00	100.0	144	-12.04	28.32	-100.0	0.00	66.7
Cycle 5 Day 22	122	20.22	26.61	0.0	0.00	100.0	115	-13.33	32.08	-100.0	0.00	100.0
Cycle 6 Day 1	126	19.58	27.74	0.0	0.00	100.0	121	-11.02	30.24	-100.0	0.00	100.0
Cycle 6 Day 22	96	18.06	27.75	0.0	0.00	100.0	92	-15.58	30.64	-100.0	0.00	33.3
Cycle 7 Day 1	101	15.51	26.48	0.0	0.00	100.0	98	-15.31	28.38	-100.0	0.00	66.7
Cycle 7 Day 22	75	12.44	23.74	0.0	0.00	100.0	73	-21.00	31.18	-100.0	0.00	33.3
Cycle 8 Day 1	82	15.85	24.13	0.0	0.00	100.0	81	-13.58	27.27	-100.0	0.00	33.3
Cycle 8 Day 22	67	15.42	24.84	0.0	0.00	100.0	65	-14.87	27.66	-100.0	0.00	66.7
Cycle 9 Day 1	64	15.62	26.54	0.0	0.00	100.0	62	-13.98	25.28	-100.0	0.00	33.3
Cycle 9 Day 22	57	11.11	23.85	0.0	0.00	100.0	55	-19.39	28.47	-100.0	0.00	33.3
Cycle 10 Day 1	58	13.79	24.21	0.0	0.00	100.0	56	-16.07	31.78	-100.0	0.00	66.7
Cycle 10 Day 22	44	13.64	25.23	0.0	0.00	100.0	43	-20.93	30.88	-100.0	-33.33	66.7
Cycle 11 Day 1	48	13.89	24.63	0.0	0.00	100.0	46	-15.94	32.00	-100.0	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.34: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Weight Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	17.17	27.79	0.0	0.00	100.0	31	-17.20	29.65	-100.0	-33.33	33.3
Cycle 12 Day 1	43	14.73	26.53	0.0	0.00	100.0	41	-18.70	28.91	-100.0	-33.33	33.3
Cycle 12 Day 22	27	17.28	33.80	0.0	0.00	100.0	25	-20.00	30.43	-100.0	-33.33	33.3
Cycle 13 Day 1	37	13.51	27.73	0.0	0.00	100.0	35	-21.90	33.28	-100.0	0.00	33.3
Cycle 13 Day 22	22	13.64	24.47	0.0	0.00	100.0	21	-25.40	23.34	-66.7	-33.33	0.0
Cycle 14 Day 1	31	9.68	19.61	0.0	0.00	66.7	30	-21.11	29.66	-100.0	0.00	33.3
Cycle 14 Day 22	20	8.33	14.81	0.0	0.00	33.3	19	-26.32	30.59	-100.0	-33.33	0.0
Cycle 15 Day 1	27	8.64	19.81	0.0	0.00	66.7	27	-23.46	34.36	-100.0	-33.33	33.3
Cycle 15 Day 22	17	9.80	19.60	0.0	0.00	66.7	17	-23.53	38.67	-100.0	-33.33	33.3
Cycle 16 Day 1	22	12.12	21.93	0.0	0.00	66.7	22	-18.18	38.11	-100.0	0.00	33.3
Cycle 16 Day 22	14	11.90	21.11	0.0	0.00	66.7	14	-23.81	27.51	-66.7	-33.33	33.3
Cycle 17 Day 1	18	5.56	12.78	0.0	0.00	33.3	18	-20.37	30.55	-100.0	-16.67	33.3
Cycle 18 Day 1	16	6.25	13.44	0.0	0.00	33.3	16	-16.67	32.20	-100.0	0.00	33.3
Cycle 18 Day 22	11	6.06	13.48	0.0	0.00	33.3	10	-30.00	29.19	-100.0	-33.33	0.0
Cycle 19 Day 1	16	6.25	13.44	0.0	0.00	33.3	15	-17.78	33.01	-100.0	0.00	33.3
Cycle 19 Day 22	12	5.56	12.97	0.0	0.00	33.3	11	-27.27	32.72	-100.0	-33.33	0.0
Cycle 20 Day 1	16	6.25	13.44	0.0	0.00	33.3	15	-17.78	27.79	-66.7	0.00	33.3
Cycle 20 Day 22	11	3.03	10.05	0.0	0.00	33.3	10	-30.00	33.15	-100.0	-33.33	0.0
Cycle 21 Day 1	15	2.22	8.61	0.0	0.00	33.3	14	-23.81	30.46	-100.0	-16.67	0.0
Cycle 22 Day 1	12	8.33	15.08	0.0	0.00	33.3	12	-16.67	36.24	-100.0	0.00	33.3
Cycle 23 Day 1	13	10.26	21.01	0.0	0.00	66.7	13	-15.38	37.55	-100.0	0.00	33.3
Study Disc 1	153	25.27	29.87	0.0	33.33	100.0	149	-6.04	33.35	-100.0	0.00	100.0
Study Disc 2	12	36.11	36.12	0.0	33.33	100.0	11	0.00	29.81	-66.7	0.00	33.3
30 D SFU Z/P	93	22.94	29.07	0.0	0.00	100.0	90	-9.63	33.98	-100.0	0.00	100.0
90 D SFU Z/P	84	26.98	36.40	0.0	0.00	100.0	82	-6.91	37.31	-100.0	0.00	100.0

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	64	15.62	26.54	0.0	0.00	100.0						
Cycle 1 Day 22	61	26.78	33.23	0.0	0.00	100.0	24	11.11	25.38	0.0	0.00	100.0
Cycle 2 Day 1	98	24.15	30.57	0.0	0.00	100.0	38	0.88	27.39	-66.7	0.00	66.7
Cycle 2 Day 22	84	24.60	31.52	0.0	0.00	100.0	33	4.04	32.01	-66.7	0.00	100.0
Cycle 3 Day 1	106	28.93	31.23	0.0	33.33	100.0	34	8.82	26.35	-33.3	0.00	66.7
Cycle 3 Day 22	96	28.82	28.04	0.0	33.33	100.0	29	10.34	25.36	-66.7	0.00	66.7
Cycle 4 Day 1	99	28.28	30.63	0.0	33.33	100.0	31	9.68	23.08	-33.3	0.00	66.7
Cycle 4 Day 22	81	26.75	29.54	0.0	33.33	100.0	26	11.54	22.98	-33.3	0.00	66.7
Cycle 5 Day 1	90	28.52	28.07	0.0	33.33	100.0	27	6.17	24.52	-33.3	0.00	66.7
Cycle 5 Day 22	63	33.33	32.79	0.0	33.33	100.0	19	10.53	27.34	-33.3	0.00	66.7
Cycle 6 Day 1	76	22.81	27.33	0.0	16.67	100.0	23	8.70	25.06	-33.3	0.00	66.7
Cycle 6 Day 22	57	21.64	25.58	0.0	0.00	100.0	16	4.17	23.96	-33.3	0.00	66.7
Cycle 7 Day 1	61	22.40	27.03	0.0	0.00	100.0	15	2.22	23.46	-33.3	0.00	33.3
Cycle 7 Day 22	48	17.36	22.79	0.0	0.00	100.0	17	1.96	18.52	-33.3	0.00	33.3
Cycle 8 Day 1	50	20.00	23.33	0.0	16.67	100.0	18	5.56	17.15	-33.3	0.00	33.3
Cycle 8 Day 22	38	19.30	24.05	0.0	0.00	100.0	11	9.09	15.57	0.0	0.00	33.3
Cycle 9 Day 1	40	16.67	22.65	0.0	0.00	100.0	11	0.00	14.91	-33.3	0.00	33.3
Cycle 9 Day 22	33	24.24	23.97	0.0	33.33	100.0	10	13.33	17.21	0.0	0.00	33.3
Cycle 10 Day 1	37	21.62	26.31	0.0	0.00	100.0	9	11.11	28.87	-33.3	0.00	66.7
Cycle 10 Day 22	29	25.29	29.08	0.0	33.33	100.0	8	12.50	17.25	0.0	0.00	33.3
Cycle 11 Day 1	33	20.20	28.79	0.0	0.00	100.0	11	15.15	17.41	0.0	0.00	33.3
Cycle 11 Day 22	24	18.06	19.61	0.0	16.67	66.7	8	12.50	17.25	0.0	0.00	33.3
Cycle 12 Day 1	26	23.08	26.28	0.0	33.33	100.0	10	13.33	23.31	0.0	0.00	66.7
Cycle 12 Day 22	21	15.87	24.99	0.0	0.00	100.0	8	12.50	35.36	0.0	0.00	100.0
Cycle 13 Day 1	26	15.38	23.53	0.0	0.00	66.7	9	7.41	14.70	0.0	0.00	33.3

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	22	21.21	24.22	0.0	16.67	66.7	5	13.33	18.26	0.0	0.00	33.3
Cycle 14 Day 1	21	19.05	22.54	0.0	0.00	66.7	7	9.52	16.27	0.0	0.00	33.3
Cycle 14 Day 22	16	22.92	29.11	0.0	16.67	100.0	5	33.33	40.82	0.0	33.33	100.0
Cycle 15 Day 1	17	25.49	27.71	0.0	33.33	100.0	7	23.81	37.09	0.0	0.00	100.0
Cycle 15 Day 22	14	16.67	21.68	0.0	0.00	66.7	4	16.67	19.25	0.0	16.67	33.3
Cycle 16 Day 1	16	20.83	23.96	0.0	16.67	66.7	5	13.33	18.26	0.0	0.00	33.3
Cycle 16 Day 22	13	23.08	21.01	0.0	33.33	66.7	4	16.67	19.25	0.0	16.67	33.3
Cycle 17 Day 1	11	21.21	22.47	0.0	33.33	66.7	4	8.33	31.91	-33.3	16.67	33.3
Cycle 17 Day 22	10	23.33	22.50	0.0	33.33	66.7	4	0.00	27.22	-33.3	0.00	33.3
Cycle 18 Day 1	10	23.33	22.50	0.0	33.33	66.7	4	0.00	27.22	-33.3	0.00	33.3
Cycle 19 Day 22	10	23.33	27.44	0.0	16.67	66.7	4	41.67	31.91	0.0	50.00	66.7
Study Disc 1	62	31.72	29.83	0.0	33.33	100.0	18	18.52	30.73	-33.3	0.00	100.0
30 D SFU Z/P	34	24.51	26.35	0.0	33.33	100.0	6	-11.11	45.54	-100.0	0.00	33.3
90 D SFU Z/P	54	29.63	25.63	0.0	33.33	100.0	14	21.43	33.61	-66.7	33.33	66.7
Placebo + mFOLFOX6 (N=282)												
Baseline	66	14.14	29.27	0.0	0.00	100.0						
Cycle 1 Day 22	85	20.78	28.63	0.0	0.00	100.0	41	4.07	29.05	-66.7	0.00	100.0
Cycle 2 Day 1	107	18.69	25.57	0.0	0.00	100.0	43	3.10	28.00	-66.7	0.00	66.7
Cycle 2 Day 22	89	19.48	24.00	0.0	0.00	100.0	29	3.45	24.14	-66.7	0.00	33.3
Cycle 3 Day 1	99	22.22	26.51	0.0	33.33	100.0	37	2.70	30.81	-66.7	0.00	66.7
Cycle 3 Day 22	80	25.42	27.17	0.0	33.33	100.0	28	0.00	27.22	-66.7	0.00	33.3
Cycle 4 Day 1	87	24.14	25.26	0.0	33.33	100.0	30	7.78	34.67	-100.0	0.00	66.7
Cycle 4 Day 22	68	24.51	26.15	0.0	33.33	100.0	23	11.59	21.58	-33.3	0.00	66.7
Cycle 5 Day 1	81	27.57	29.25	0.0	33.33	100.0	25	10.67	26.74	-66.7	0.00	66.7
Cycle 5 Day 22	59	22.03	28.10	0.0	0.00	100.0	17	0.00	37.27	-66.7	0.00	66.7
Cycle 6 Day 1	61	26.78	29.70	0.0	33.33	100.0	21	9.52	28.17	-66.7	0.00	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.35: EORTC QLQ-OG25 - Observed Means and Change from Baseline of Hair Loss - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 6 Day 22	46	19.57	25.89	0.0	0.00	100.0	14	4.76	38.91	-100.0	0.00	66.7
Cycle 7 Day 1	49	23.13	24.72	0.0	33.33	100.0	17	7.84	30.11	-66.7	0.00	66.7
Cycle 7 Day 22	34	17.65	20.49	0.0	0.00	66.7	12	5.56	37.15	-100.0	0.00	33.3
Cycle 8 Day 1	39	20.51	26.06	0.0	0.00	100.0	15	0.00	30.86	-100.0	0.00	33.3
Cycle 8 Day 22	30	15.56	24.34	0.0	0.00	100.0	12	2.78	26.43	-66.7	0.00	33.3
Cycle 9 Day 1	28	17.86	29.37	0.0	0.00	100.0	11	0.00	36.51	-100.0	0.00	33.3
Cycle 9 Day 22	27	11.11	16.01	0.0	0.00	33.3	9	0.00	40.82	-100.0	0.00	33.3
Cycle 10 Day 1	24	22.22	28.94	0.0	16.67	100.0	10	6.67	40.98	-100.0	16.67	33.3
Cycle 10 Day 22	16	12.50	16.67	0.0	0.00	33.3	7	-9.52	53.45	-100.0	0.00	33.3
Cycle 11 Day 1	18	20.37	32.62	0.0	0.00	100.0	8	0.00	43.64	-100.0	0.00	33.3
Cycle 11 Day 22	12	13.89	22.29	0.0	0.00	66.7	7	4.76	23.00	-33.3	0.00	33.3
Cycle 12 Day 1	15	13.33	21.08	0.0	0.00	66.7	6	-5.56	49.07	-100.0	0.00	33.3
Cycle 12 Day 22	13	15.38	22.01	0.0	0.00	66.7	6	-16.67	40.82	-66.7	0.00	33.3
Cycle 13 Day 1	13	28.21	35.61	0.0	0.00	100.0	7	4.76	29.99	-33.3	0.00	66.7
Cycle 14 Day 1	11	27.27	25.03	0.0	33.33	66.7	5	6.67	27.89	-33.3	0.00	33.3
Study Disc 1	62	23.66	27.25	0.0	33.33	100.0	27	8.64	27.10	-66.7	0.00	66.7
30 D SFU Z/P	37	33.33	28.33	0.0	33.33	100.0	11	18.18	22.92	0.0	0.00	66.7
90 D SFU Z/P	46	32.61	31.02	0.0	33.33	100.0	14	16.67	25.32	-33.3	16.67	66.7

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

Table 301.3.3004.20.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	157 (55.5%)	143 (50.7%)	
Number of patients censored	126 (44.5%)	139 (49.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.9 [1.7, 4.3]	5.6 [4.2, 7.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.274 [1.013, 1.603]
Log-rank test			
Two-sided stratified log-rank p-value			0.0380

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.20.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dysphagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	99 (54.7)	3.0 [1.4, 4.9]	181	84 (46.4)	7.4 [4.9, 12.3]	1.414 [1.057, 1.893]	0.0197	0.1880
>65 years	102	58 (56.9)	2.9 [1.5, 4.7]	101	59 (58.4)	3.0 [1.4, 4.9]	1.049 [0.730, 1.507]	0.7886	
Sex									
Male	176	92 (52.3)	3.9 [2.6, 5.8]	175	96 (54.9)	4.6 [2.5, 6.4]	0.974 [0.731, 1.298]	0.8632	0.0027
Female	107	65 (60.7)	1.4 [1.0, 2.9]	107	47 (43.9)	8.0 [4.8, 17.5]	2.027 [1.386, 2.966]	0.0002	
Region									
Asia	88	51 (58.0)	3.9 [2.4, 8.0]	89	47 (52.8)	6.1 [3.2, 9.4]	1.113 [0.748, 1.656]	0.5929	0.3821
Non-Asia	195	106 (54.4)	2.3 [1.4, 3.8]	193	96 (49.7)	4.9 [3.7, 8.7]	1.368 [1.037, 1.803]	0.0267	
Number of Organs with Metastatic Sites									
0-2	219	117 (53.4)	3.3 [2.1, 5.1]	219	113 (51.6)	5.3 [4.2, 8.0]	1.200 [0.926, 1.554]	0.1699	0.3167
>=3	64	40 (62.5)	1.7 [1.4, 3.6]	63	30 (47.6)	6.3 [2.2, 11.1]	1.604 [0.997, 2.582]	0.0491	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.21.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	141 (49.8%)	121 (42.9%)	
Number of patients censored	142 (50.2%)	161 (57.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.0, 6.1]	8.1 [5.5, 11.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.205 [0.943, 1.540]
Log-rank test			
Two-sided stratified log-rank p-value			0.1383

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.21.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating Restrictions by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	89 (49.2)	5.1 [2.3, 7.5]	181	74 (40.9)	11.1 [4.9, 15.1]	1.286 [0.944, 1.752]	0.1100	0.5786
>65 years	102	52 (51.0)	4.9 [2.3, 8.5]	101	47 (46.5)	7.2 [2.2, 14.0]	1.131 [0.762, 1.679]	0.5261	
Sex									
Male	176	90 (51.1)	5.1 [3.0, 6.1]	175	82 (46.9)	7.2 [3.7, 9.7]	1.090 [0.808, 1.471]	0.5661	0.2049
Female	107	51 (47.7)	3.7 [1.4, 8.7]	107	39 (36.4)	11.9 [6.2, NC]	1.518 [1.000, 2.306]	0.0478	
Region									
Asia	88	48 (54.5)	5.7 [3.0, 14.9]	89	40 (44.9)	8.1 [5.5, 16.3]	1.117 [0.732, 1.706]	0.6015	0.6904
Non-Asia	195	93 (47.7)	3.6 [2.3, 6.0]	193	81 (42.0)	8.0 [4.2, 11.9]	1.267 [0.940, 1.707]	0.1196	
Number of Organs with Metastatic Sites									
0-2	219	113 (51.6)	4.9 [2.3, 6.0]	219	97 (44.3)	8.1 [4.4, 12.7]	1.247 [0.950, 1.637]	0.1079	0.7551
>=3	64	28 (43.8)	5.3 [1.5, NC]	63	24 (38.1)	8.0 [4.2, 11.1]	1.134 [0.656, 1.958]	0.6599	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.22.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	140 (49.5%)	133 (47.2%)	
Number of patients censored	143 (50.5%)	149 (52.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.1 [3.9, 7.0]	7.4 [5.3, 10.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.060 [0.831, 1.351]
Log-rank test			
Two-sided stratified log-rank p-value			0.6429

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.22.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Reflux by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	92 (50.8)	4.7 [3.2, 8.2]	181	81 (44.8)	9.5 [5.5, 15.1]	1.144 [0.847, 1.545]	0.3826	0.4582
>65 years	102	48 (47.1)	5.7 [3.0, 9.2]	101	52 (51.5)	5.6 [3.1, 9.2]	0.970 [0.655, 1.436]	0.8783	
Sex									
Male	176	80 (45.5)	5.8 [4.4, 9.2]	175	88 (50.3)	6.3 [3.9, 9.4]	0.895 [0.661, 1.212]	0.4757	0.0302
Female	107	60 (56.1)	3.1 [2.1, 7.8]	107	45 (42.1)	9.5 [5.3, 19.8]	1.531 [1.036, 2.263]	0.0317	
Region									
Asia	88	51 (58.0)	4.9 [3.0, 9.5]	89	40 (44.9)	8.1 [5.5, 31.3]	1.337 [0.881, 2.030]	0.1723	0.2995
Non-Asia	195	89 (45.6)	5.1 [3.4, 8.3]	193	93 (48.2)	6.4 [3.7, 9.5]	0.992 [0.741, 1.327]	0.9571	
Number of Organs with Metastatic Sites									
0-2	219	117 (53.4)	4.6 [3.1, 6.4]	219	110 (50.2)	6.7 [4.2, 12.3]	1.105 [0.851, 1.436]	0.4552	0.7576
>=3	64	23 (35.9)	8.5 [3.8, NC]	63	23 (36.5)	9.2 [5.5, NC]	0.990 [0.555, 1.766]	0.9698	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.23.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	145 (51.2%)	121 (42.9%)	
Number of patients censored	138 (48.8%)	161 (57.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.6 [3.5, 8.5]	9.2 [7.2, 12.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.230 [0.963, 1.571]
Log-rank test			
Two-sided stratified log-rank p-value			0.0953

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.23.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Odynophagia by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	93 (51.4)	5.7 [3.2, 8.5]	181	76 (42.0)	10.0 [6.4, 14.3]	1.284 [0.947, 1.741]	0.1057	0.8477
>65 years	102	52 (51.0)	5.1 [1.7, 10.5]	101	45 (44.6)	8.6 [4.6, 15.8]	1.206 [0.809, 1.798]	0.3487	
Sex									
Male	176	88 (50.0)	5.1 [3.3, 8.5]	175	79 (45.1)	8.7 [4.6, 11.1]	1.087 [0.802, 1.473]	0.5792	0.1310
Female	107	57 (53.3)	5.8 [1.8, 10.5]	107	42 (39.3)	10.0 [8.0, 18.4]	1.595 [1.070, 2.379]	0.0212	
Region									
Asia	88	51 (58.0)	4.9 [1.7, 12.3]	89	50 (56.2)	8.1 [3.7, 10.4]	0.970 [0.650, 1.448]	0.8742	0.1684
Non-Asia	195	94 (48.2)	5.9 [3.3, 9.0]	193	71 (36.8)	10.0 [8.0, 18.7]	1.429 [1.050, 1.946]	0.0219	
Number of Organs with Metastatic Sites									
0-2	219	114 (52.1)	5.1 [2.8, 9.0]	219	100 (45.7)	8.7 [6.3, 14.3]	1.200 [0.917, 1.571]	0.1833	0.3901
>=3	64	31 (48.4)	6.2 [1.8, 10.3]	63	21 (33.3)	10.0 [6.2, NC]	1.539 [0.882, 2.685]	0.1269	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.24.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	131 (46.3%)	124 (44.0%)	
Number of patients censored	152 (53.7%)	158 (56.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	7.4 [4.5, 10.0]	8.5 [5.1, 12.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.018 [0.794, 1.304]
Log-rank test			
Two-sided stratified log-rank p-value			0.8864

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.24.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Pain and Discomfort by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	86 (47.5)	7.4 [4.4, 10.4]	181	81 (44.8)	7.9 [4.4, 12.3]	0.997 [0.735, 1.351]	0.9831	0.9772
>65 years	102	45 (44.1)	6.5 [3.5, 22.4]	101	43 (42.6)	9.5 [5.0, 18.3]	1.032 [0.679, 1.569]	0.8747	
Sex									
Male	176	81 (46.0)	6.8 [4.4, 10.4]	175	72 (41.1)	8.8 [5.6, 15.0]	1.110 [0.807, 1.525]	0.5142	0.3591
Female	107	50 (46.7)	7.4 [3.7, 15.2]	107	52 (48.6)	6.3 [3.5, 14.3]	0.866 [0.586, 1.278]	0.4652	
Region									
Asia	88	48 (54.5)	5.7 [3.0, 10.7]	89	43 (48.3)	7.9 [4.0, 18.3]	1.066 [0.703, 1.615]	0.7623	0.8269
Non-Asia	195	83 (42.6)	7.8 [4.4, 10.1]	193	81 (42.0)	8.8 [4.9, 14.3]	0.986 [0.726, 1.340]	0.9367	
Number of Organs with Metastatic Sites									
0-2	219	103 (47.0)	7.4 [4.5, 10.1]	219	101 (46.1)	7.9 [4.7, 13.4]	0.962 [0.730, 1.266]	0.7825	0.4533
>=3	64	28 (43.8)	6.5 [3.0, NC]	63	23 (36.5)	9.3 [5.6, NC]	1.224 [0.705, 2.125]	0.4712	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.25.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	122 (43.1%)	117 (41.5%)	
Number of patients censored	161 (56.9%)	165 (58.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.3 [4.8, 8.1]	6.3 [3.9, 9.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.962 [0.744, 1.243]
Log-rank test			
Two-sided stratified log-rank p-value			0.7671

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.25.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Anxiety by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	82 (45.3)	5.7 [3.5, 8.0]	181	71 (39.2)	7.3 [3.6, 12.9]	1.134 [0.824, 1.561]	0.4311	0.0834
>65 years	102	40 (39.2)	8.0 [5.7, 17.9]	101	46 (45.5)	5.6 [1.7, 12.3]	0.738 [0.482, 1.129]	0.1613	
Sex									
Male	176	66 (37.5)	6.9 [5.1, NC]	175	74 (42.3)	5.5 [2.7, 12.3]	0.772 [0.554, 1.076]	0.1287	0.0226
Female	107	56 (52.3)	5.4 [2.6, 7.5]	107	43 (40.2)	6.7 [3.6, 14.9]	1.353 [0.908, 2.018]	0.1362	
Region									
Asia	88	48 (54.5)	6.6 [3.8, 10.3]	89	42 (47.2)	8.1 [5.5, 16.3]	1.019 [0.670, 1.550]	0.9300	0.5676
Non-Asia	195	74 (37.9)	6.2 [3.9, 9.0]	193	75 (38.9)	4.6 [2.2, 8.8]	0.903 [0.654, 1.245]	0.5401	
Number of Organs with Metastatic Sites									
0-2	219	103 (47.0)	5.8 [3.8, 7.5]	219	93 (42.5)	6.3 [3.7, 12.3]	1.067 [0.806, 1.413]	0.6460	0.1275
>=3	64	19 (29.7)	31.8 [4.8, 31.8]	63	24 (38.1)	6.5 [1.6, 14.9]	0.640 [0.350, 1.169]	0.1437	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.26.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	95 (33.6%)	91 (32.3%)	
Number of patients censored	188 (66.4%)	191 (67.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	20.7 [14.7, NC]	23.7 [12.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.038 [0.777, 1.387]
Log-rank test			
Two-sided stratified log-rank p-value			0.7966

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.26.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Eating in Front of Others by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	61 (33.7)	26.8 [8.0, NC]	181	55 (30.4)	23.7 [12.3, NC]	1.113 [0.773, 1.603]	0.5687	0.6011
>65 years	102	34 (33.3)	15.7 [8.3, NC]	101	36 (35.6)	29.1 [7.4, NC]	0.944 [0.591, 1.509]	0.8213	
Sex									
Male	176	66 (37.5)	17.2 [5.8, NC]	175	60 (34.3)	18.0 [8.1, NC]	1.127 [0.795, 1.599]	0.4986	0.4996
Female	107	29 (27.1)	NC [15.7, NC]	107	31 (29.0)	29.1 [12.0, NC]	0.912 [0.549, 1.515]	0.7229	
Region									
Asia	88	37 (42.0)	17.2 [5.4, NC]	89	35 (39.3)	12.3 [6.3, NC]	1.029 [0.647, 1.636]	0.9049	0.9407
Non-Asia	195	58 (29.7)	20.7 [13.3, NC]	193	56 (29.0)	29.1 [15.0, NC]	1.054 [0.730, 1.522]	0.7825	
Number of Organs with Metastatic Sites									
0-2	219	75 (34.2)	20.7 [13.3, NC]	219	75 (34.2)	23.7 [12.0, NC]	1.015 [0.737, 1.398]	0.9245	0.6855
>=3	64	20 (31.3)	NC [5.1, NC]	63	16 (25.4)	29.1 [8.0, NC]	1.193 [0.618, 2.303]	0.6012	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.27.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	146 (51.6%)	151 (53.5%)	
Number of patients censored	137 (48.4%)	131 (46.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.5 [2.9, 5.2]	3.7 [2.6, 4.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.967 [0.768, 1.216]
Log-rank test			
Two-sided stratified log-rank p-value			0.7536

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.27.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Dry Mouth Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	93 (51.4)	3.8 [2.2, 6.7]	181	97 (53.6)	2.8 [2.2, 3.9]	0.884 [0.664, 1.177]	0.3949	0.2389
>65 years	102	53 (52.0)	3.4 [1.6, 4.6]	101	54 (53.5)	4.6 [3.5, 6.7]	1.156 [0.791, 1.690]	0.4533	
Sex									
Male	176	91 (51.7)	3.4 [2.8, 6.5]	175	93 (53.1)	4.0 [2.5, 5.4]	0.967 [0.724, 1.293]	0.8146	0.8903
Female	107	55 (51.4)	3.7 [1.4, 9.0]	107	58 (54.2)	3.3 [2.2, 4.6]	0.937 [0.647, 1.358]	0.7215	
Region									
Asia	88	41 (46.6)	8.0 [3.0, NC]	89	45 (50.6)	5.6 [2.6, 14.7]	0.863 [0.563, 1.325]	0.4985	0.4645
Non-Asia	195	105 (53.8)	3.0 [1.5, 3.7]	193	106 (54.9)	3.0 [2.3, 4.0]	1.021 [0.779, 1.337]	0.8938	
Number of Organs with Metastatic Sites									
0-2	219	117 (53.4)	3.1 [1.9, 4.6]	219	126 (57.5)	3.3 [2.4, 4.6]	0.944 [0.733, 1.216]	0.6462	0.7316
>=3	64	29 (45.3)	5.2 [2.2, NC]	63	25 (39.7)	4.9 [2.6, NC]	1.055 [0.618, 1.803]	0.8460	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.28.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	167 (59.0%)	172 (61.0%)	
Number of patients censored	116 (41.0%)	110 (39.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.4 [1.9, 3.1]	2.8 [2.3, 3.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.040 [0.838, 1.291]
Log-rank test			
Two-sided stratified log-rank p-value			0.7287

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.28.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Taste by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	113 (62.4)	2.2 [1.6, 3.1]	181	108 (59.7)	2.8 [2.3, 3.5]	1.163 [0.893, 1.515]	0.2674	0.2667
>65 years	102	54 (52.9)	2.8 [1.6, 5.7]	101	64 (63.4)	3.0 [2.1, 4.4]	0.861 [0.596, 1.242]	0.4206	
Sex									
Male	176	98 (55.7)	2.8 [2.1, 3.7]	175	106 (60.6)	2.8 [2.3, 4.4]	0.956 [0.725, 1.261]	0.7577	0.3562
Female	107	69 (64.5)	1.9 [1.4, 2.8]	107	66 (61.7)	2.6 [2.1, 3.5]	1.210 [0.862, 1.697]	0.2731	
Region									
Asia	88	51 (58.0)	3.5 [1.6, 6.7]	89	55 (61.8)	2.9 [2.1, 5.7]	0.914 [0.623, 1.342]	0.6429	0.3578
Non-Asia	195	116 (59.5)	2.1 [1.6, 3.0]	193	117 (60.6)	2.8 [2.2, 3.5]	1.139 [0.880, 1.474]	0.3244	
Number of Organs with Metastatic Sites									
0-2	219	128 (58.4)	2.6 [1.6, 3.3]	219	142 (64.8)	2.6 [2.2, 3.3]	0.942 [0.741, 1.197]	0.6167	0.0606
>=3	64	39 (60.9)	2.1 [1.6, 3.7]	63	30 (47.6)	4.2 [2.3, 8.0]	1.641 [1.014, 2.654]	0.0417	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.29.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	152 (53.7%)	128 (45.4%)	
Number of patients censored	131 (46.3%)	154 (54.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.1 [2.7, 5.1]	7.1 [3.3, 10.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.283 [1.010, 1.630]
Log-rank test			
Two-sided stratified log-rank p-value			0.0380

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.29.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Body Image by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	105 (58.0)	3.4 [2.2, 4.6]	181	71 (39.2)	10.4 [5.7, 22.8]	1.641 [1.213, 2.220]	0.0011	0.0081
>65 years	102	47 (46.1)	4.4 [2.2, 8.6]	101	57 (56.4)	3.0 [2.1, 8.0]	0.853 [0.579, 1.256]	0.4254	
Sex									
Male	176	91 (51.7)	4.2 [2.8, 6.2]	175	76 (43.4)	9.4 [5.7, 19.5]	1.421 [1.047, 1.929]	0.0229	0.3312
Female	107	61 (57.0)	2.8 [2.1, 5.3]	107	52 (48.6)	3.0 [2.3, 8.7]	1.086 [0.749, 1.574]	0.6538	
Region									
Asia	88	53 (60.2)	4.4 [2.5, 8.1]	89	46 (51.7)	7.5 [3.9, 20.7]	1.218 [0.819, 1.814]	0.3182	0.8124
Non-Asia	195	99 (50.8)	3.1 [2.1, 4.8]	193	82 (42.5)	5.2 [2.8, 12.7]	1.300 [0.969, 1.743]	0.0765	
Number of Organs with Metastatic Sites									
0-2	219	118 (53.9)	4.1 [2.5, 5.1]	219	97 (44.3)	8.7 [5.2, 12.7]	1.377 [1.052, 1.803]	0.0194	0.2598
>=3	64	34 (53.1)	3.5 [1.6, 6.8]	63	31 (49.2)	2.6 [1.5, 5.7]	0.974 [0.598, 1.585]	0.9282	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.30.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	108 (38.2%)	91 (32.3%)	
Number of patients censored	175 (61.8%)	191 (67.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.3 [6.2, NC]	17.1 [11.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.305 [0.985, 1.729]
Log-rank test			
Two-sided stratified log-rank p-value			0.0629

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.30.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Swallowing Saliva by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	74 (40.9)	10.4 [5.3, NC]	181	48 (26.5)	20.7 [11.2, NC]	1.727 [1.200, 2.485]	0.0029	0.0096
>65 years	102	34 (33.3)	17.9 [6.5, NC]	101	43 (42.6)	7.7 [6.2, 18.2]	0.794 [0.506, 1.246]	0.3193	
Sex									
Male	176	67 (38.1)	10.4 [5.7, NC]	175	61 (34.9)	12.9 [10.6, NC]	1.217 [0.860, 1.723]	0.2663	0.6631
Female	107	41 (38.3)	17.9 [4.4, NC]	107	30 (28.0)	NC [8.4, NC]	1.419 [0.886, 2.274]	0.1433	
Region									
Asia	88	33 (37.5)	17.9 [8.7, NC]	89	26 (29.2)	NC [11.2, NC]	1.200 [0.717, 2.011]	0.4828	0.8318
Non-Asia	195	75 (38.5)	9.4 [4.4, NC]	193	65 (33.7)	15.4 [8.4, NC]	1.312 [0.940, 1.830]	0.1089	
Number of Organs with Metastatic Sites									
0-2	219	84 (38.4)	13.3 [6.0, NC]	219	76 (34.7)	15.4 [10.6, NC]	1.177 [0.863, 1.606]	0.3016	0.2854
>=3	64	24 (37.5)	10.8 [5.5, NC]	63	15 (23.8)	NC [7.8, NC]	1.770 [0.926, 3.385]	0.0806	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.31.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	93 (32.9%)	77 (27.3%)	
Number of patients censored	190 (67.1%)	205 (72.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	23.3 [12.9, NC]	NC [15.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.304 [0.962, 1.767]
Log-rank test			
Two-sided stratified log-rank p-value			0.0857

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.31.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Choked When Swallowing Score by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	64 (35.4)	17.2 [10.8, NC]	181	41 (22.7)	NC [15.0, NC]	1.717 [1.160, 2.542]	0.0064	0.0156
>65 years	102	29 (28.4)	NC [9.4, NC]	101	36 (35.6)	NC [6.7, NC]	0.827 [0.507, 1.350]	0.4482	
Sex									
Male	176	59 (33.5)	NC [9.4, NC]	175	53 (30.3)	NC [10.8, NC]	1.232 [0.850, 1.786]	0.2719	0.5674
Female	107	34 (31.8)	23.3 [11.5, NC]	107	24 (22.4)	NC [15.0, NC]	1.418 [0.840, 2.395]	0.1895	
Region									
Asia	88	34 (38.6)	NC [6.4, NC]	89	27 (30.3)	NC [12.3, NC]	1.255 [0.755, 2.085]	0.3785	0.8614
Non-Asia	195	59 (30.3)	23.3 [12.9, NC]	193	50 (25.9)	NC [14.1, NC]	1.313 [0.900, 1.914]	0.1583	
Number of Organs with Metastatic Sites									
0-2	219	73 (33.3)	23.3 [12.2, NC]	219	68 (31.1)	NC [12.3, NC]	1.137 [0.817, 1.584]	0.4479	0.0790
>=3	64	20 (31.3)	16.6 [6.5, NC]	63	9 (14.3)	NC [NC, NC]	2.388 [1.086, 5.252]	0.0254	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.32.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	143 (50.5%)	107 (37.9%)	
Number of patients censored	140 (49.5%)	175 (62.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.9 [3.7, 6.7]	12.3 [7.5, 20.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.537 [1.192, 1.982]
Log-rank test			
Two-sided stratified log-rank p-value			0.0008

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.32.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble with Coughing by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	92 (50.8)	5.0 [3.5, 8.3]	181	60 (33.1)	17.3 [7.6, NC]	1.757 [1.269, 2.434]	0.0006	0.1356
>65 years	102	51 (50.0)	4.7 [3.0, 6.9]	101	47 (46.5)	8.1 [3.5, 20.9]	1.175 [0.789, 1.750]	0.4217	
Sex									
Male	176	93 (52.8)	4.6 [3.1, 6.6]	175	72 (41.1)	8.8 [5.6, NC]	1.479 [1.087, 2.013]	0.0122	0.8382
Female	107	50 (46.7)	5.3 [3.5, 12.9]	107	35 (32.7)	17.3 [7.6, NC]	1.528 [0.991, 2.355]	0.0524	
Region									
Asia	88	41 (46.6)	9.7 [5.0, NC]	89	26 (29.2)	NC [12.3, NC]	1.638 [1.000, 2.685]	0.0477	0.7622
Non-Asia	195	102 (52.3)	3.8 [2.7, 5.6]	193	81 (42.0)	7.6 [5.2, 17.3]	1.487 [1.110, 1.992]	0.0074	
Number of Organs with Metastatic Sites									
0-2	219	110 (50.2)	4.9 [3.7, 6.7]	219	80 (36.5)	14.1 [8.1, NC]	1.618 [1.212, 2.159]	0.0010	0.2930
>=3	64	33 (51.6)	5.5 [2.6, 12.9]	63	27 (42.9)	6.7 [2.2, NC]	1.177 [0.707, 1.960]	0.5217	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.33.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	109 (38.5%)	87 (30.9%)	
Number of patients censored	174 (61.5%)	195 (69.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.3 [8.3, NC]	40.8 [14.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.367 [1.030, 1.814]
Log-rank test			
Two-sided stratified log-rank p-value			0.0290

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.33.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Trouble Talking by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	76 (42.0)	8.7 [5.1, NC]	181	50 (27.6)	40.8 [14.1, NC]	1.736 [1.214, 2.483]	0.0022	0.0168
>65 years	102	33 (32.4)	19.1 [10.3, NC]	101	37 (36.6)	NC [4.2, NC]	0.837 [0.523, 1.339]	0.4569	
Sex									
Male	176	69 (39.2)	13.2 [5.5, NC]	175	55 (31.4)	NC [12.3, NC]	1.343 [0.941, 1.917]	0.1038	0.9920
Female	107	40 (37.4)	16.4 [8.0, NC]	107	32 (29.9)	40.8 [8.7, NC]	1.325 [0.832, 2.109]	0.2337	
Region									
Asia	88	33 (37.5)	37.7 [9.6, NC]	89	24 (27.0)	40.8 [12.3, NC]	1.319 [0.777, 2.237]	0.3016	0.9360
Non-Asia	195	76 (39.0)	10.3 [5.1, 19.4]	193	63 (32.6)	NC [8.7, NC]	1.355 [0.970, 1.893]	0.0748	
Number of Organs with Metastatic Sites									
0-2	219	81 (37.0)	16.4 [8.3, NC]	219	70 (32.0)	40.8 [12.9, NC]	1.247 [0.905, 1.718]	0.1762	0.3883
>=3	64	28 (43.8)	13.2 [3.7, NC]	63	17 (27.0)	NC [6.5, NC]	1.691 [0.924, 3.096]	0.0850	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.34.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	137 (48.4%)	103 (36.5%)	
Number of patients censored	146 (51.6%)	179 (63.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.7 [2.8, 5.1]	15.1 [7.2, 20.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.503 [1.160, 1.947]
Log-rank test			
Two-sided stratified log-rank p-value			0.0018

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.34.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Weight Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	87 (48.1)	4.2 [2.7, 6.5]	181	59 (32.6)	19.2 [12.9, NC]	1.626 [1.168, 2.264]	0.0036	0.4241
>65 years	102	50 (49.0)	3.3 [2.1, 5.8]	101	44 (43.6)	6.6 [2.4, NC]	1.357 [0.903, 2.039]	0.1371	
Sex									
Male	176	79 (44.9)	4.4 [2.8, 6.5]	175	59 (33.7)	16.3 [9.7, NC]	1.647 [1.174, 2.310]	0.0034	0.4255
Female	107	58 (54.2)	2.9 [1.8, 6.0]	107	44 (41.1)	5.9 [2.4, 19.2]	1.301 [0.879, 1.925]	0.1832	
Region									
Asia	88	50 (56.8)	5.1 [2.8, 6.6]	89	36 (40.4)	15.1 [6.6, NC]	1.495 [0.973, 2.298]	0.0632	0.9011
Non-Asia	195	87 (44.6)	3.0 [2.1, 5.1]	193	67 (34.7)	15.7 [4.5, 20.7]	1.501 [1.091, 2.067]	0.0117	
Number of Organs with Metastatic Sites									
0-2	219	109 (49.8)	3.9 [2.8, 5.8]	219	76 (34.7)	16.3 [12.3, NC]	1.650 [1.230, 2.212]	0.0007	0.1696
>=3	64	28 (43.8)	3.3 [1.6, 15.5]	63	27 (42.9)	4.7 [2.3, NC]	1.065 [0.626, 1.811]	0.8165	

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 [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: 08SEP23

Table 301.3.3004.35.1: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	29 (10.2%)	33 (11.7%)	
Number of patients censored	254 (89.8%)	249 (88.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	4.4 [3.5, 15.5]	4.5 [2.8, 7.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.606 [0.354, 1.036]
Log-rank test			
Two-sided stratified log-rank p-value			0.0671

Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; MID=minimally important difference; 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: 08SEP23

Table 301.3.3004.35.2: EORTC QLQ-OG25 - Summary of Time to First Deterioration of Hair Loss by Subgroups (MID=10) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	21 (11.6)	4.1 [2.3, 10.8]	181	25 (13.8)	3.0 [1.4, 4.7]	0.729 [0.405, 1.314]	0.3020	0.8927
>65 years	102	8 (7.8)	15.5 [3.4, 25.5]	101	8 (7.9)	12.3 [4.5, NC]	0.615 [0.210, 1.800]	0.3730	
Sex									
Male	176	13 (7.4)	15.5 [4.1, 25.5]	175	18 (10.3)	4.7 [2.8, 12.5]	0.472 [0.222, 1.005]	0.0473	0.1179
Female	107	16 (15.0)	2.3 [1.4, 4.4]	107	15 (14.0)	3.1 [0.8, 4.8]	1.075 [0.520, 2.221]	0.8241	
Region									
Asia	88	15 (17.0)	4.4 [3.5, NC]	89	13 (14.6)	4.0 [1.4, 10.2]	0.651 [0.303, 1.396]	0.2742	0.8905
Non-Asia	195	14 (7.2)	4.7 [2.3, 25.5]	193	20 (10.4)	4.5 [2.5, 12.3]	0.718 [0.354, 1.457]	0.3625	
Number of Organs with Metastatic Sites									
0-2	219	26 (11.9)	4.4 [3.5, 15.5]	219	28 (12.8)	3.1 [1.4, 7.5]	0.572 [0.328, 0.997]	0.0477	0.3139
>=3	64	3 (4.7)	10.8 [0.9, 10.8]	63	5 (7.9)	NC [2.3, NC]	1.145 [0.269, 4.873]	0.8543	

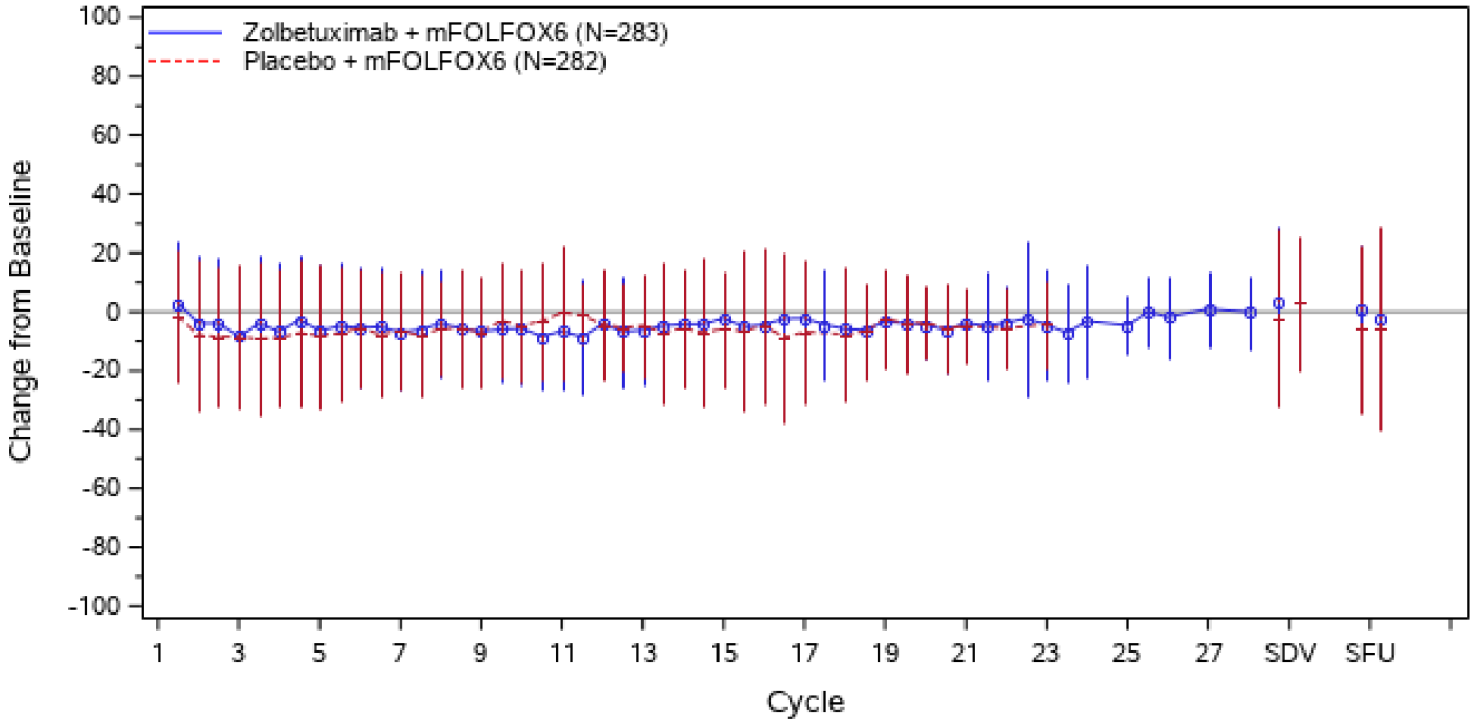
Abbreviations: CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; 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 [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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

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

The SAS System

Figure 301.3.3002.20: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia - Full Analysis Set

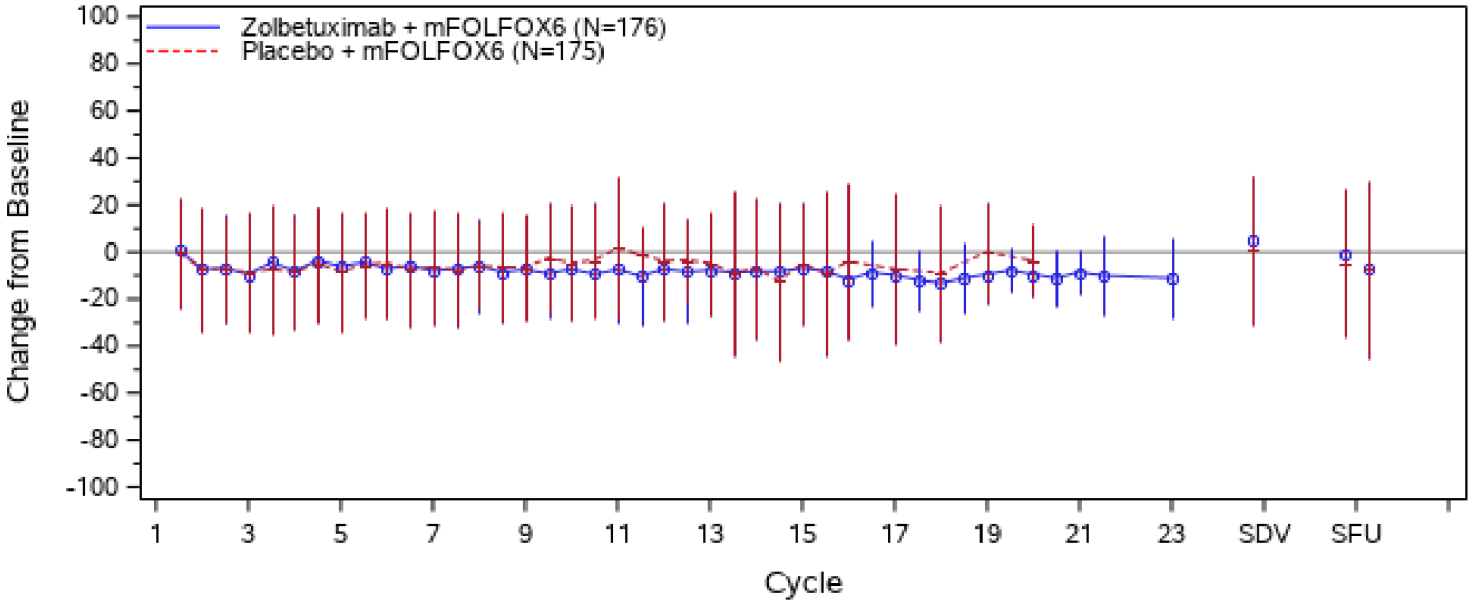


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.20.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia by Sex - Full Analysis Set

Sex: Male

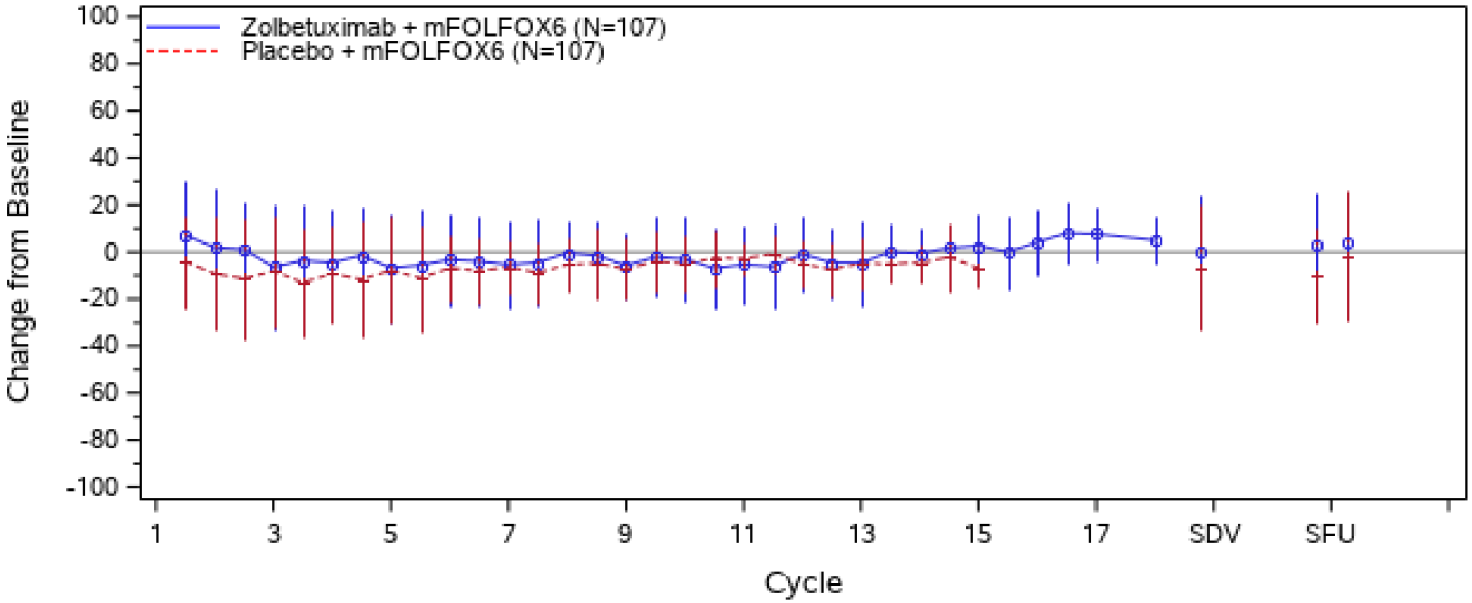


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.20.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dysphagia by Sex - Full Analysis Set

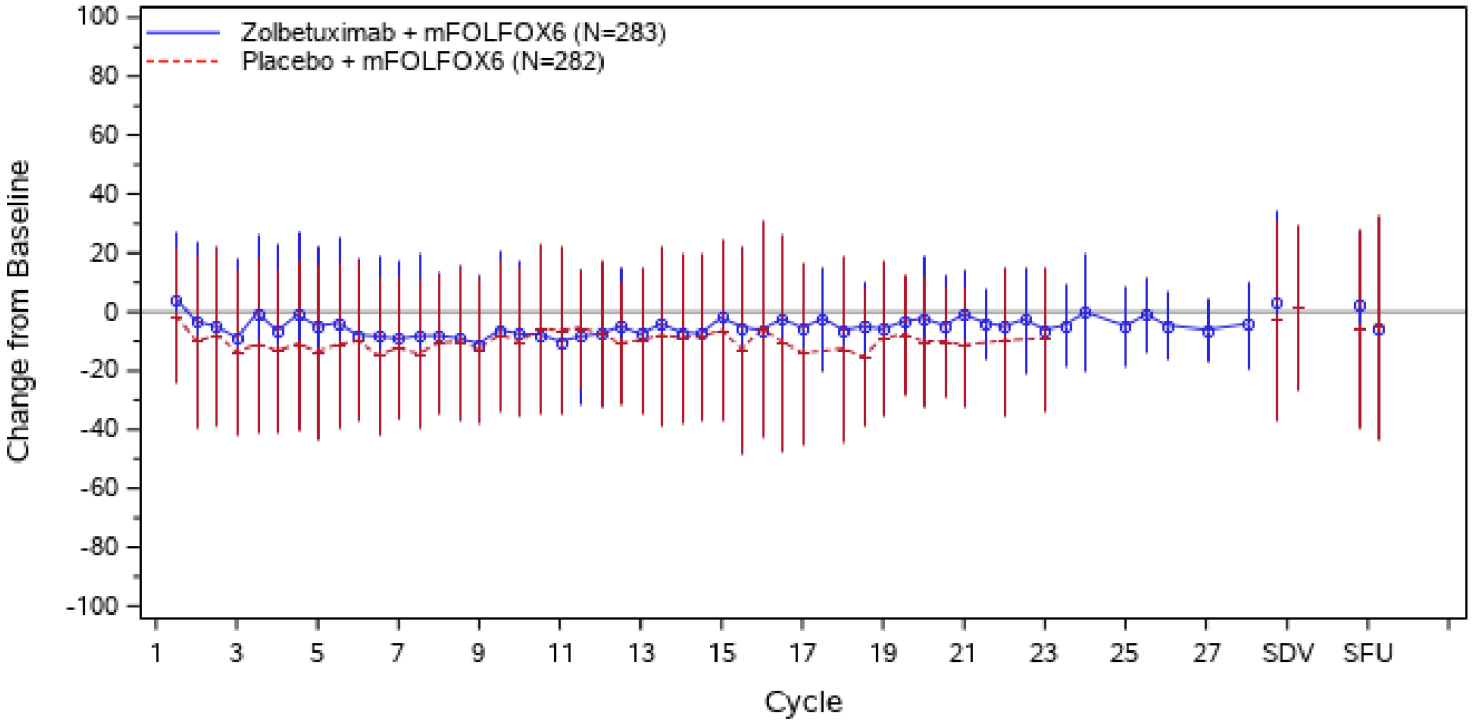
Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

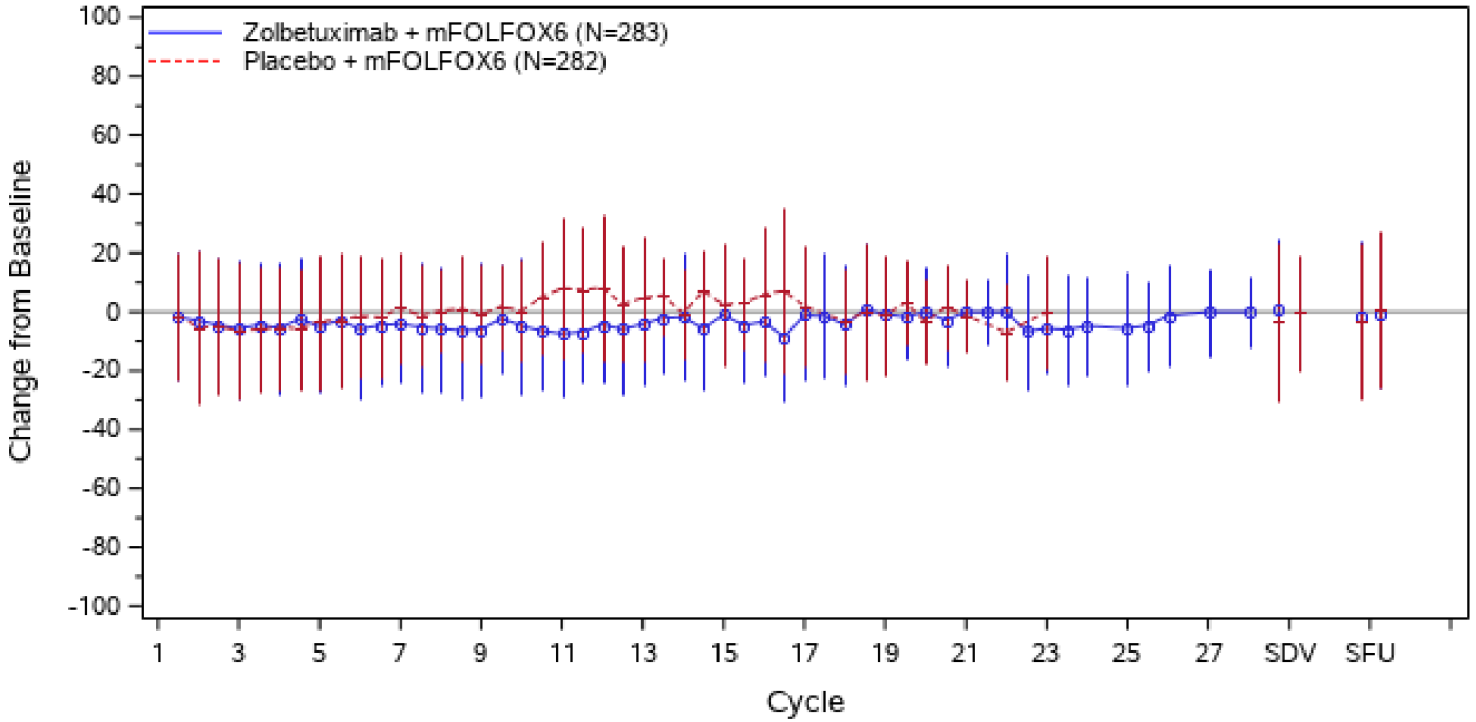
Figure 301.3.3002.21: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating Restrictions - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.22: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux - Full Analysis Set

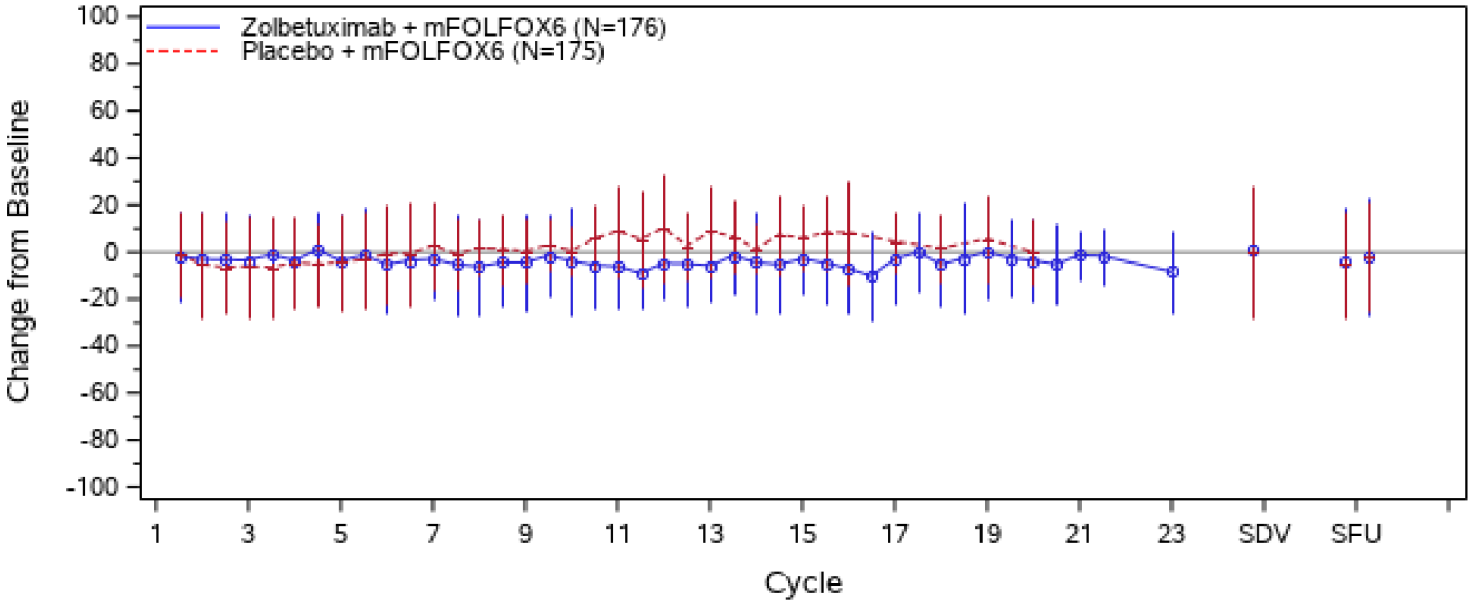


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.22.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux by Sex - Full Analysis Set

Sex: Male

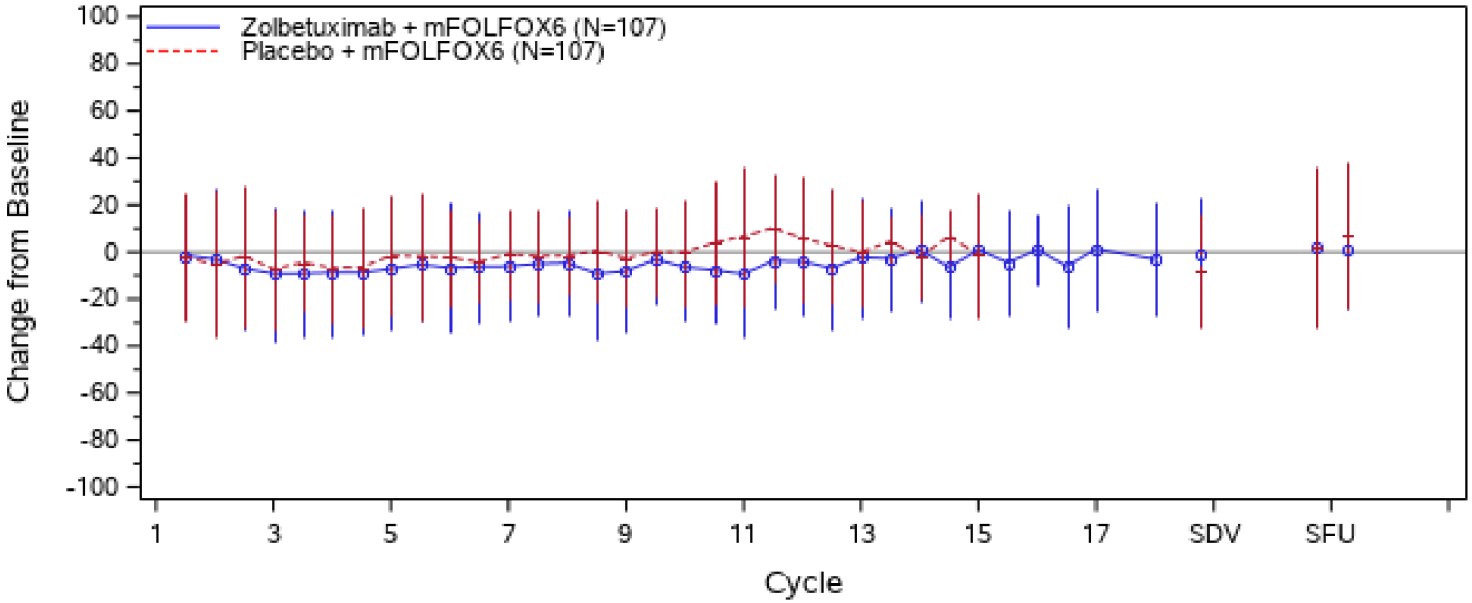


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.22.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Reflux by Sex - Full Analysis Set

Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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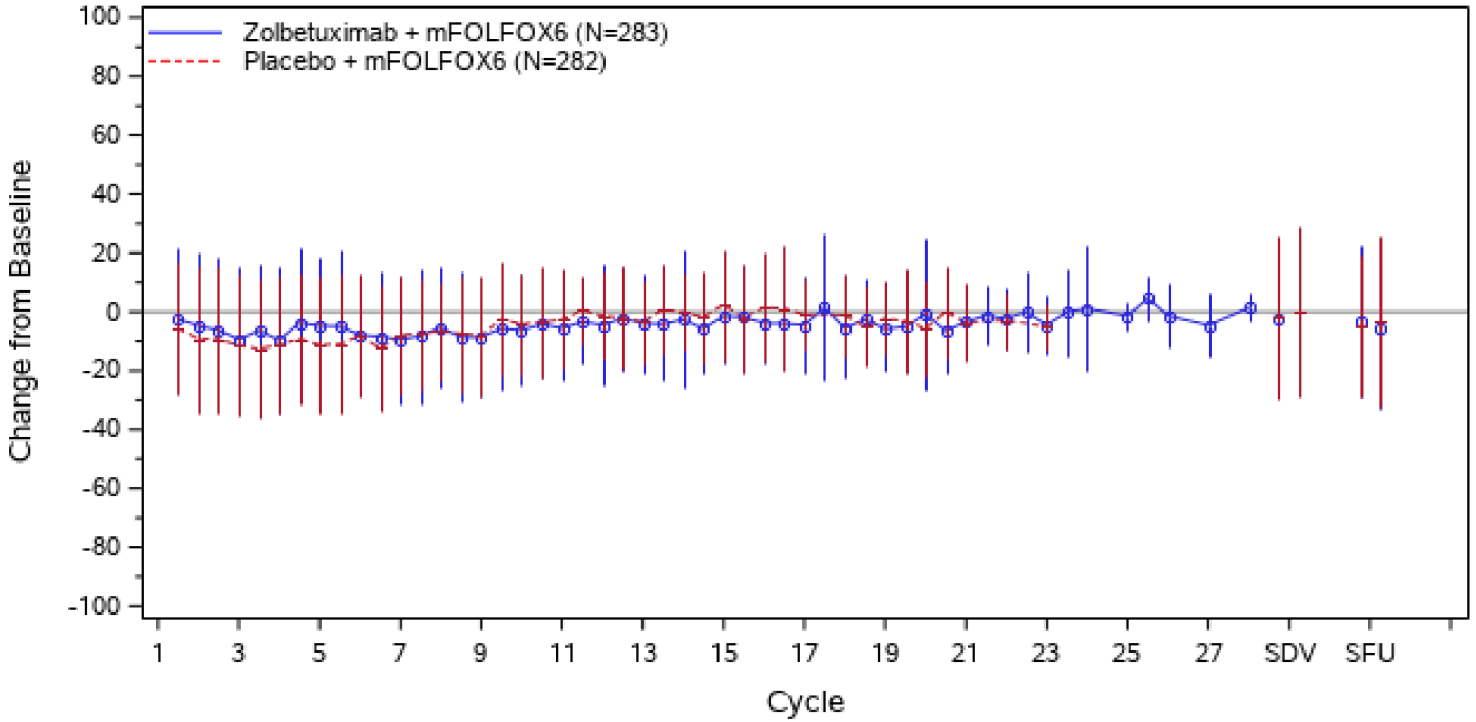
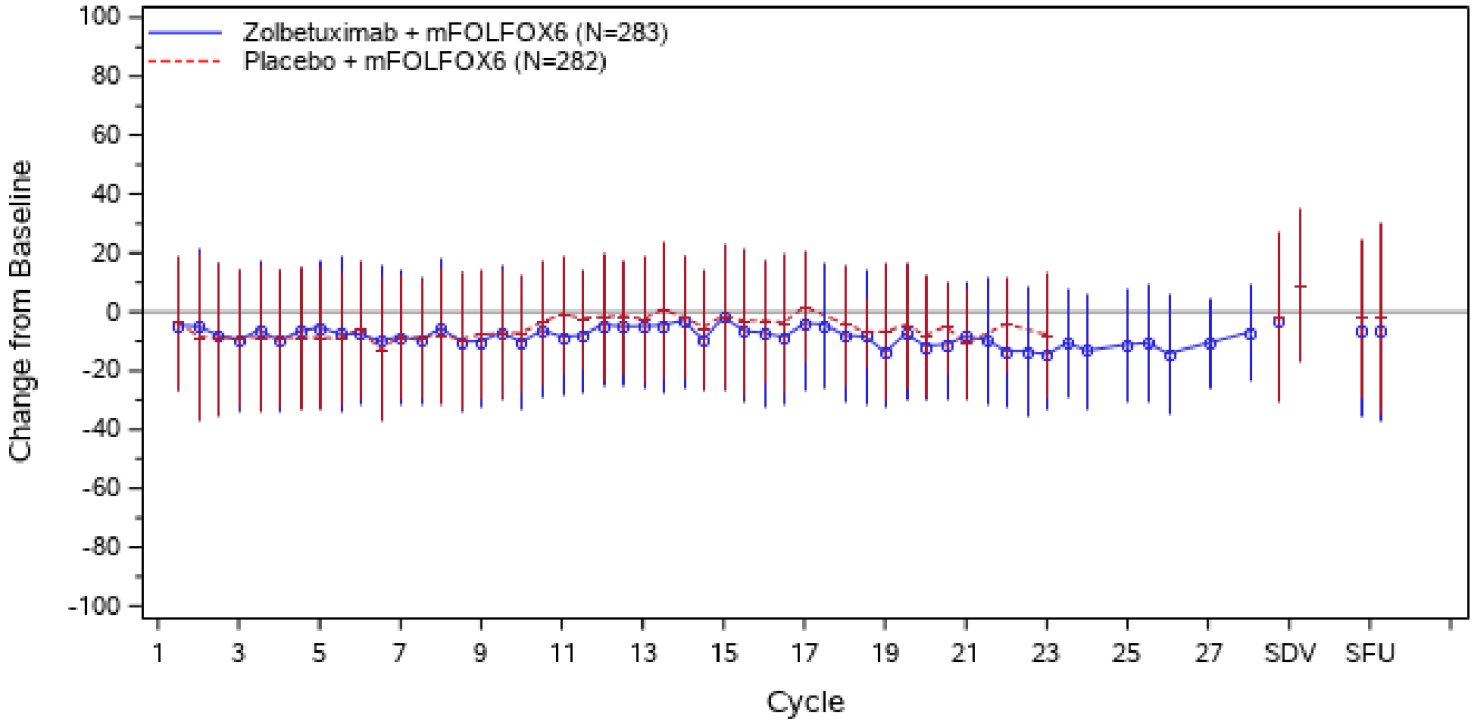
Figure 301.3.3002.23: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Odynophagia - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

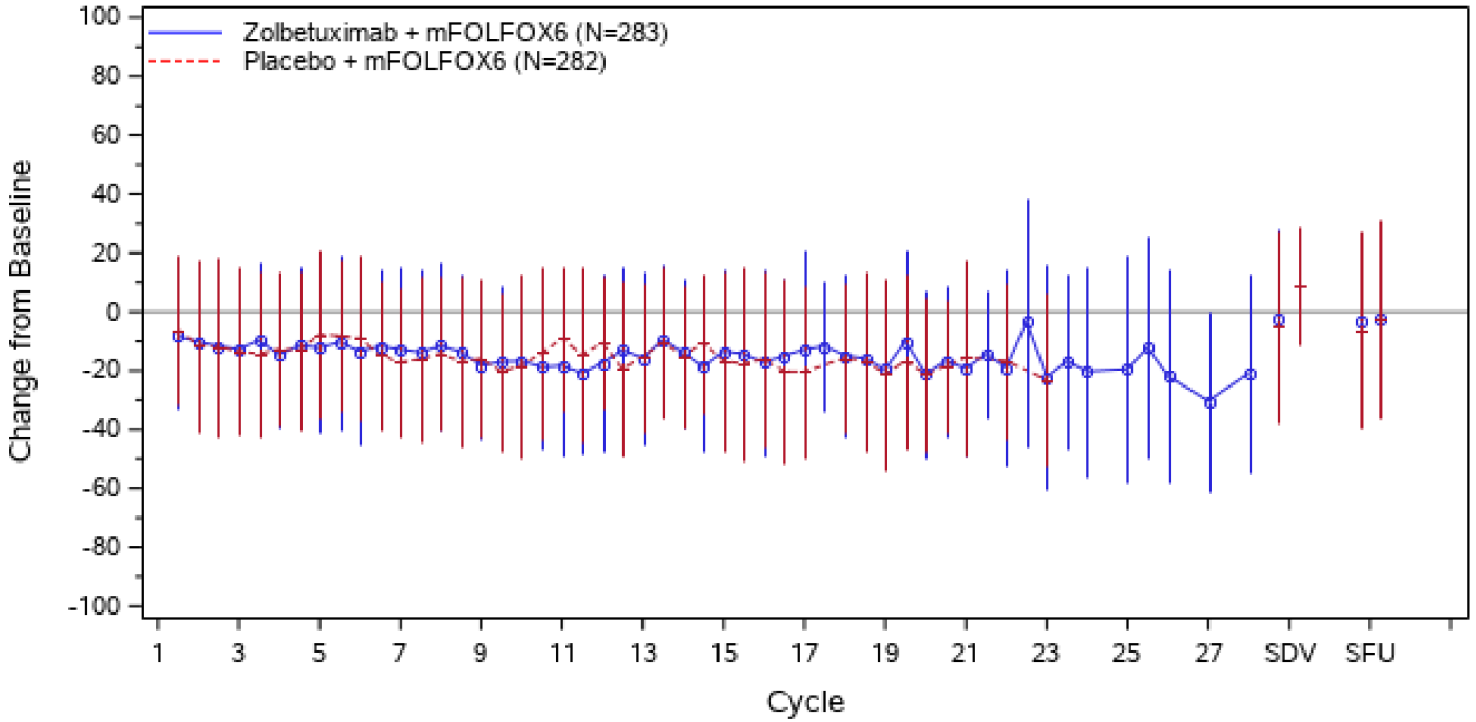
Figure 301.3.3002.24: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Pain and Discomfort - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.25: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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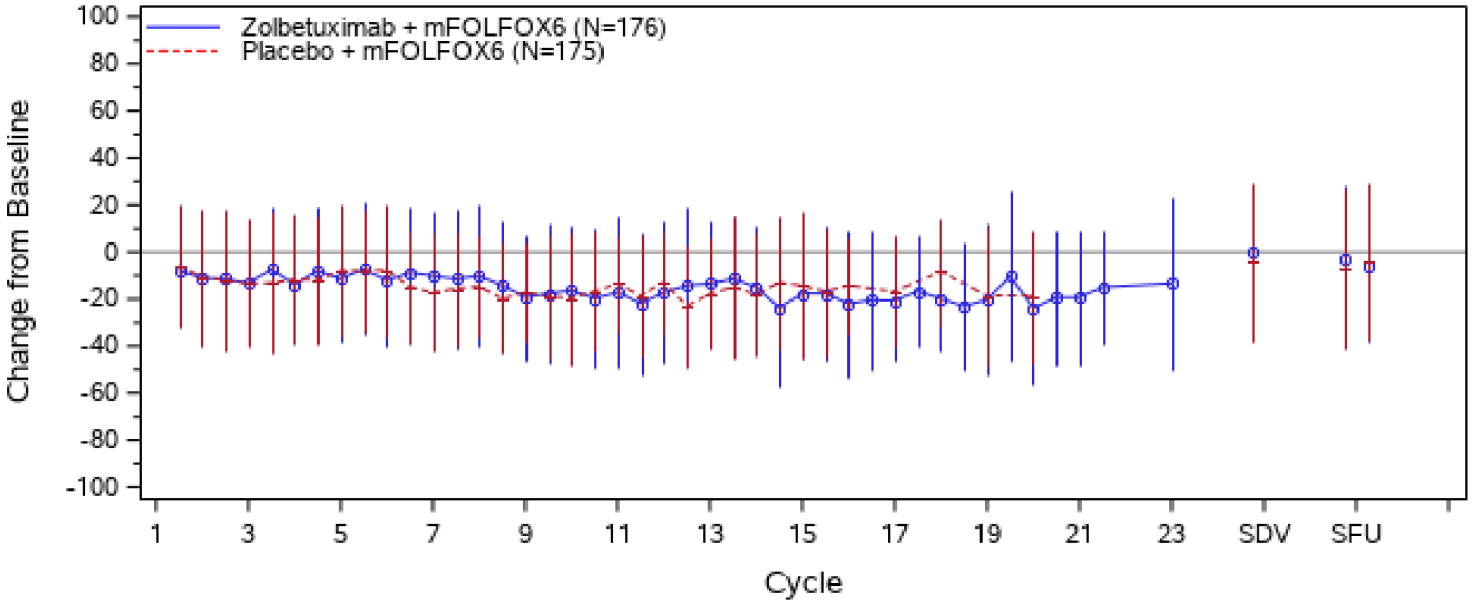
Figure 301.3.3002.25.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety by Sex - Full Analysis Set

Sex: Male



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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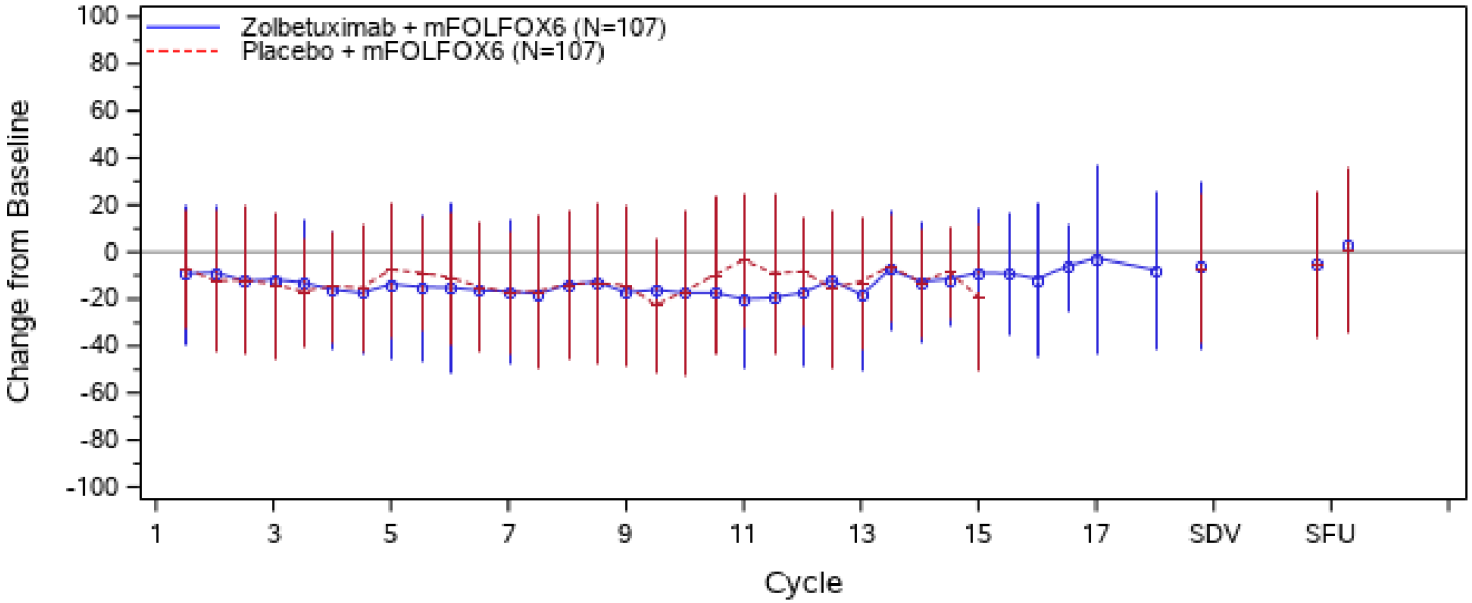
Figure 301.3.3002.25.2: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Anxiety by Sex - Full Analysis Set

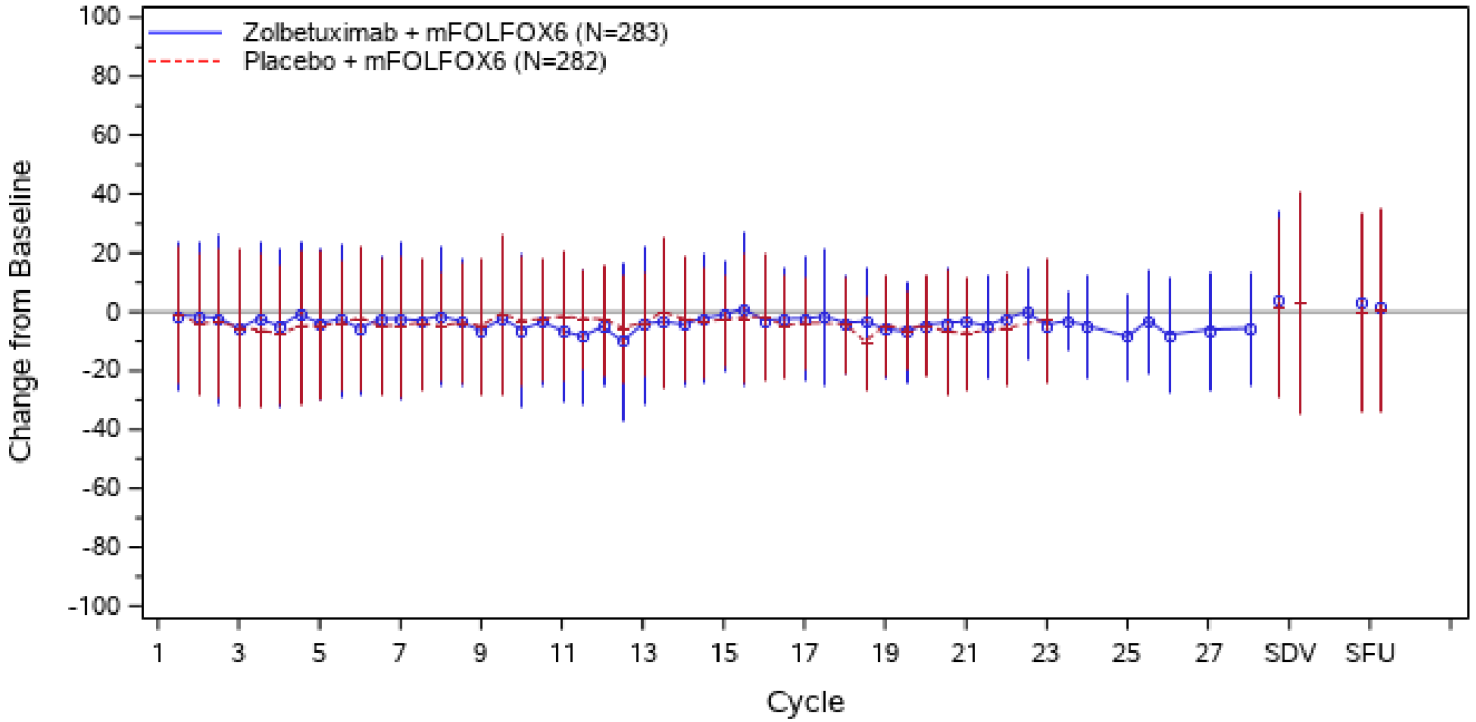
Sex: Female



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

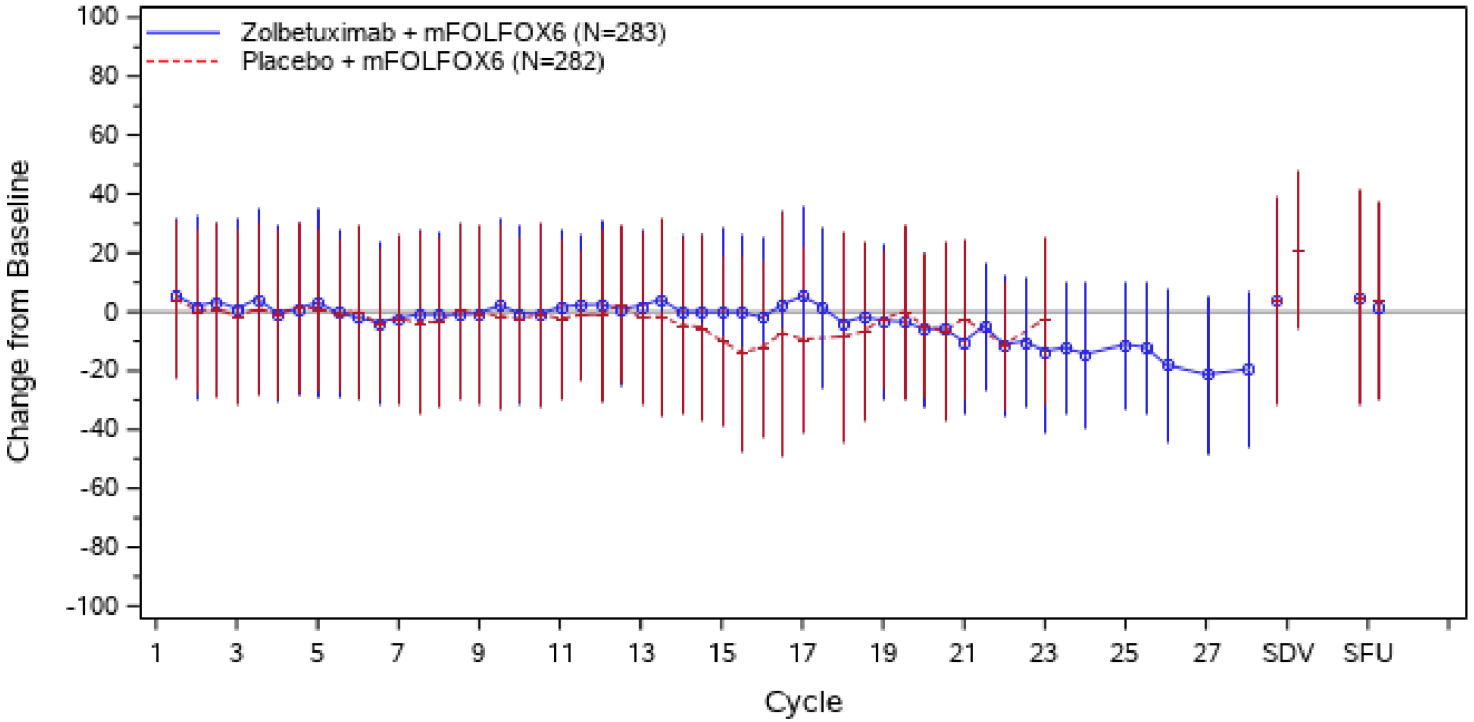
Figure 301.3.3002.26: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Eating in Front of Others - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.27: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Dry Mouth - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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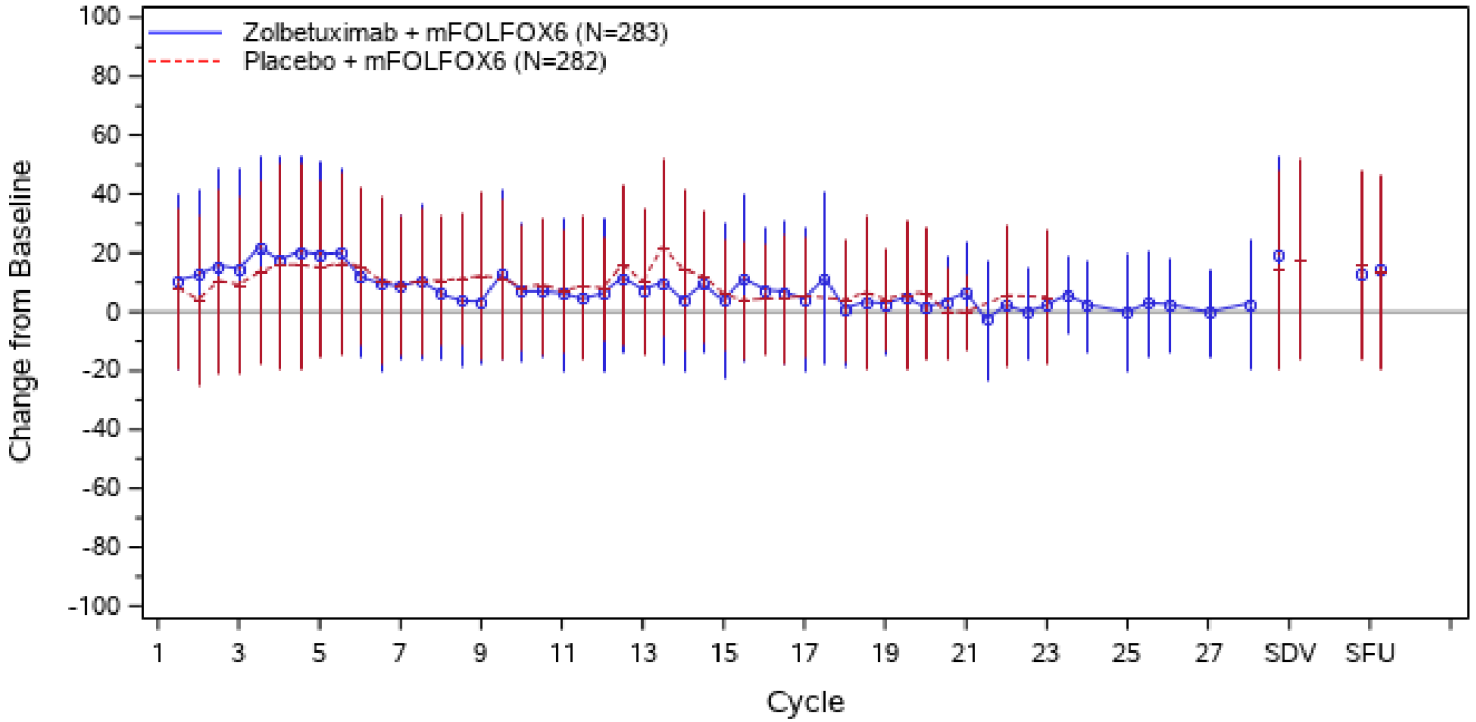
Figure 301.3.3002.28: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Taste - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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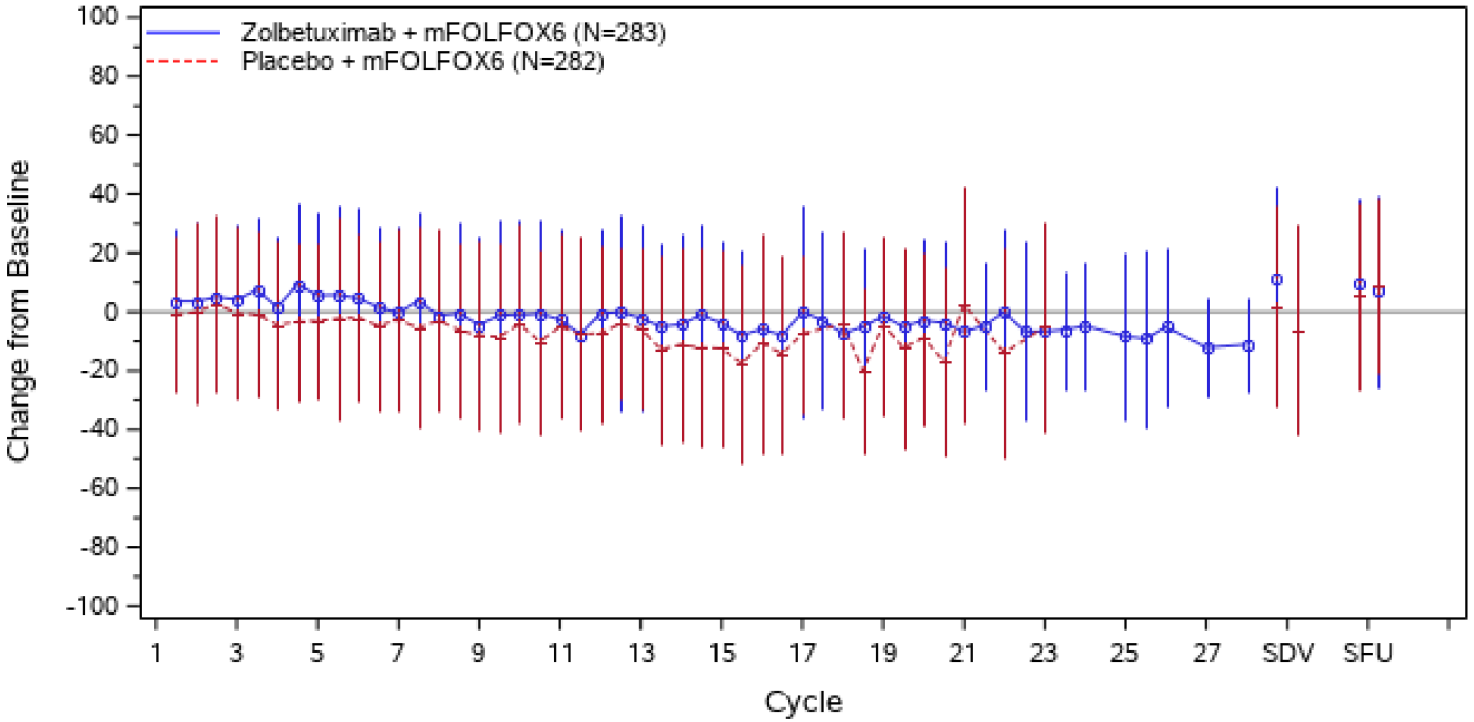
Figure 301.3.3002.29: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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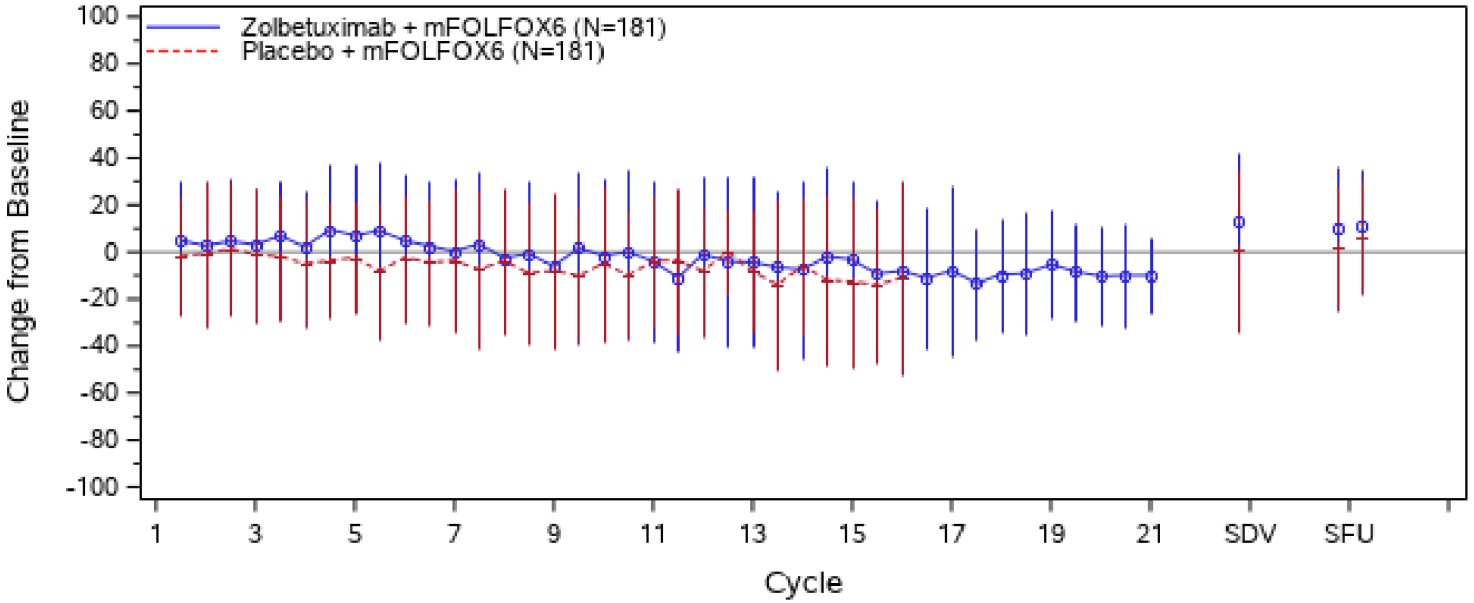
Figure 301.3.3002.29.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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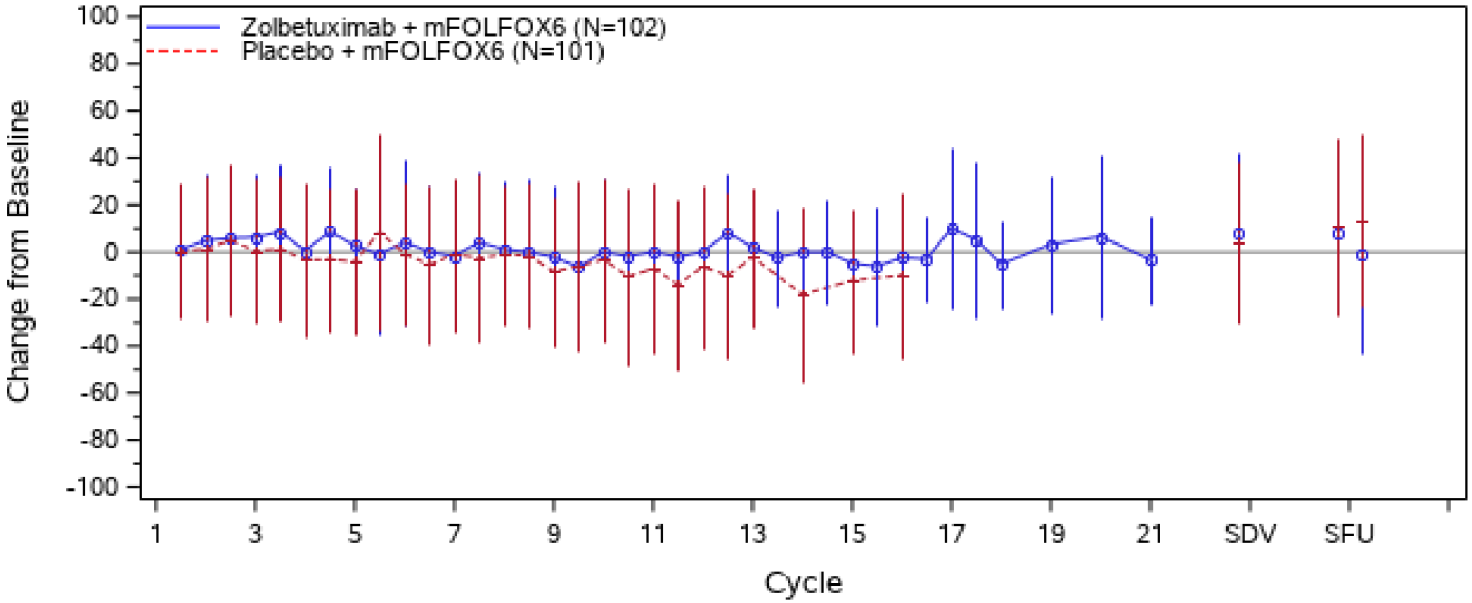
Figure 301.3.3002.29.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Body Image by Age Group 1 - Full Analysis Set

Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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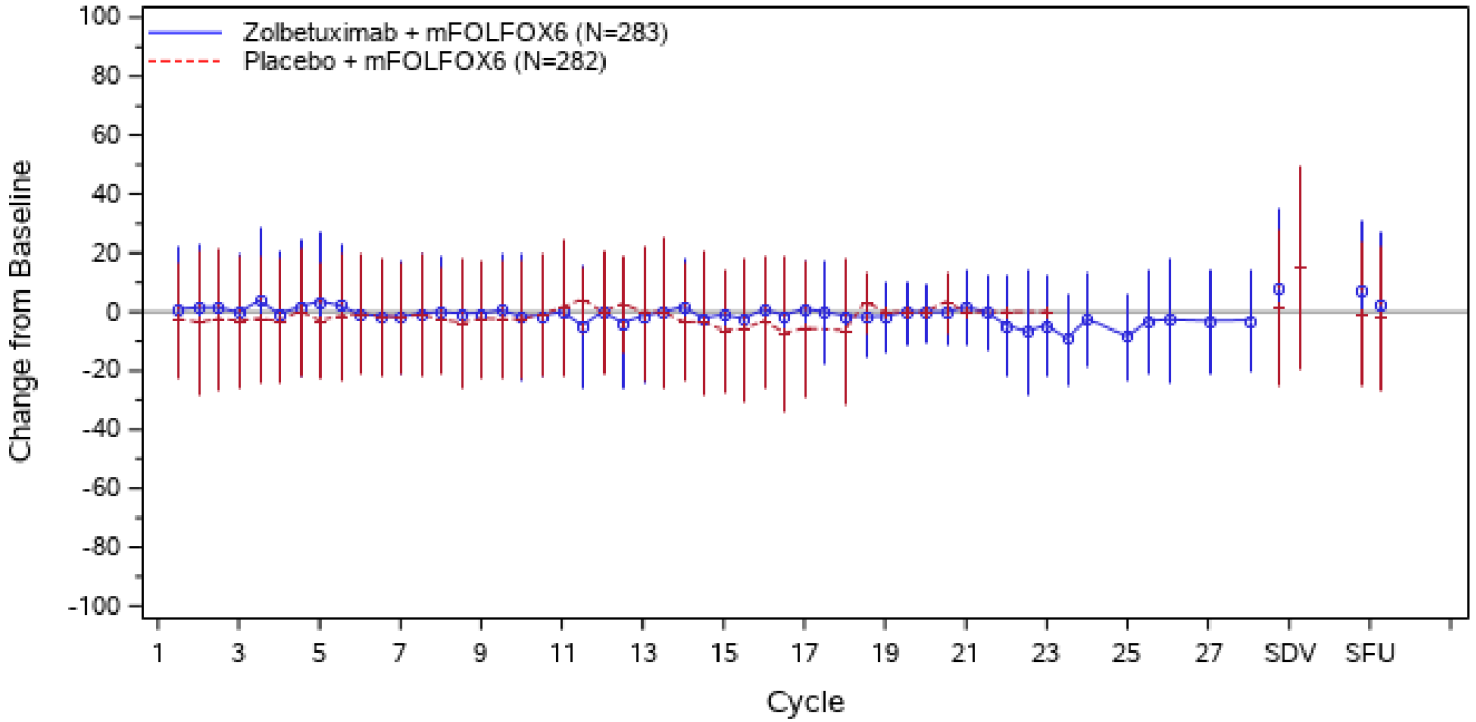
Figure 301.3.3002.30: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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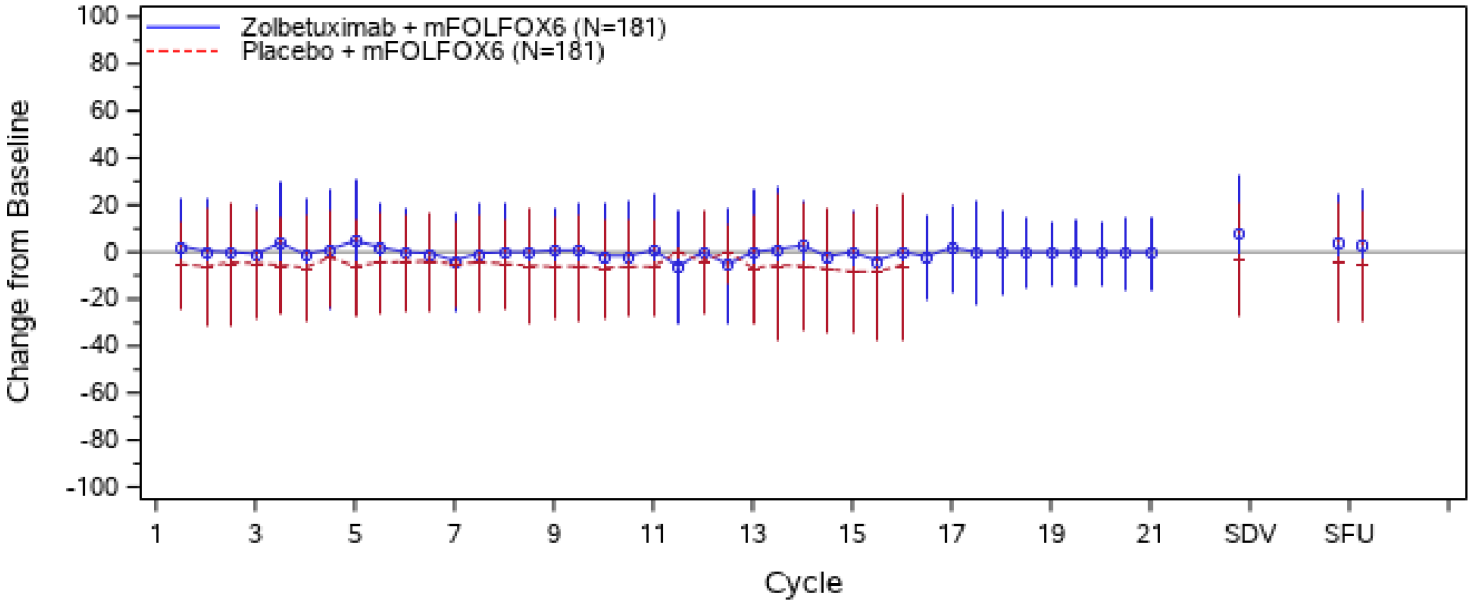
Figure 301.3.3002.30.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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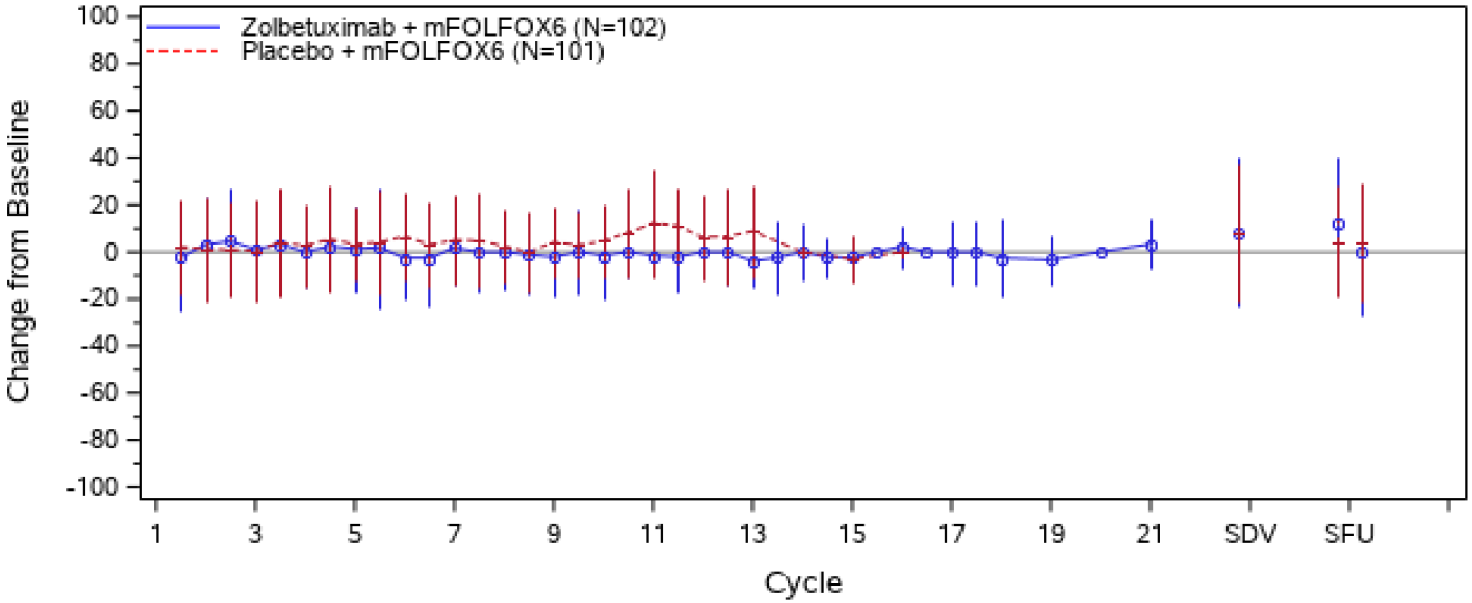
Figure 301.3.3002.30.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Swallowing Saliva by Age Group 1 - Full Analysis Set

Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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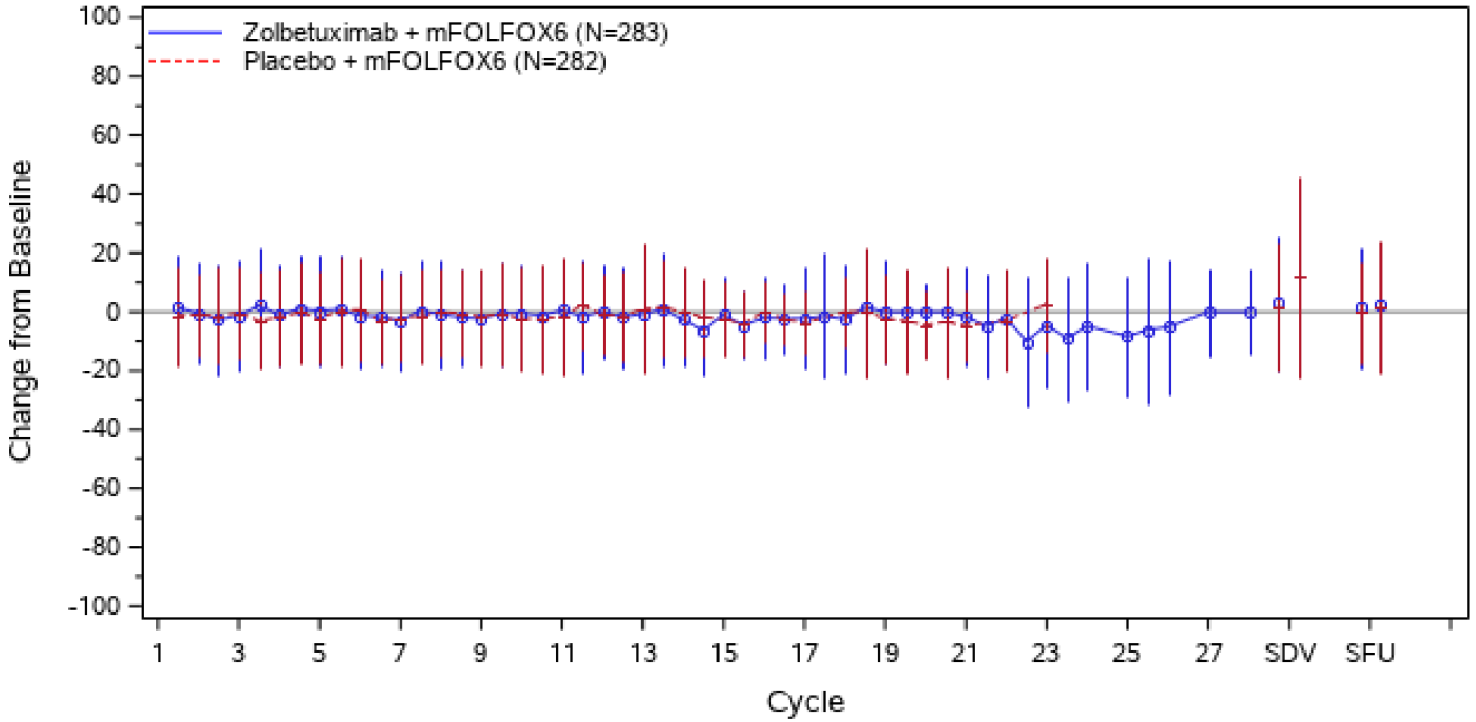
Figure 301.3.3002.31: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

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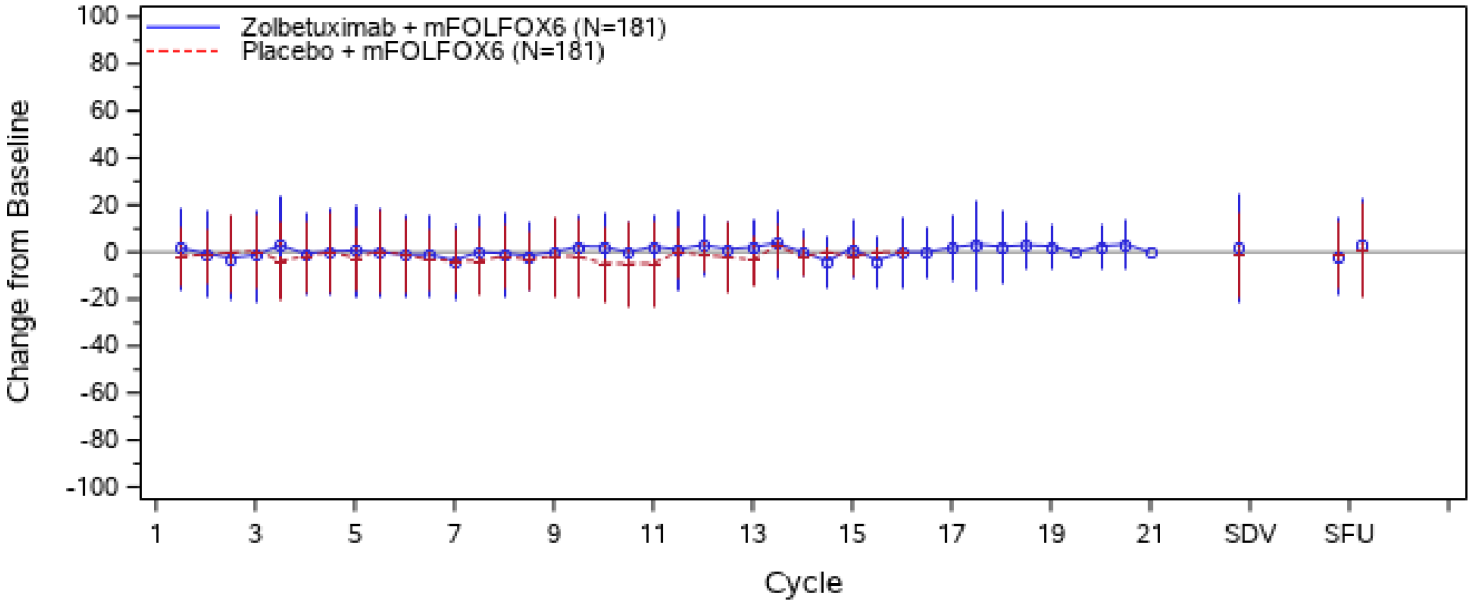
Figure 301.3.3002.31.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

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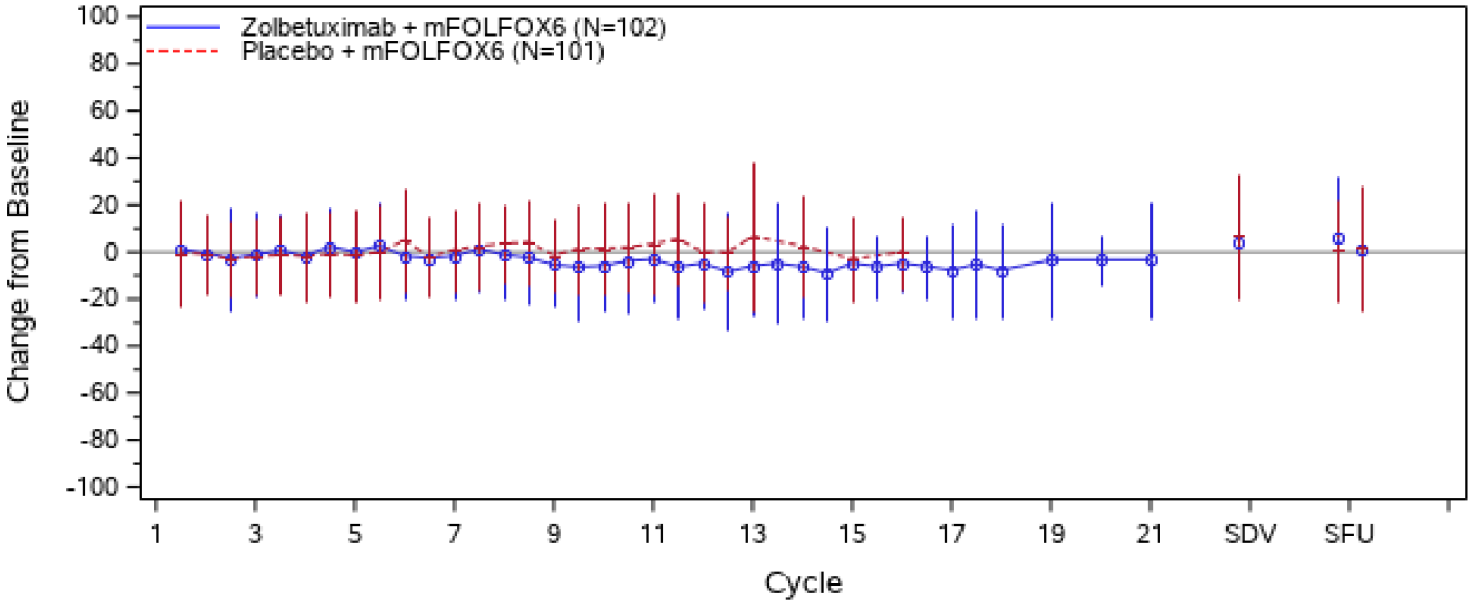
Figure 301.3.3002.31.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Choked when Swallowing Score by Age Group 1 - Full Analysis Set

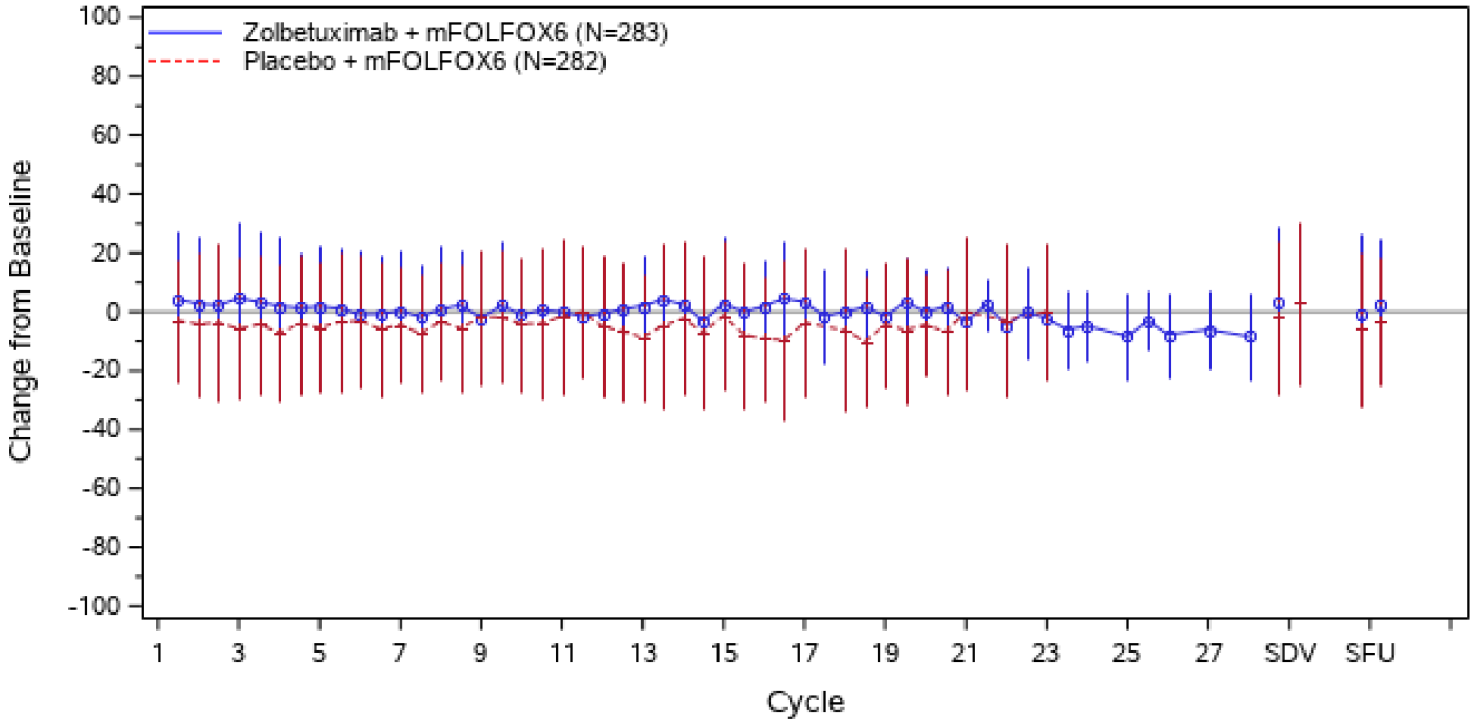
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

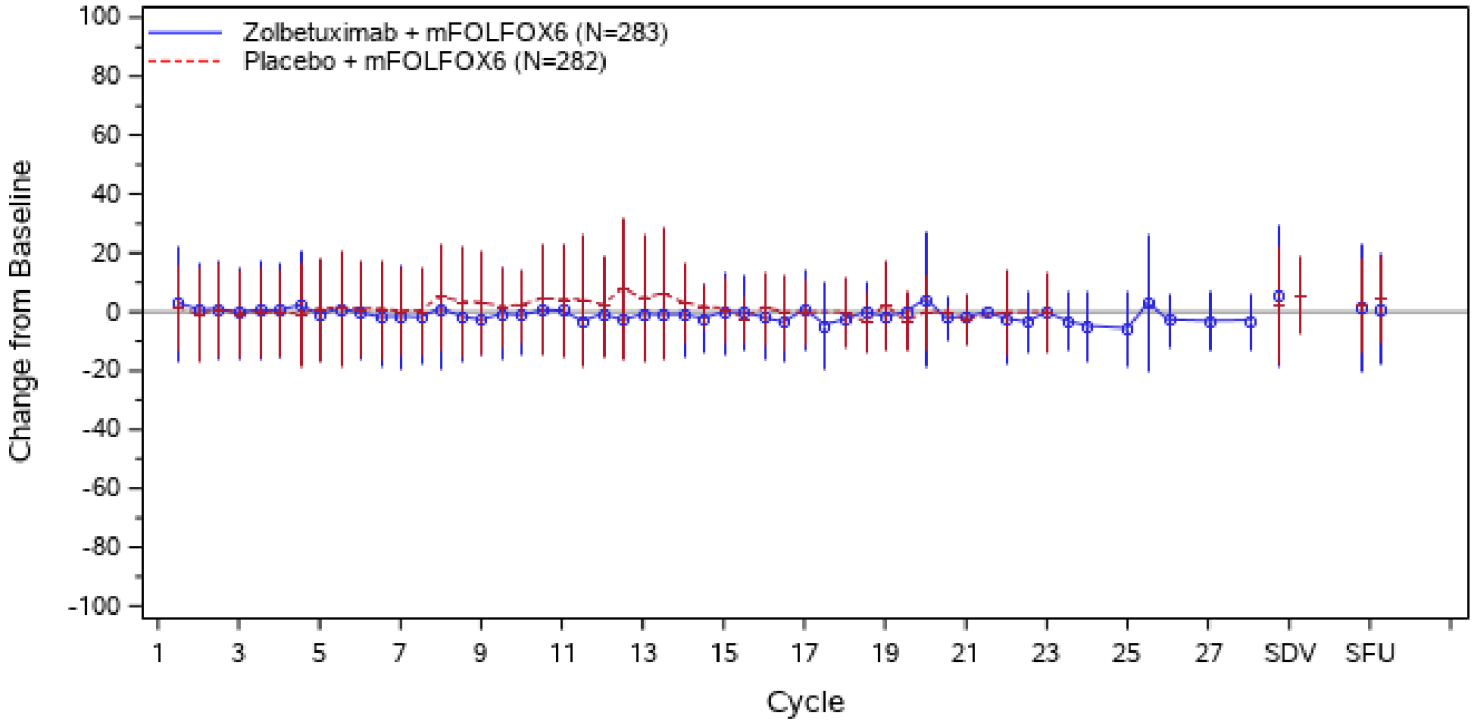
Figure 301.3.3002.32: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble with Coughing - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.33: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking - Full Analysis Set

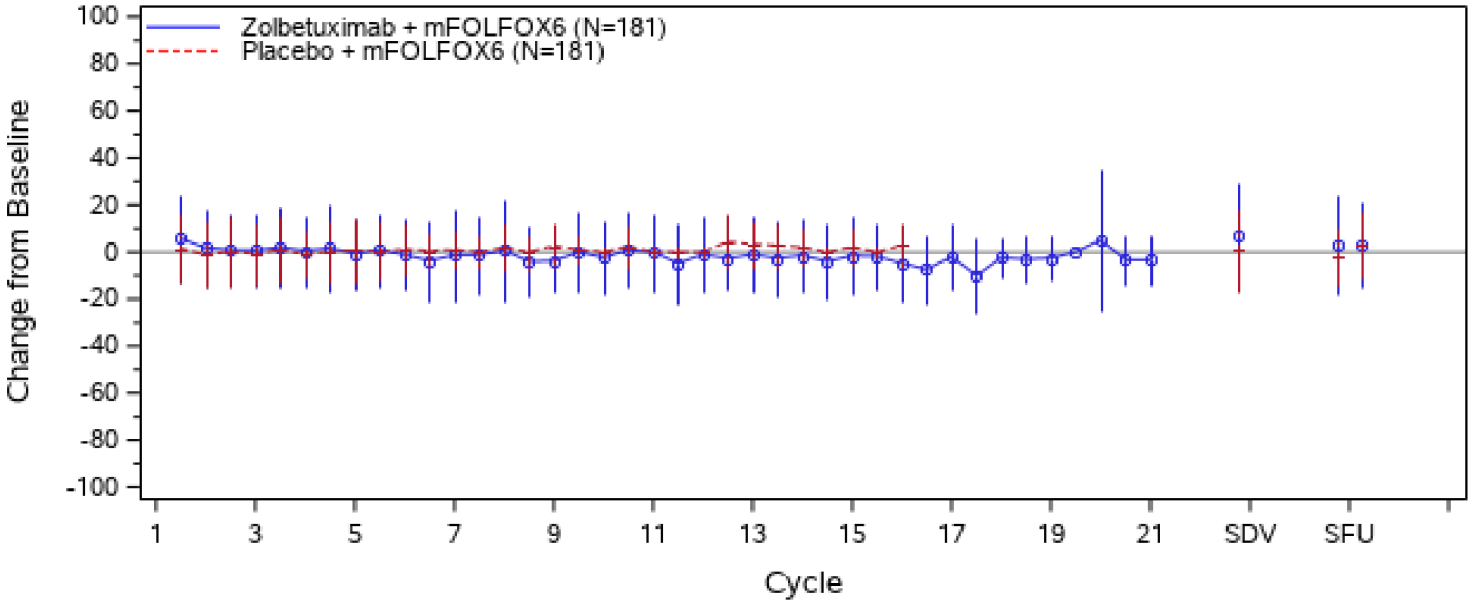


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.33.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

Age Group 1: <=65 years

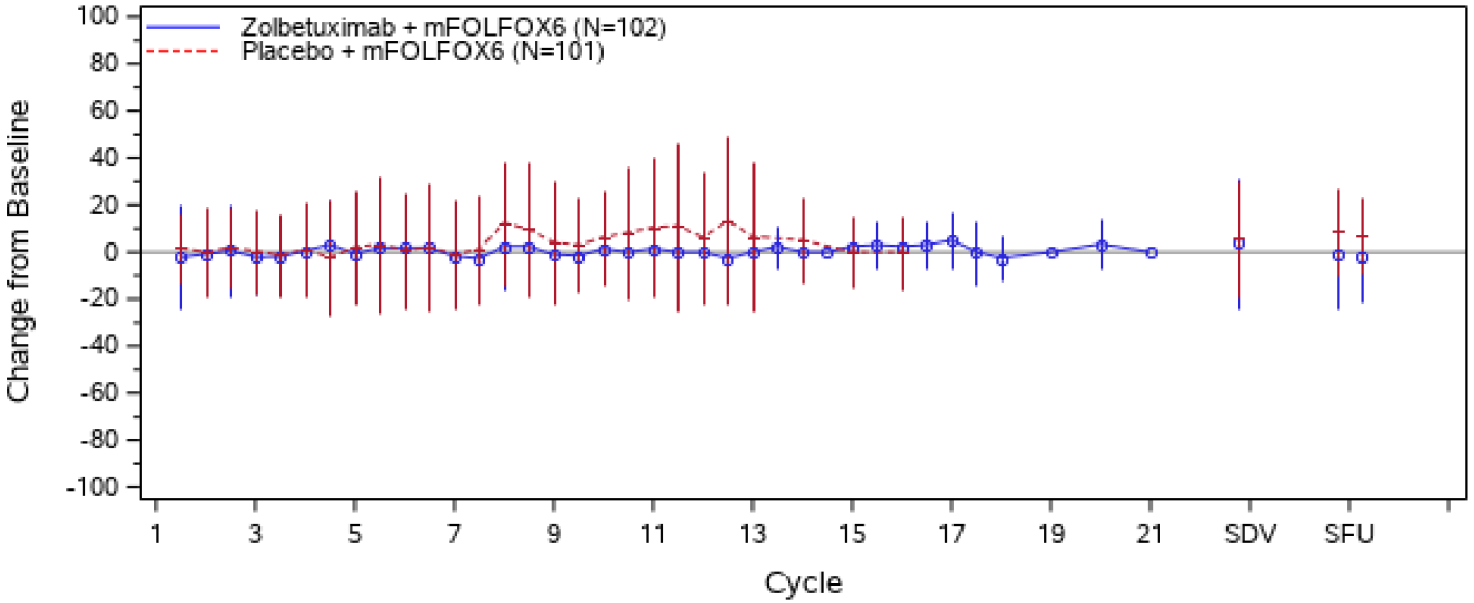


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

Figure 301.3.3002.33.1: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Trouble Talking by Age Group 1 - Full Analysis Set

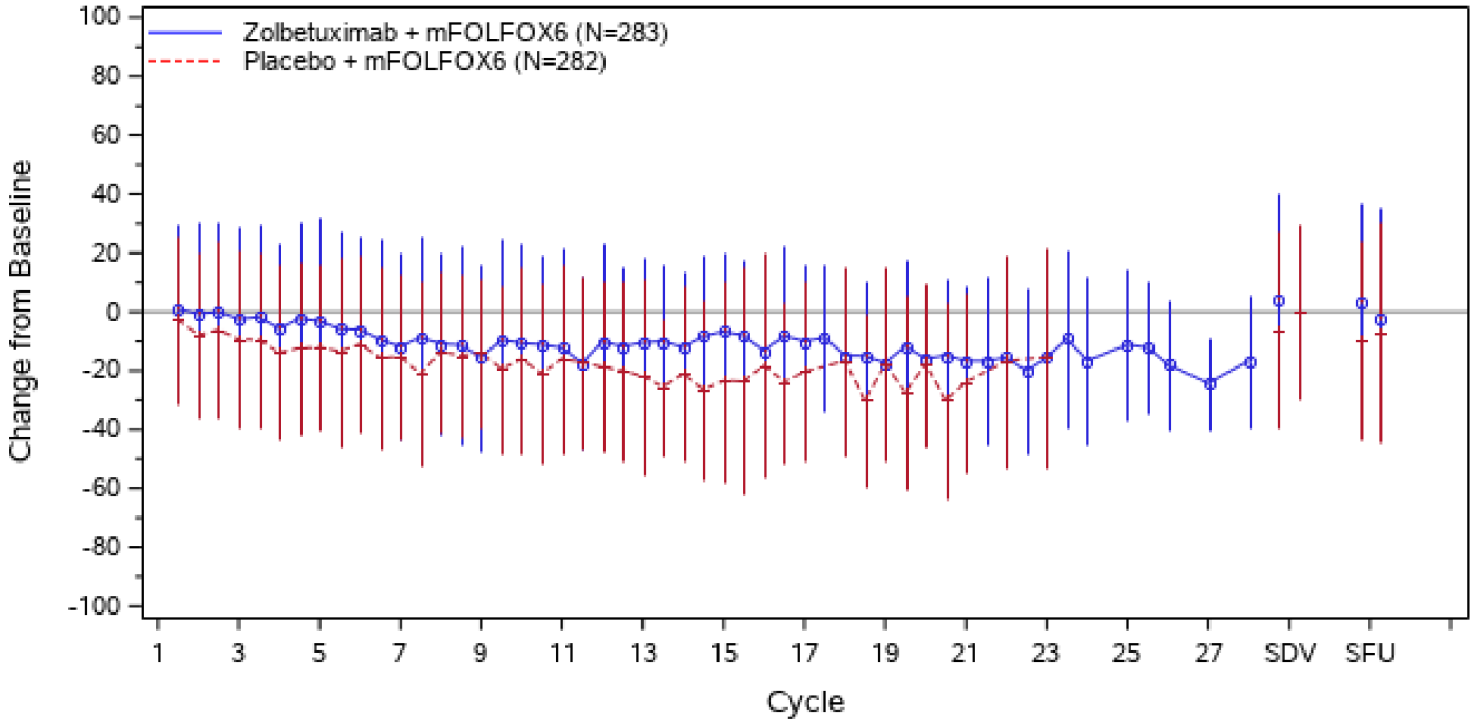
Age Group 1: >65 years



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
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: 08SEP23

The SAS System

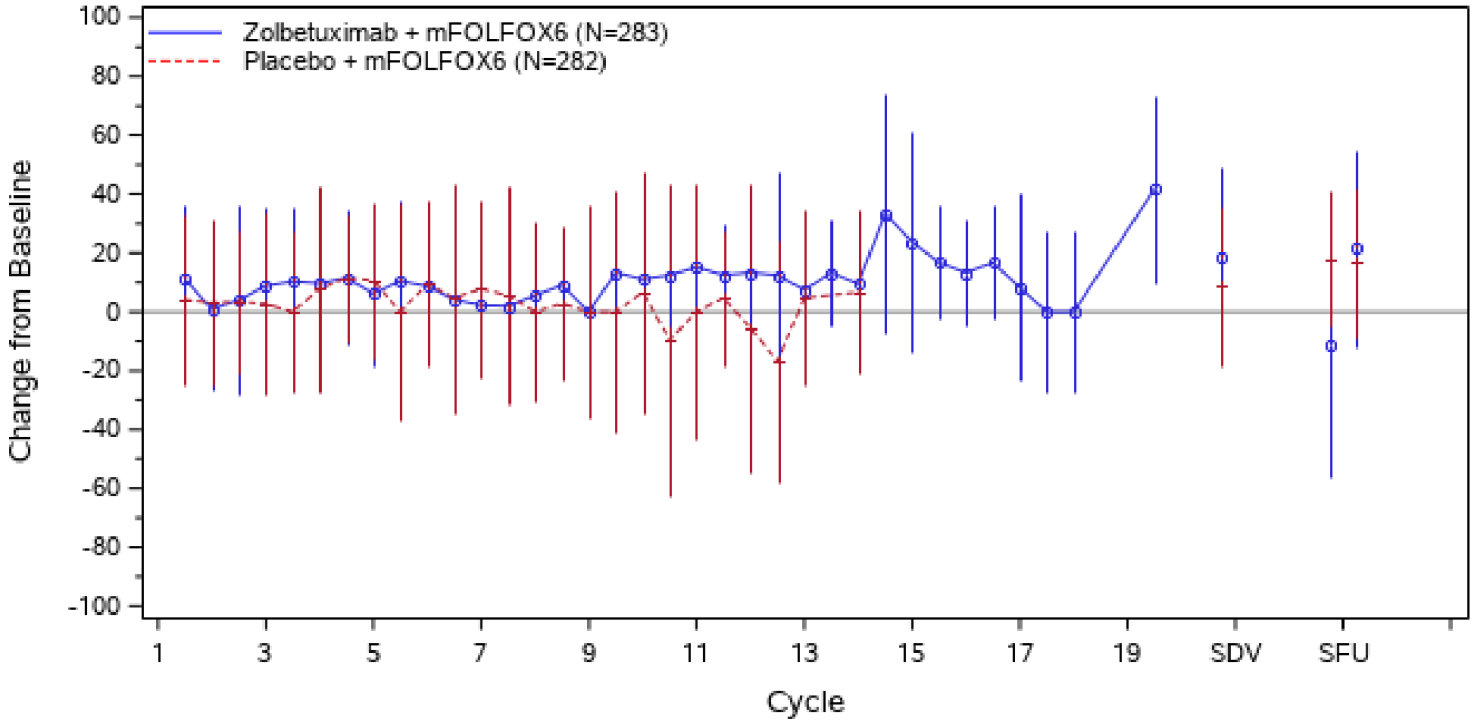
Figure 301.3.3002.34: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Weight Loss - Full Analysis Set



Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.3002.35: EORTC QLQ-OG25 - Plot of Mean Change from Baseline of Hair Loss - Full Analysis Set

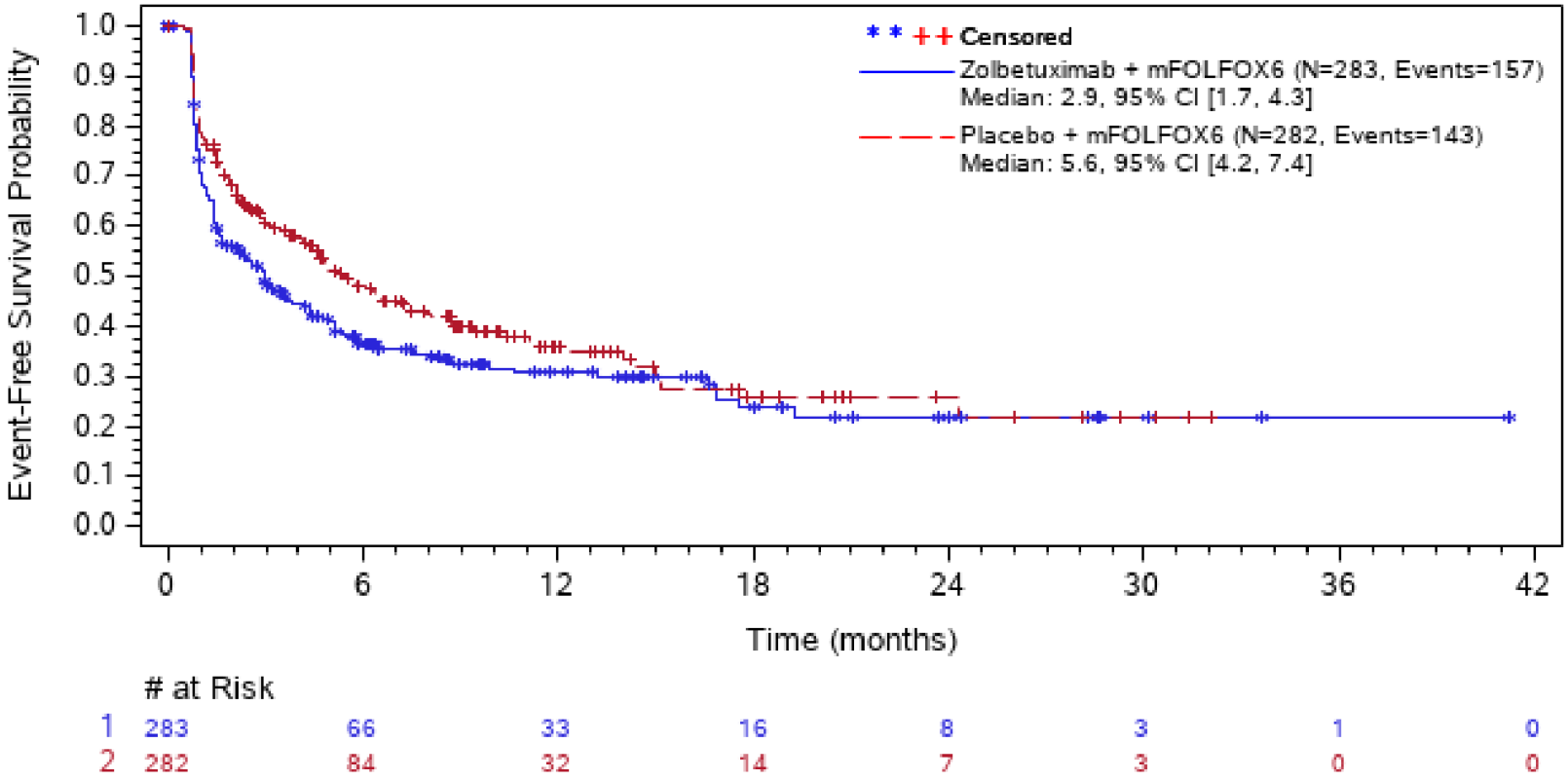


Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Symptomatik anhand des EORTC QLQ-OG25

5. Kaplan-Meier-Plots

Figure 301.3.3004.20: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

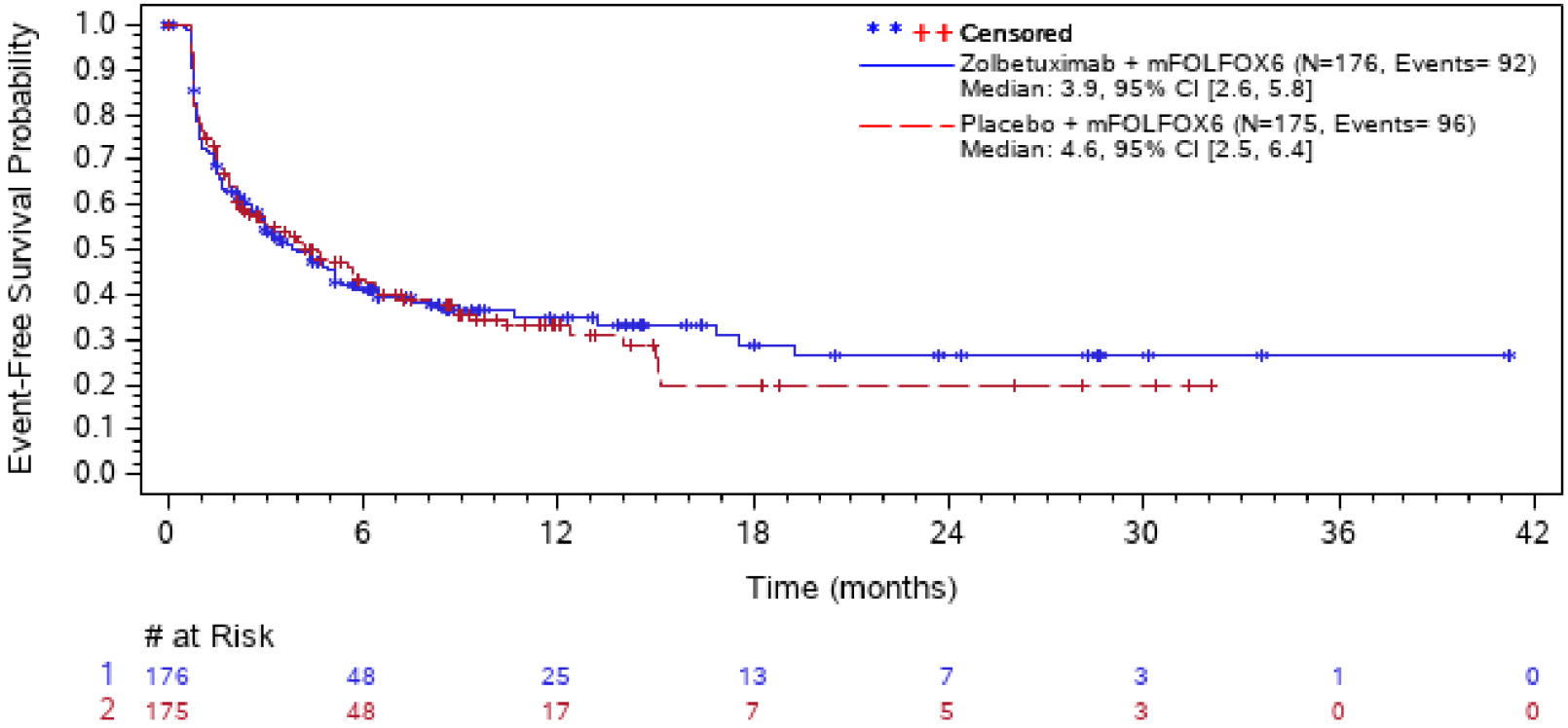
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.20.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - Full Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

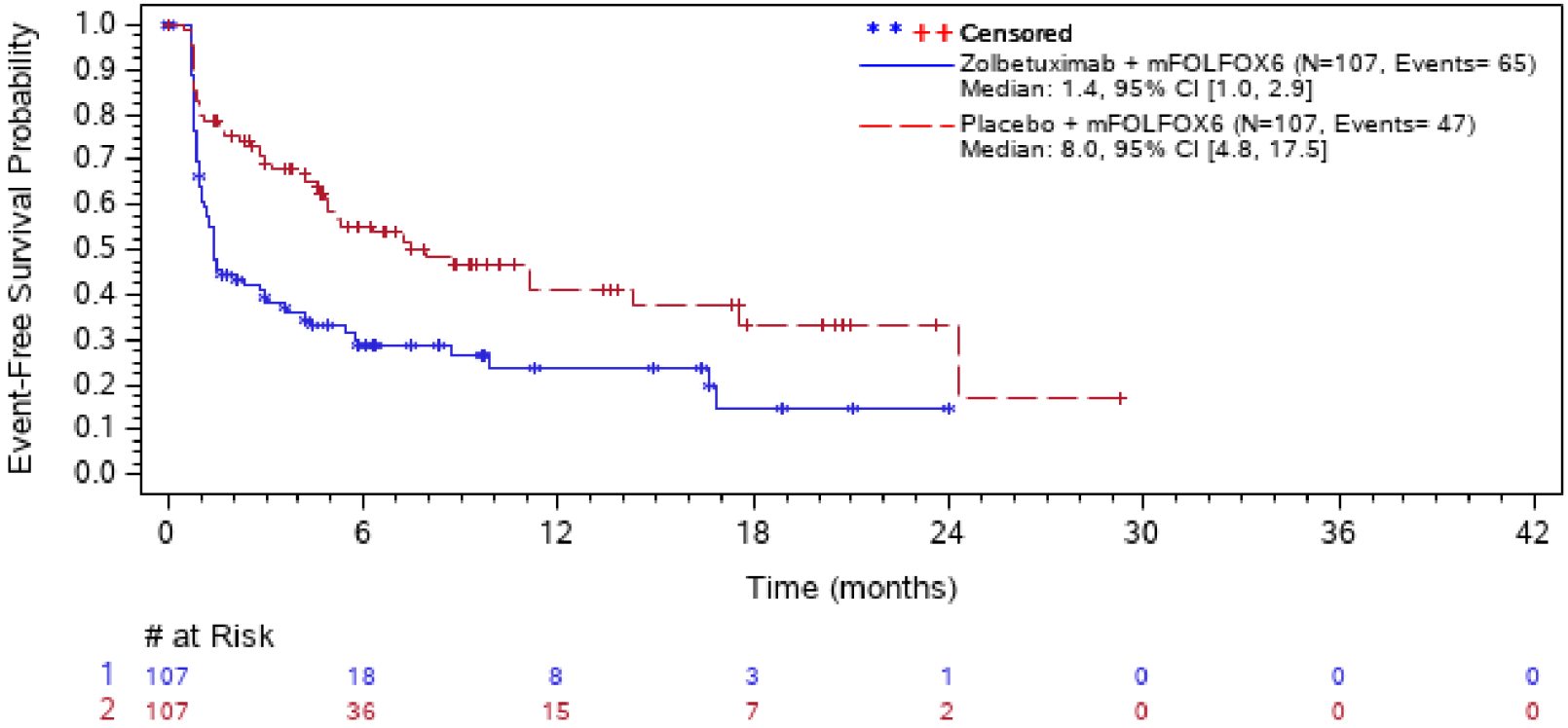
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.20.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dysphagia by Sex (MID=10) - Full Analysis Set

Sex: Female



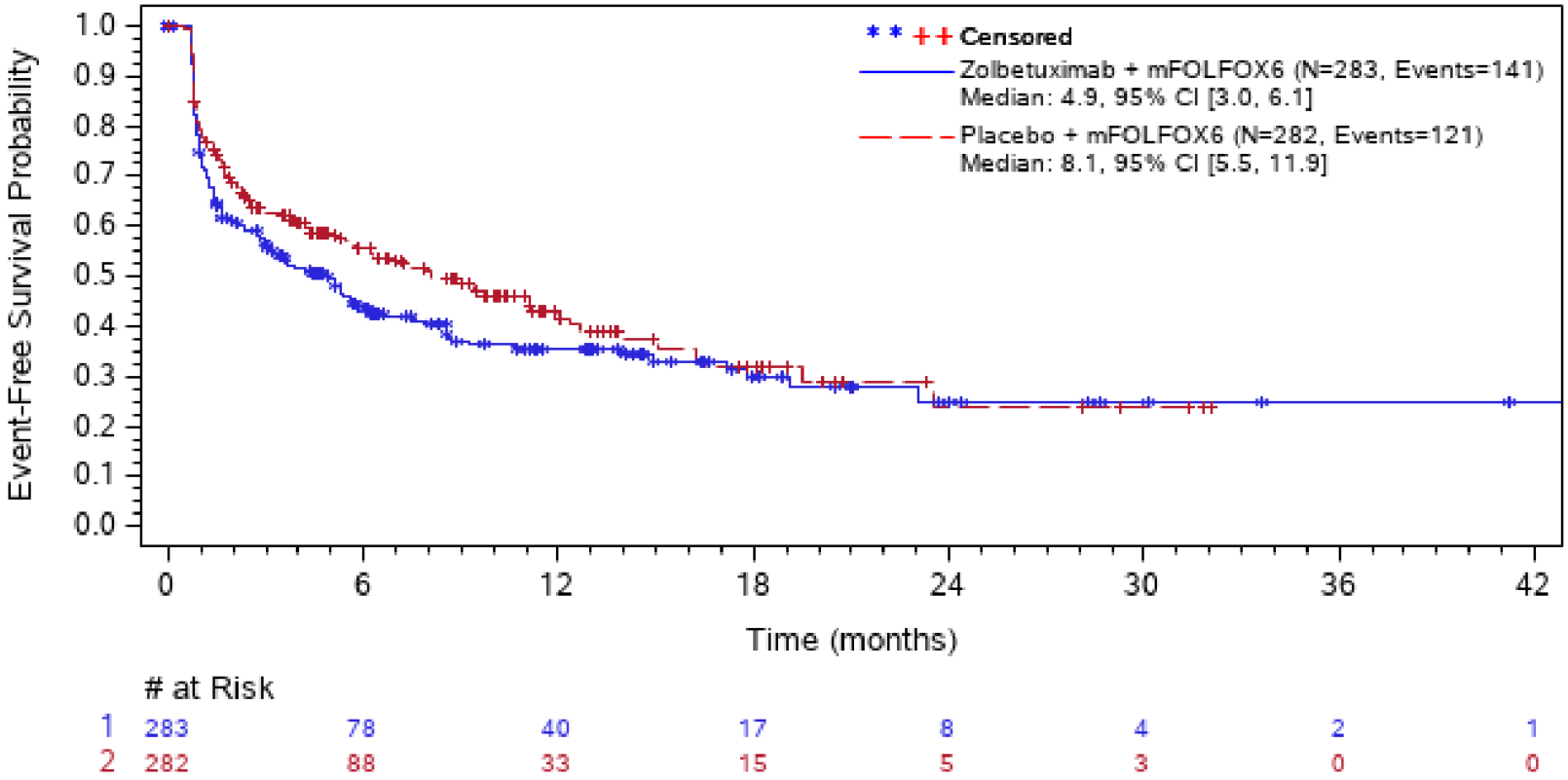
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.21: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating Restrictions (MID=10) - Full Analysis Set



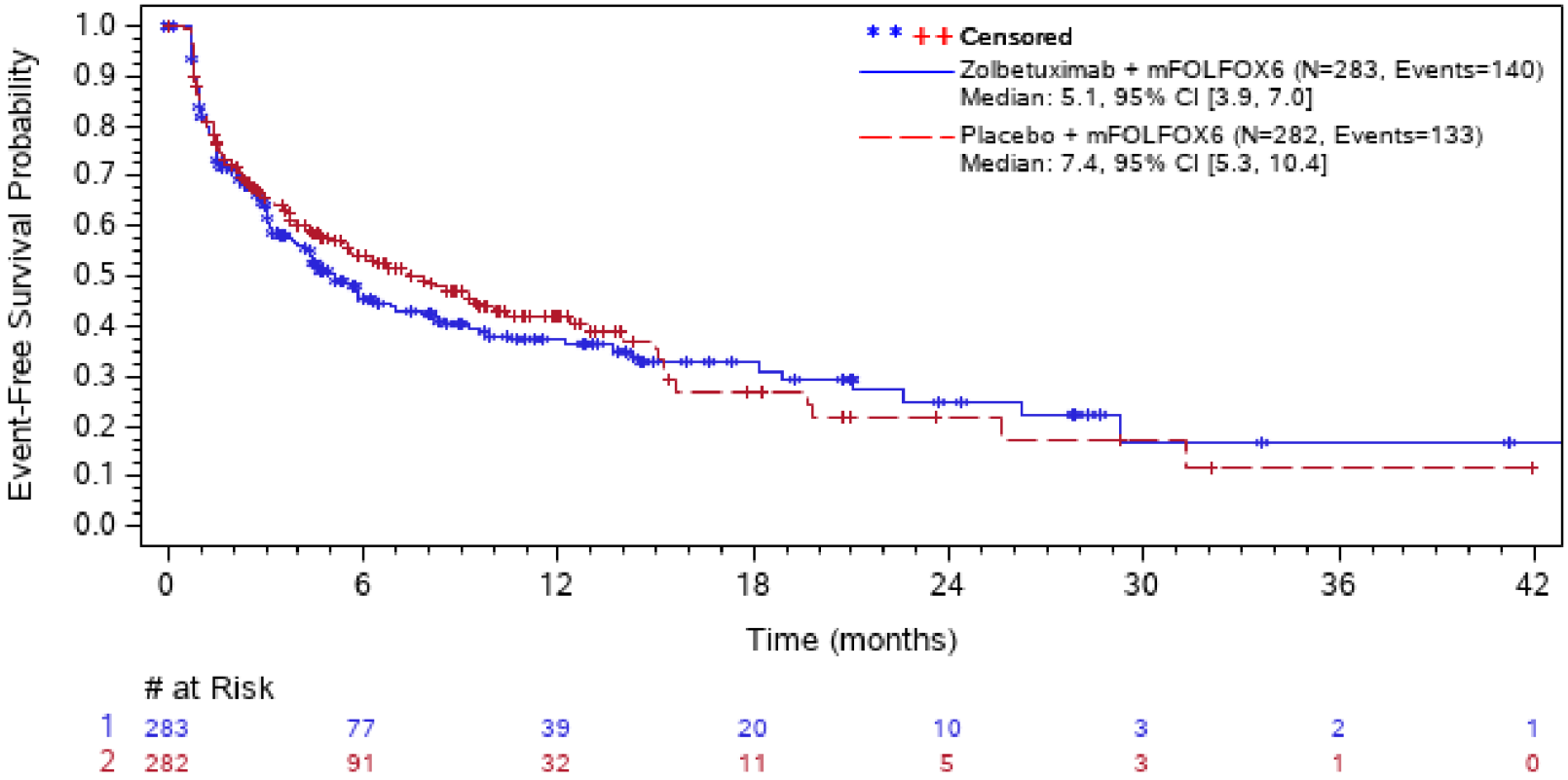
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.22: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

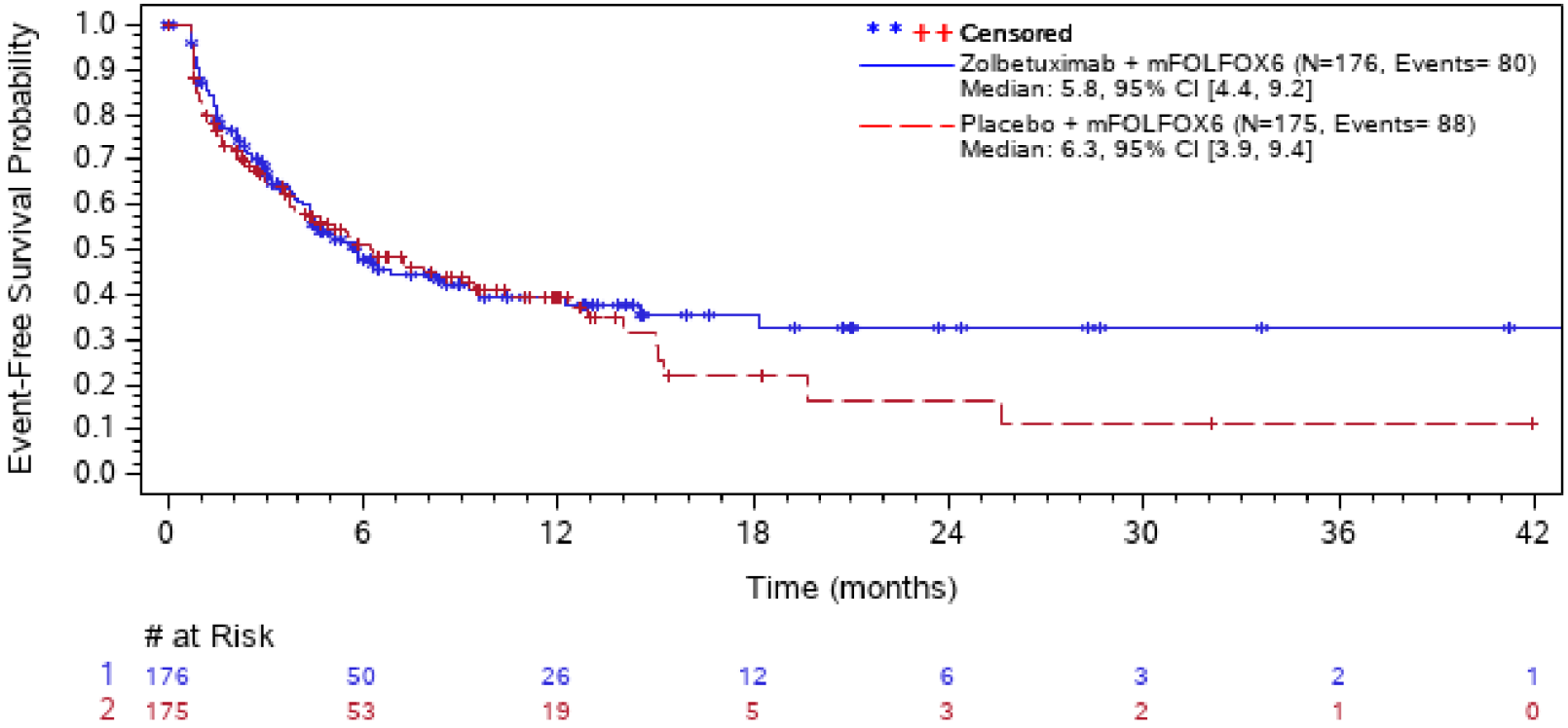
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.22.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux by Sex (MID=10) - Full Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

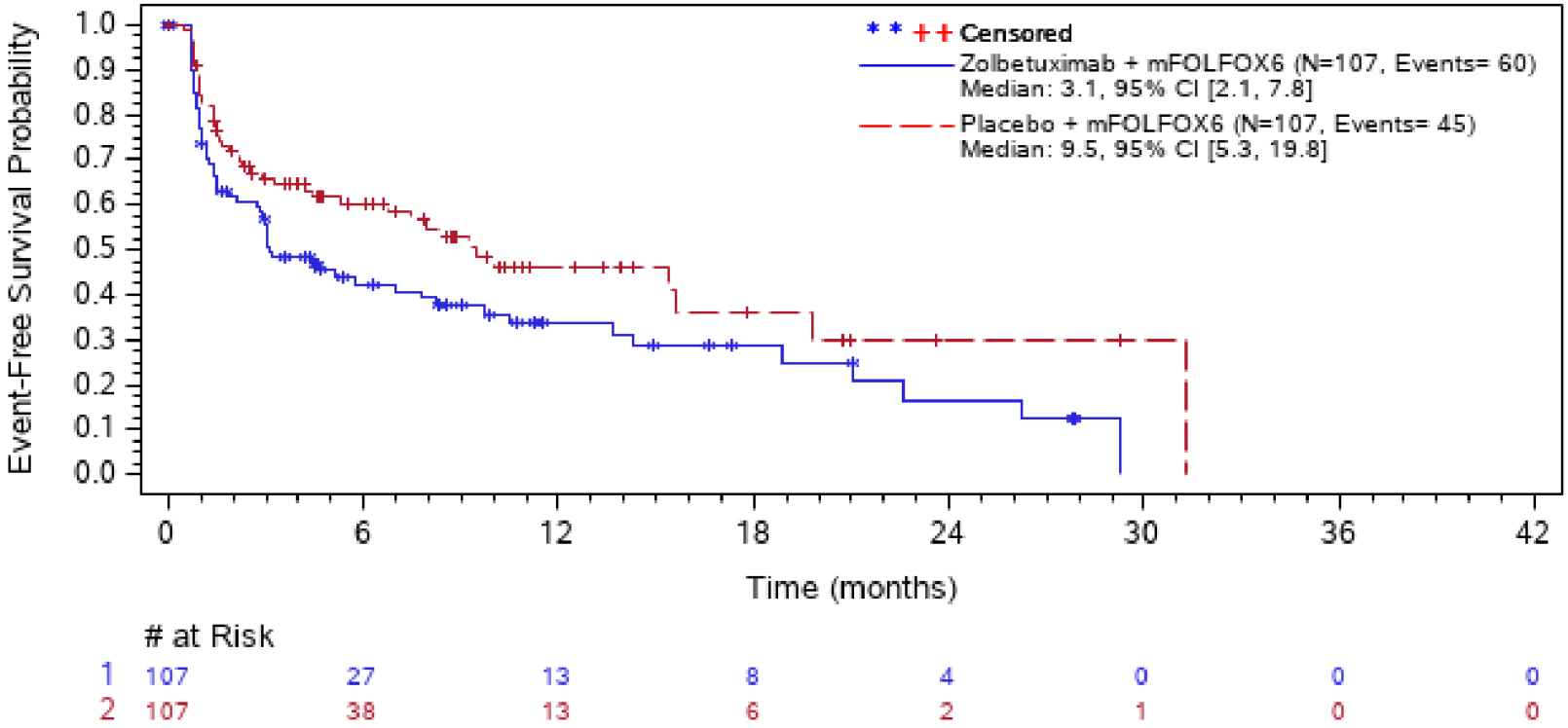
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.22.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Reflux by Sex (MID=10) - Full Analysis Set

Sex: Female



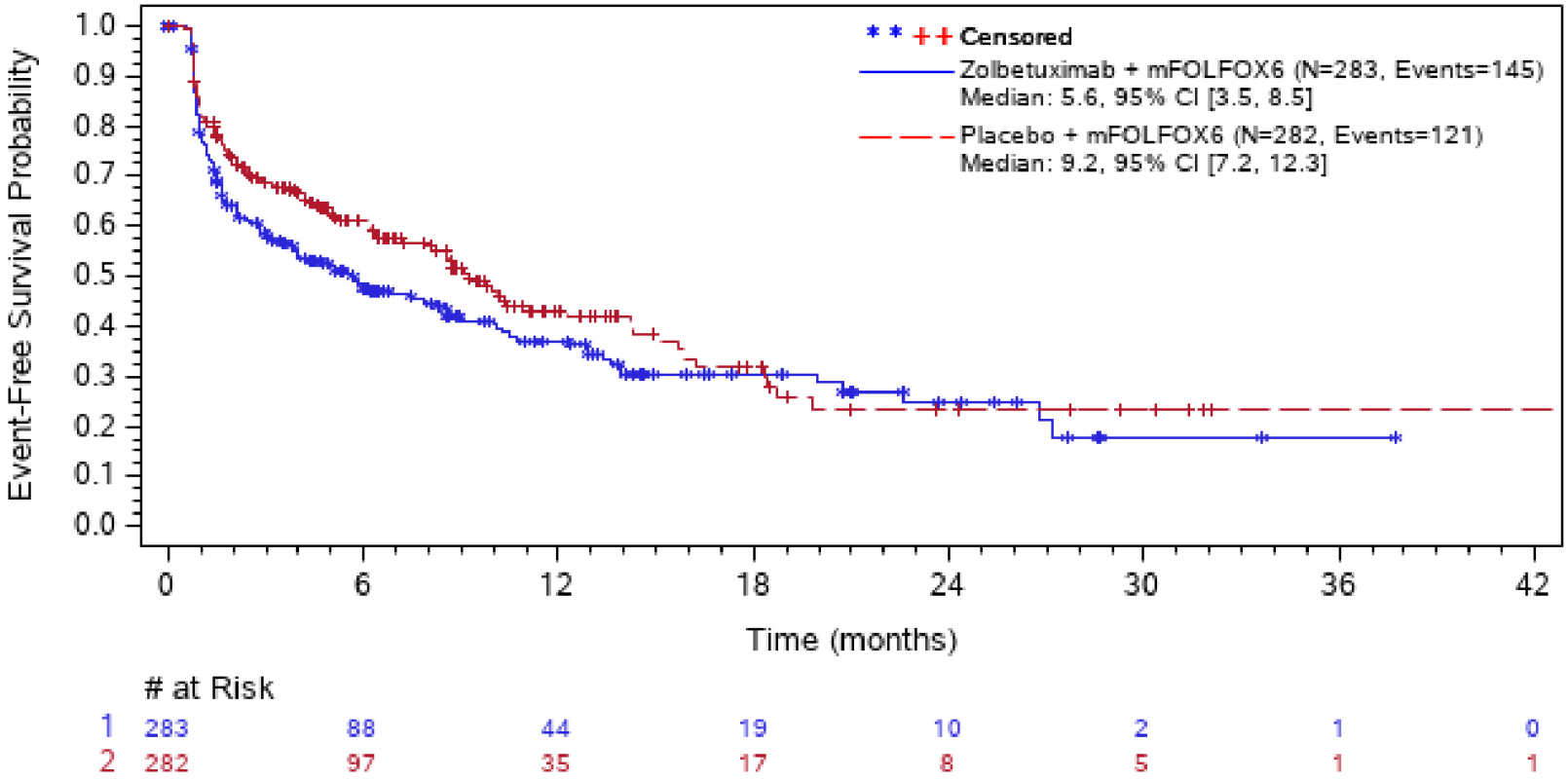
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.23: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Odynophagia (MID=10) - Full Analysis Set



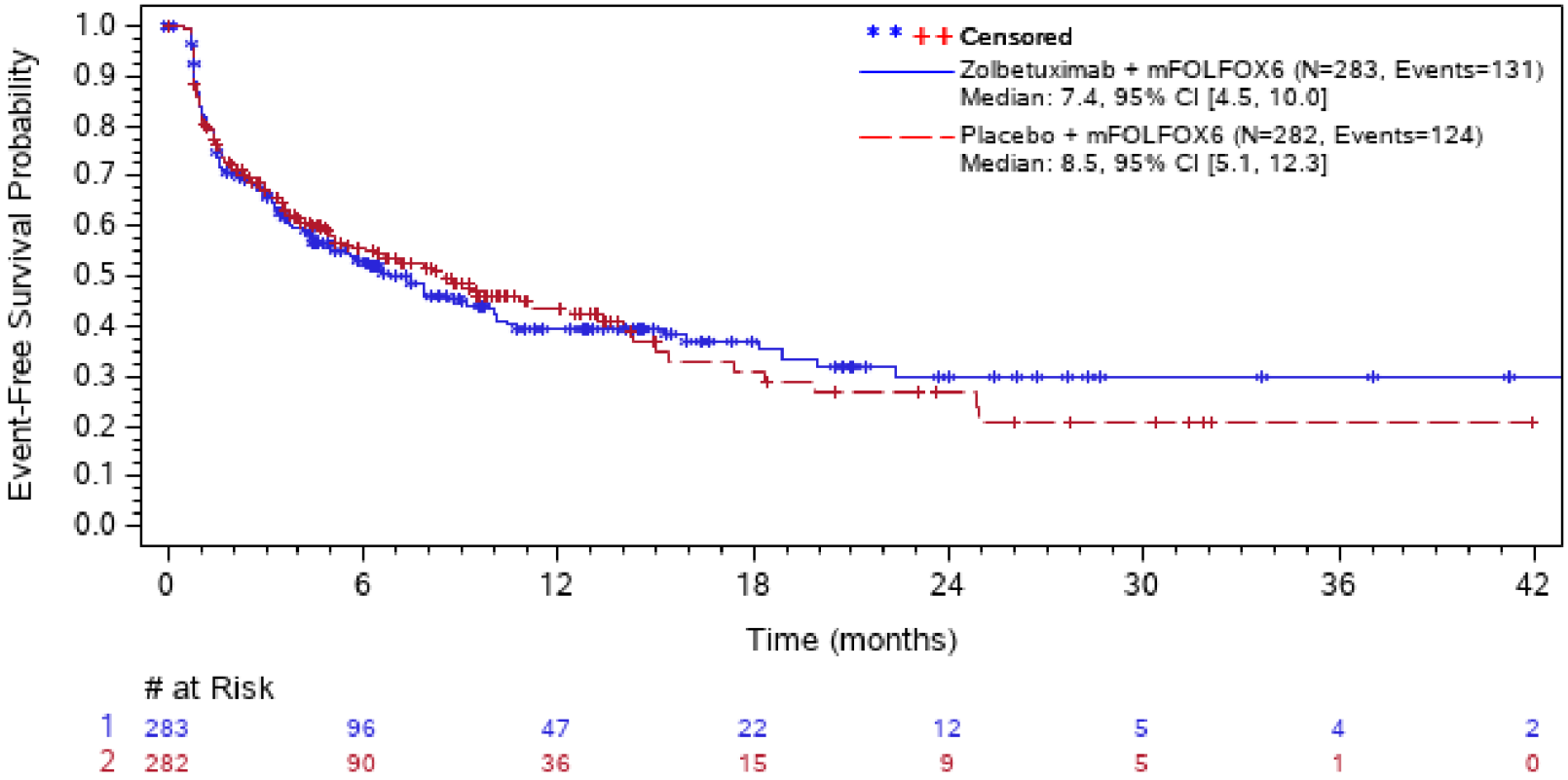
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.24: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Pain and Discomfort (MID=10) - Full Analysis Set



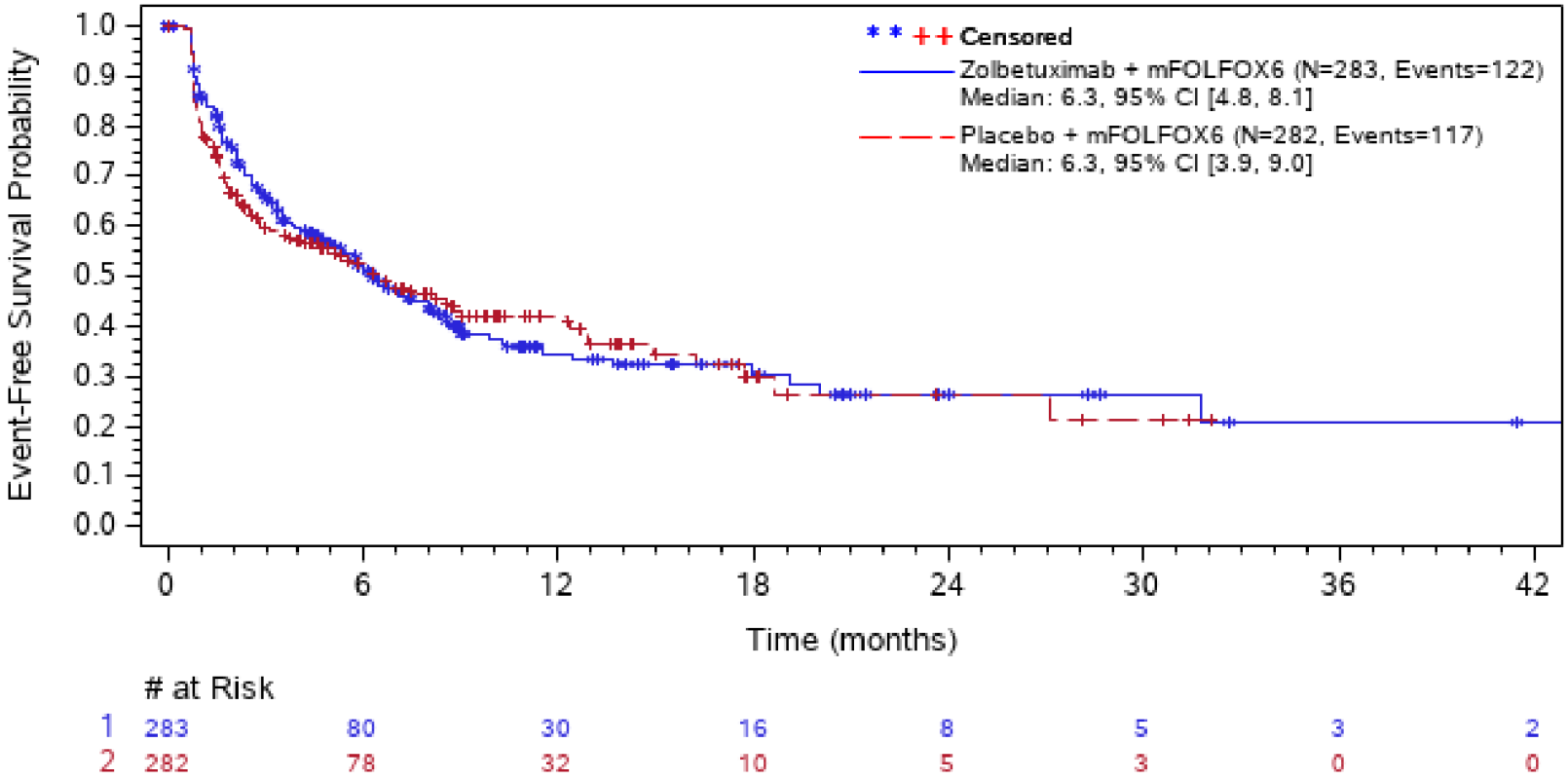
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.25: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

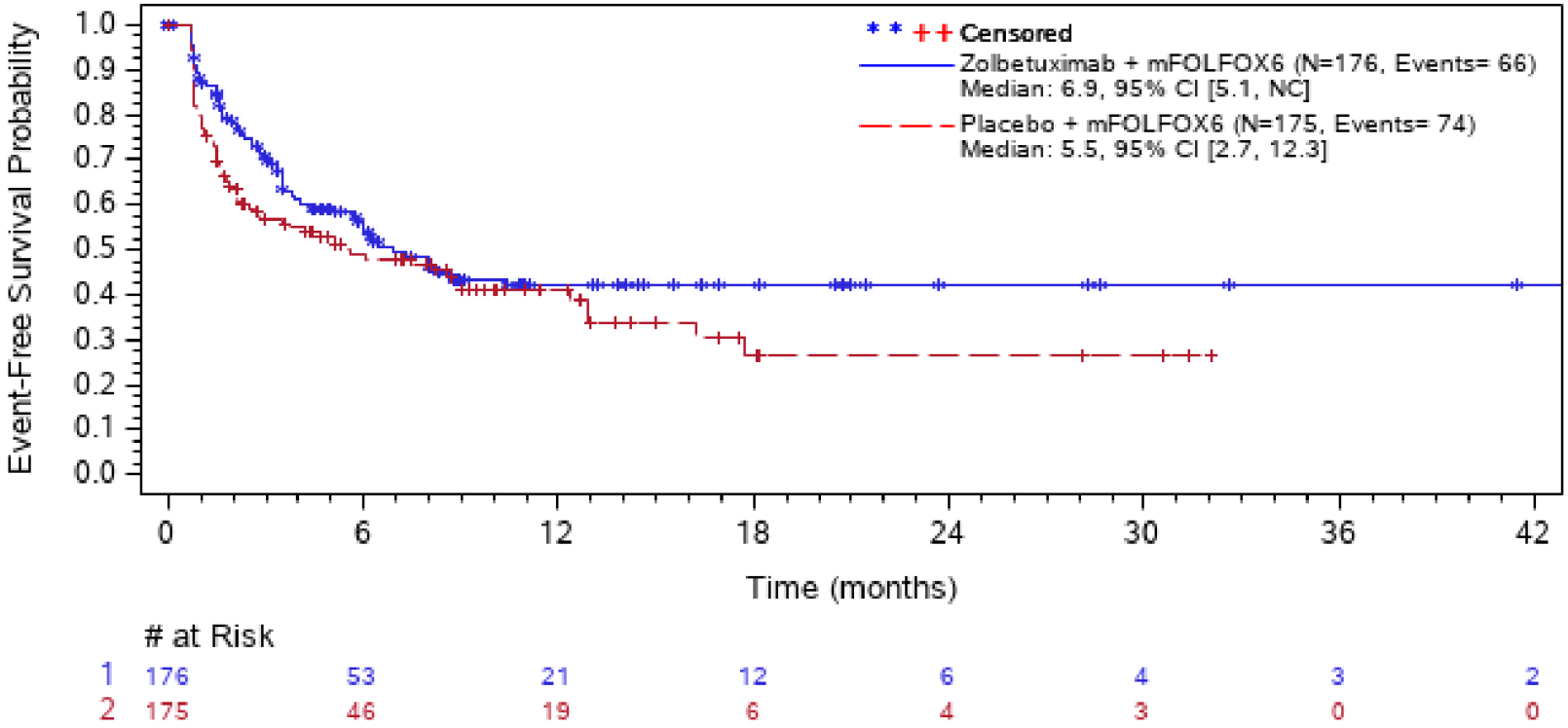
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.25.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety by Sex (MID=10) - Full Analysis Set

Sex: Male



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

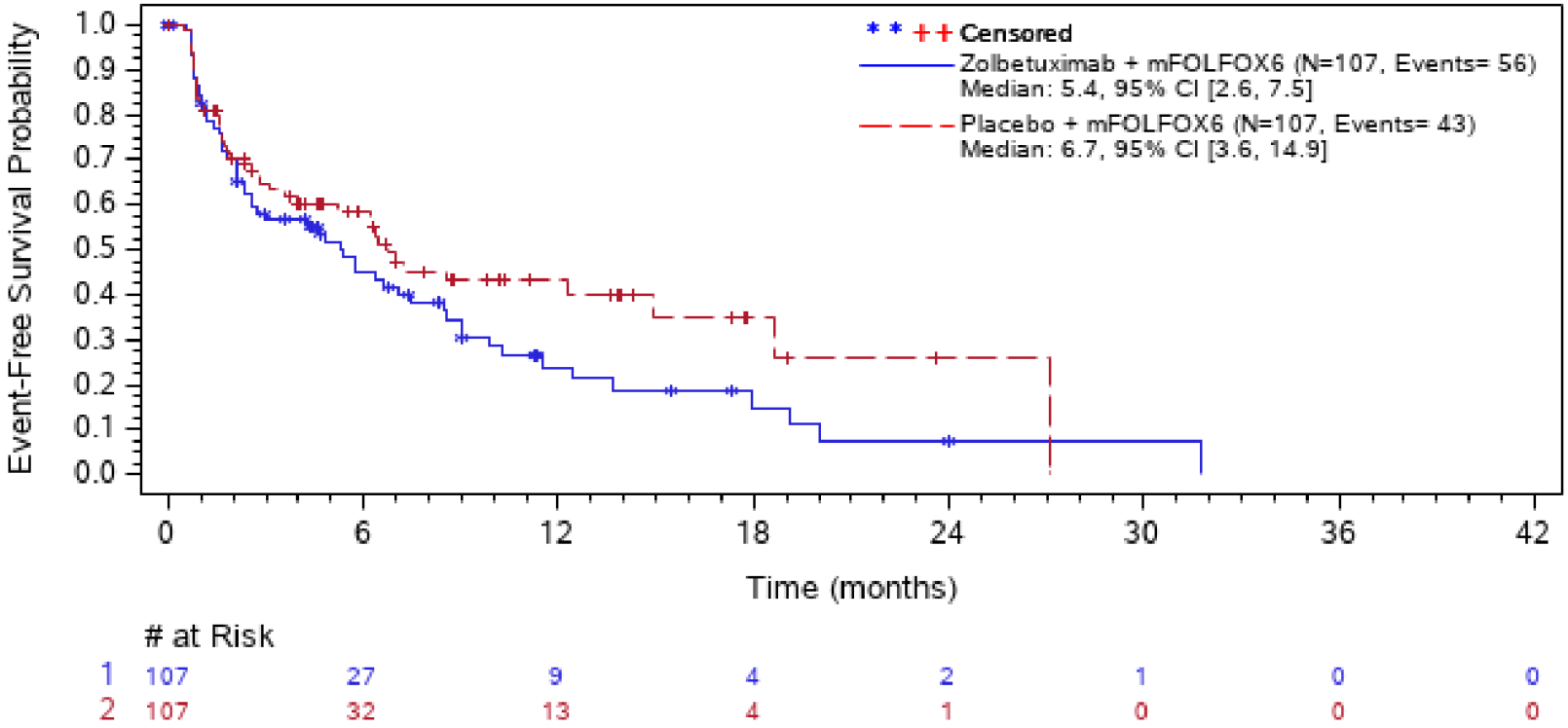
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.25.2: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Anxiety by Sex (MID=10) - Full Analysis Set

Sex: Female



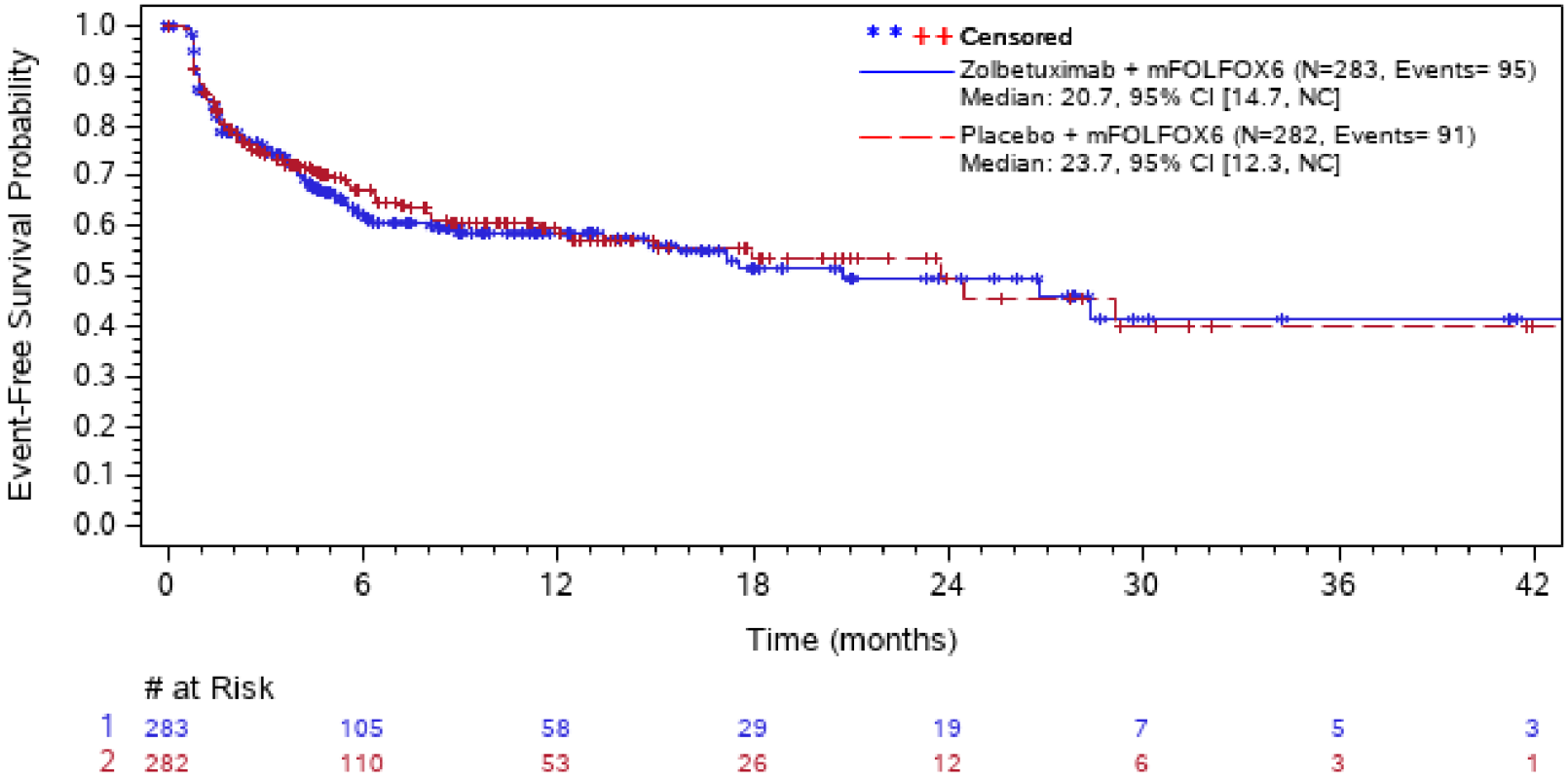
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.26: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Eating in Front of Others (MID=10) - Full Analysis Set



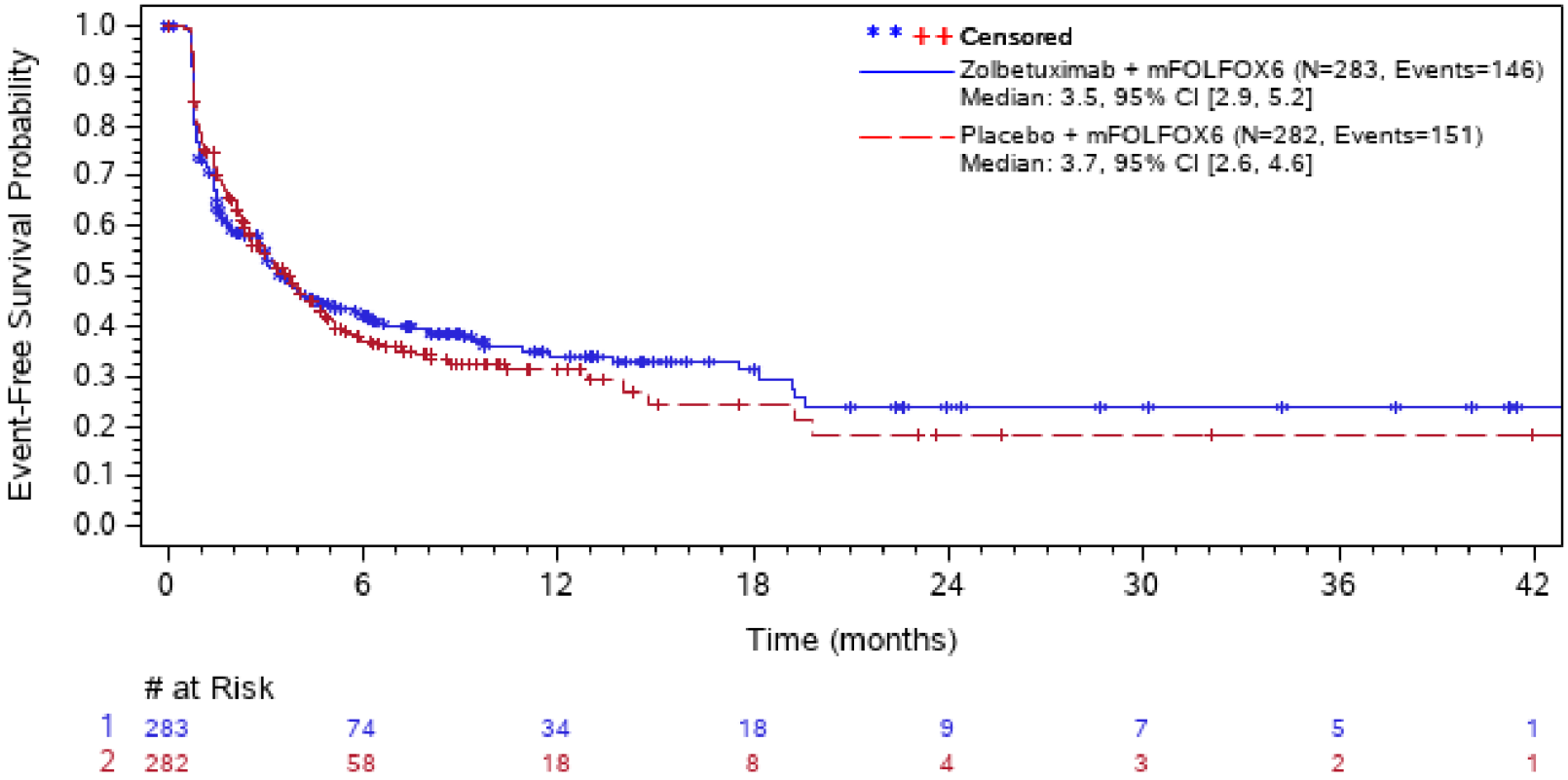
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.27: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Dry Mouth Score (MID=10) - Full Analysis Set



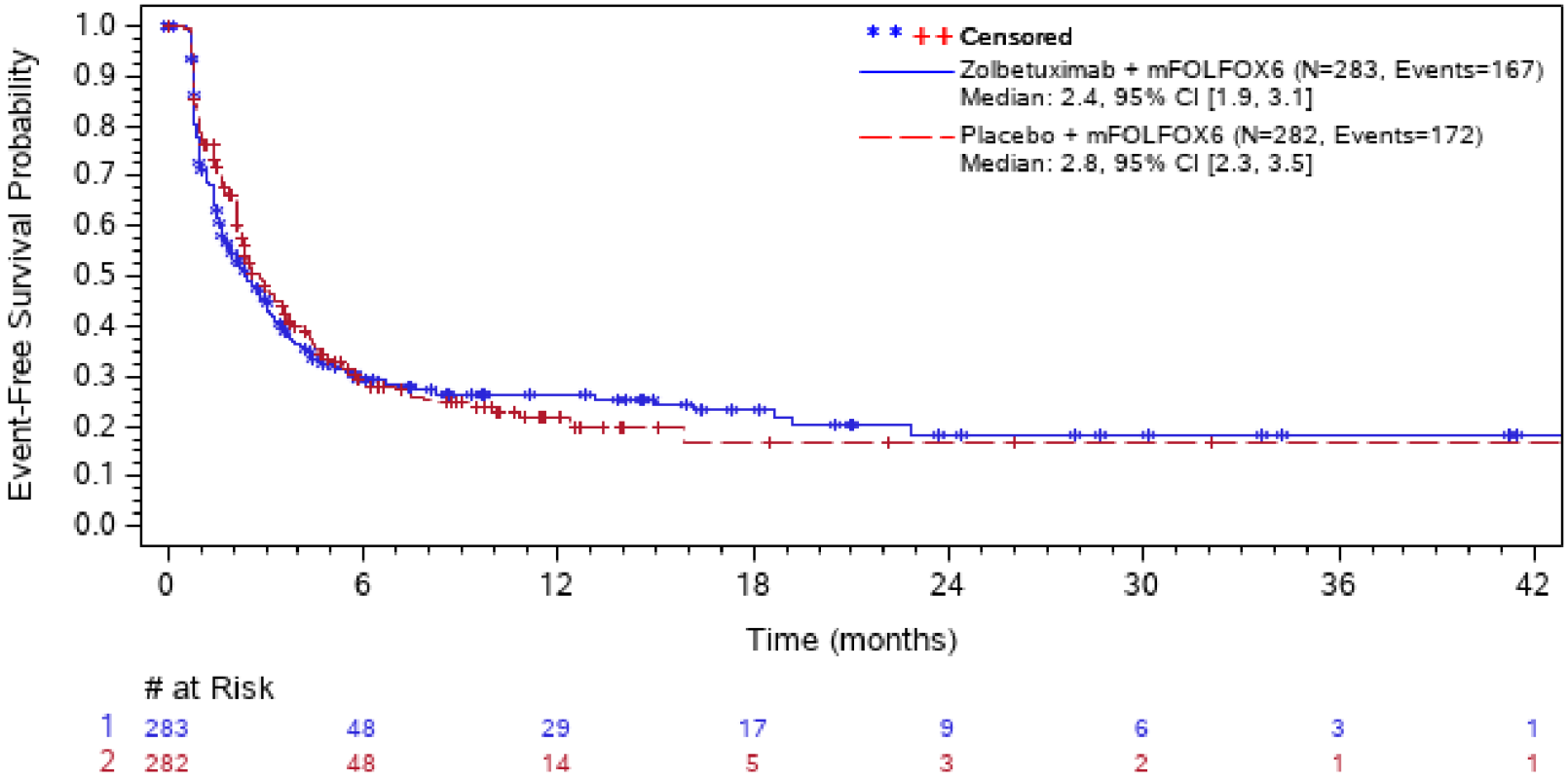
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.28: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Taste (MID=10) - Full Analysis Set



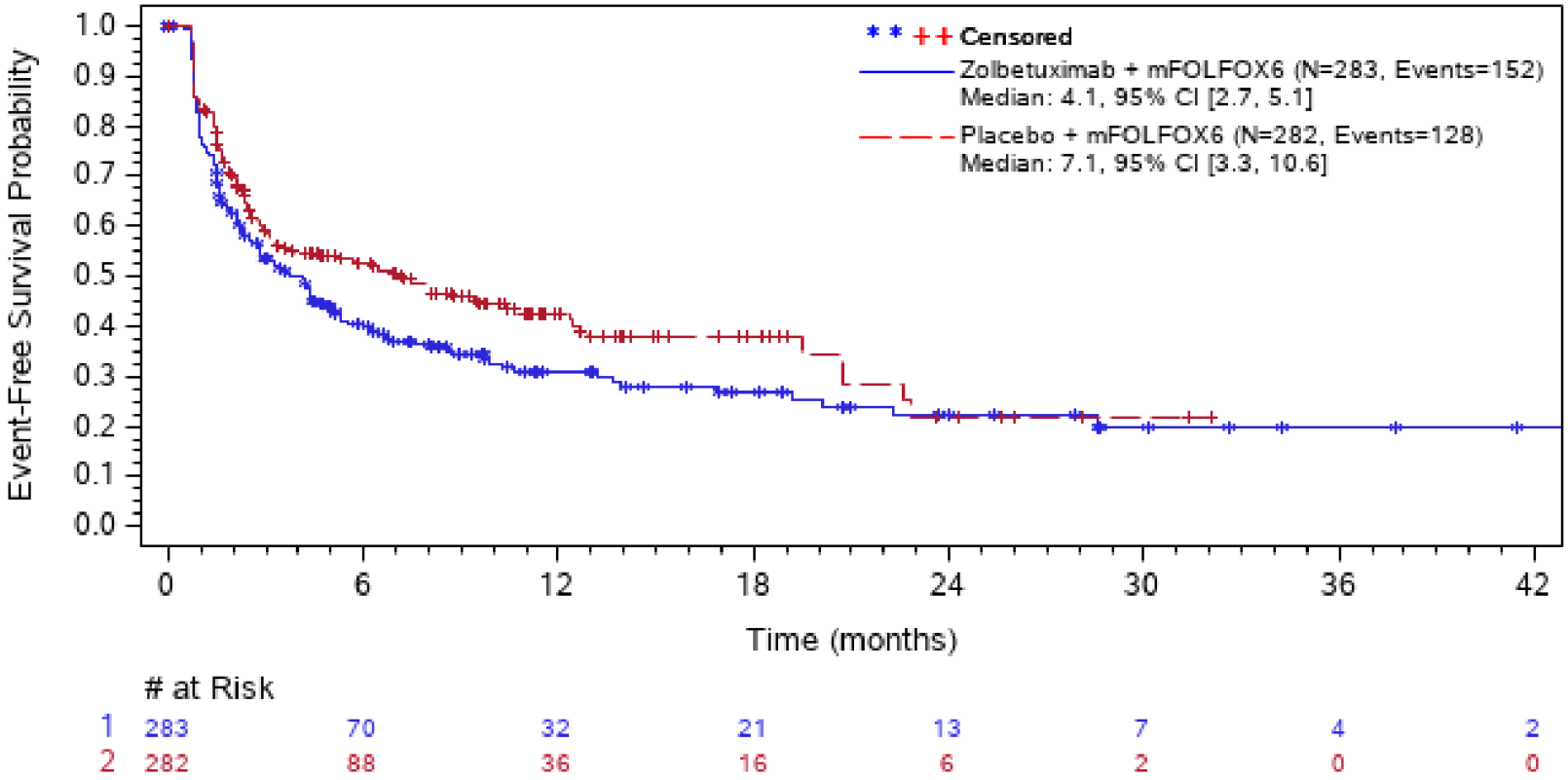
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.29: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

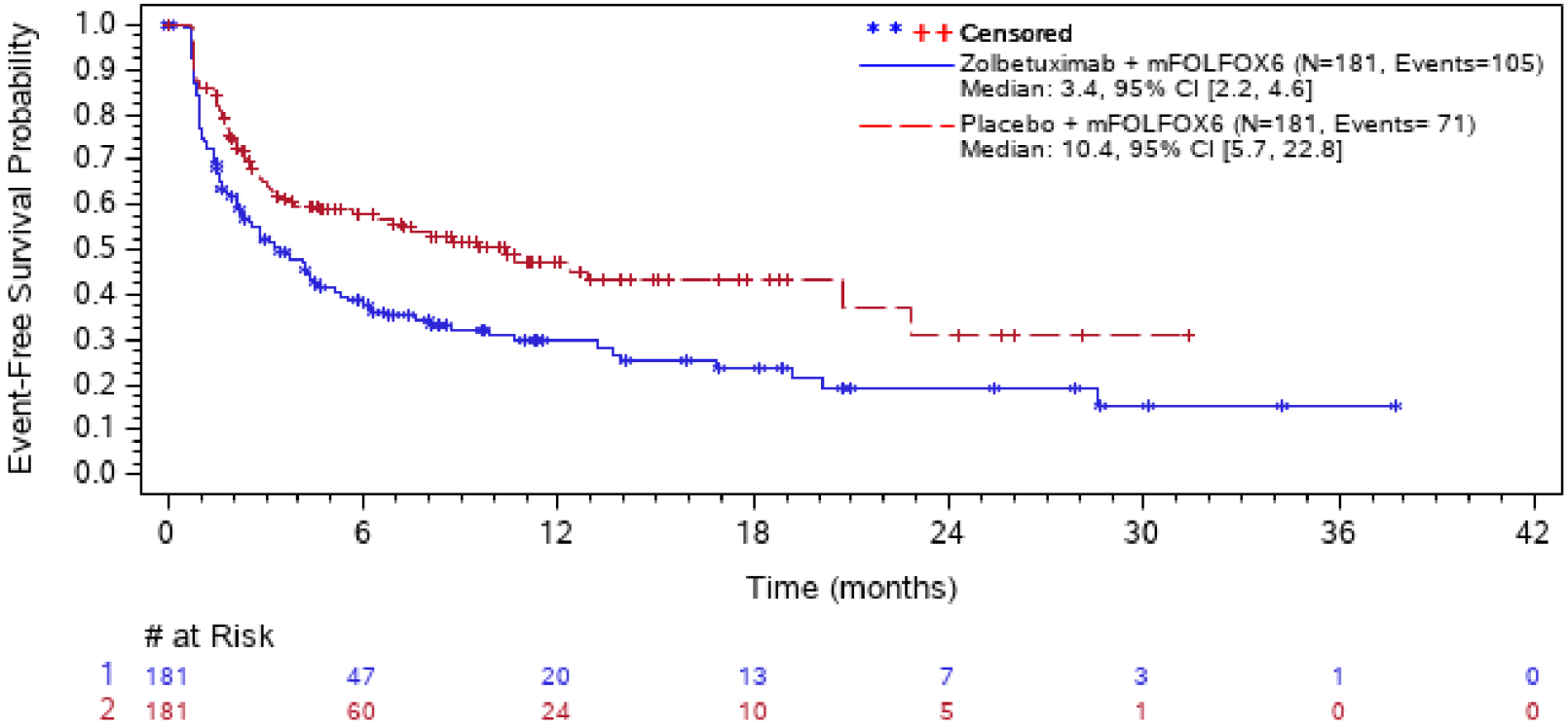
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.29.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

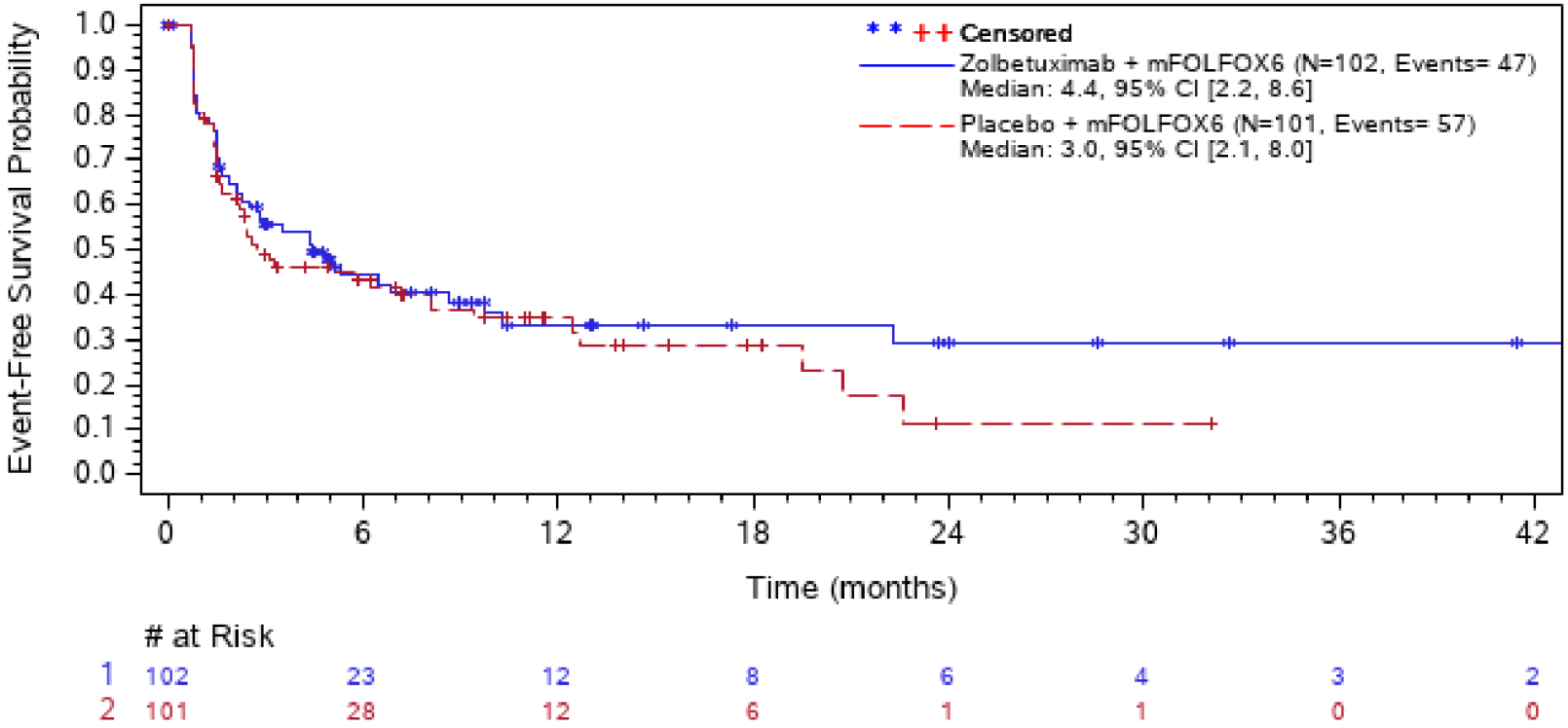
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.29.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Body Image by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



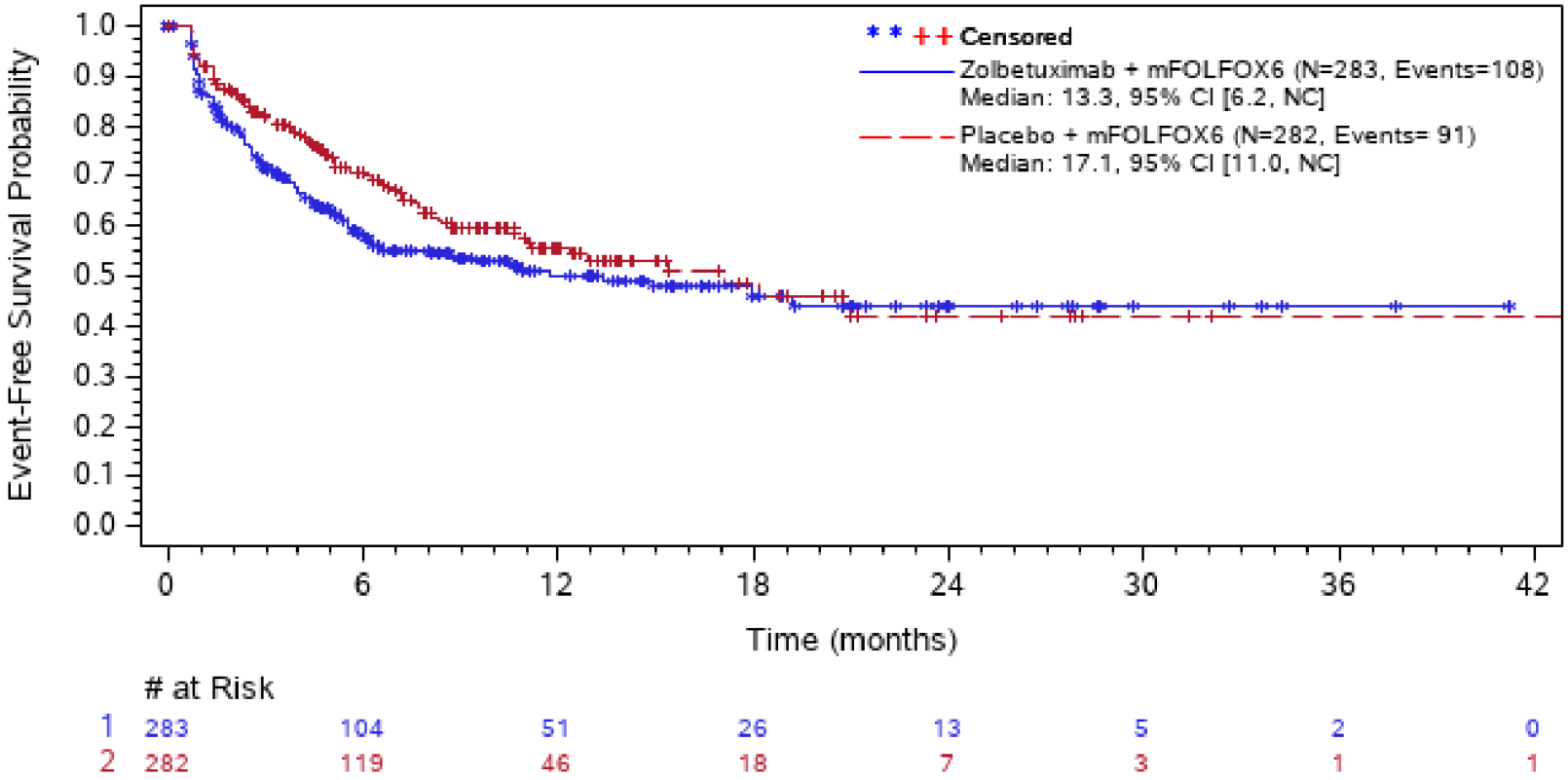
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.30: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

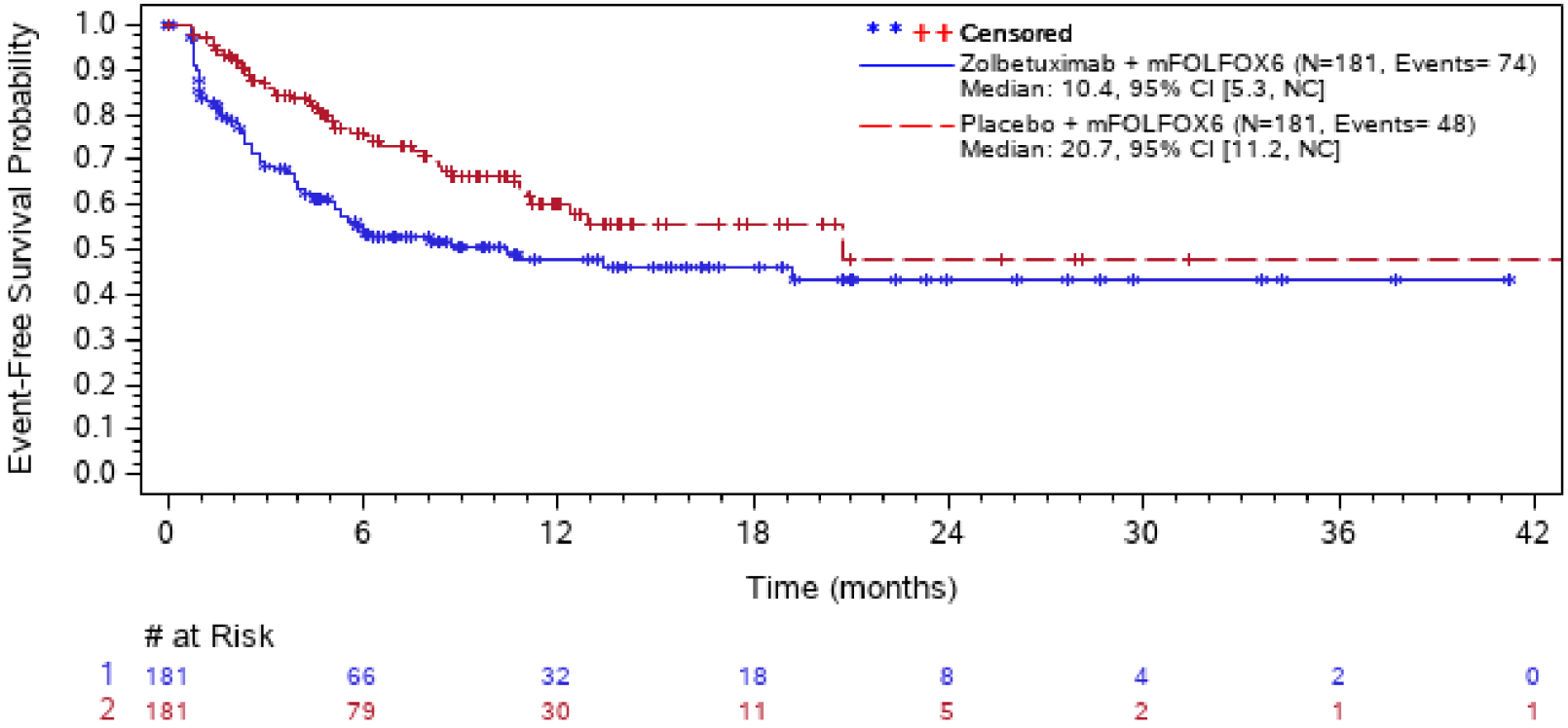
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.30.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

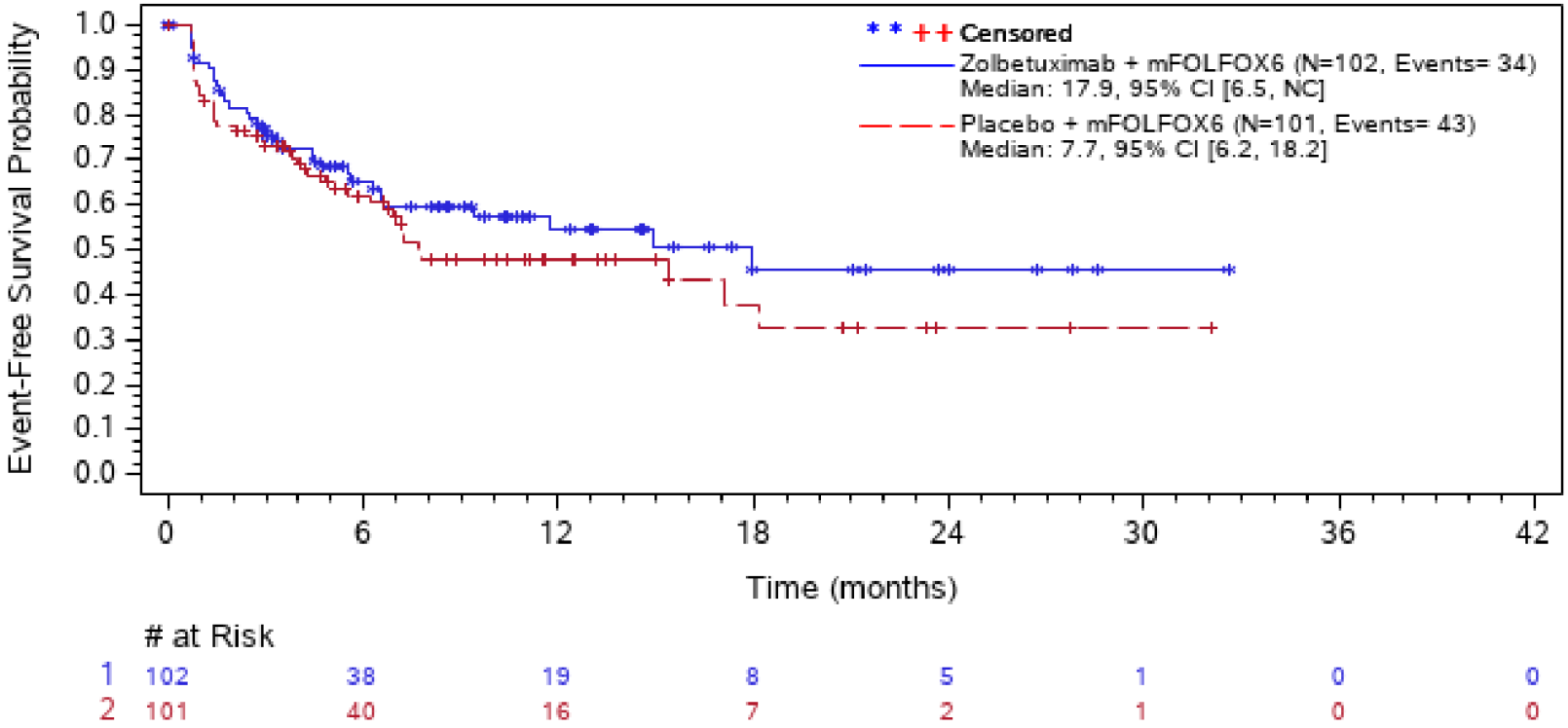
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.30.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Swallowing Saliva by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



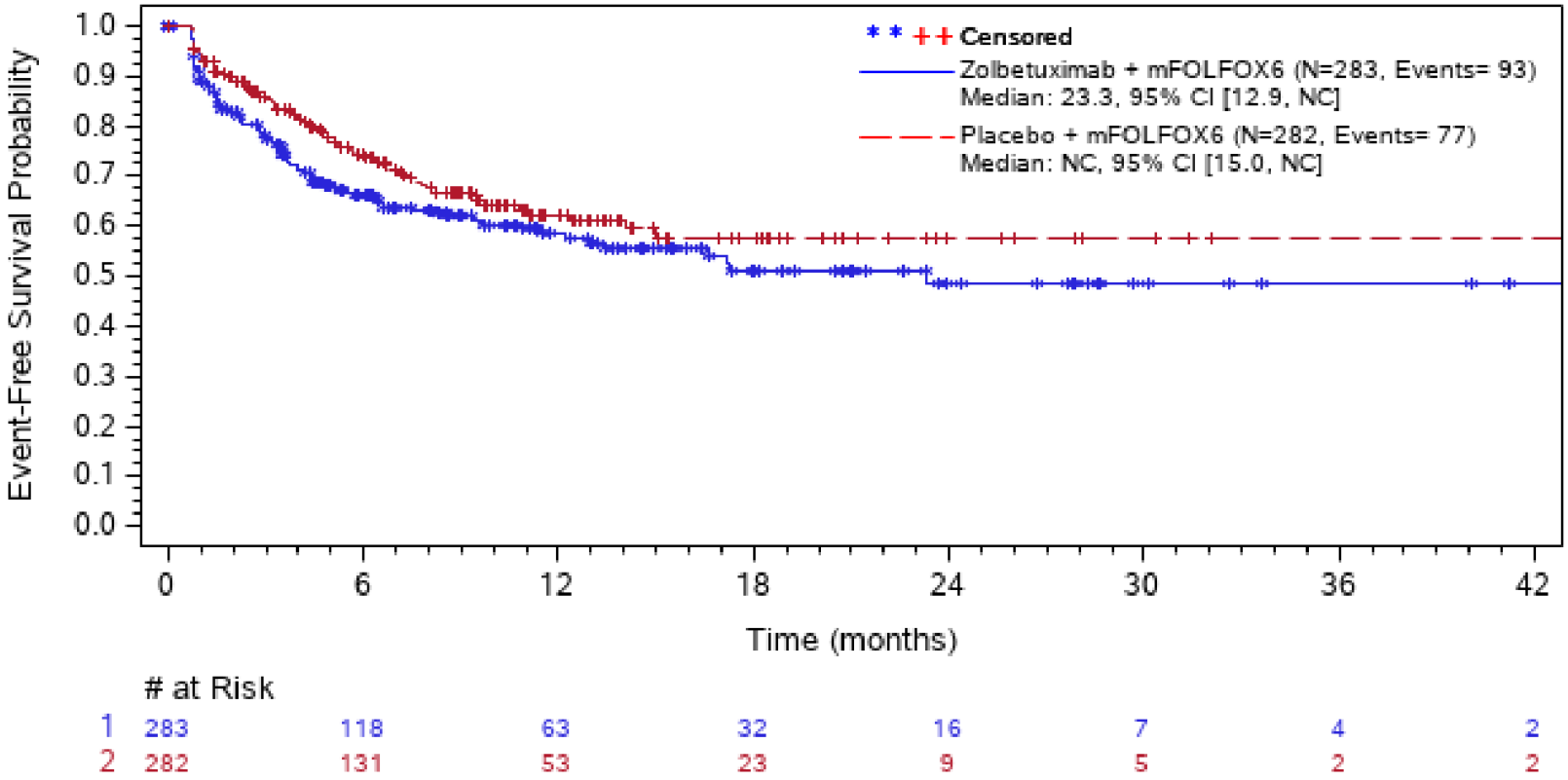
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.31: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

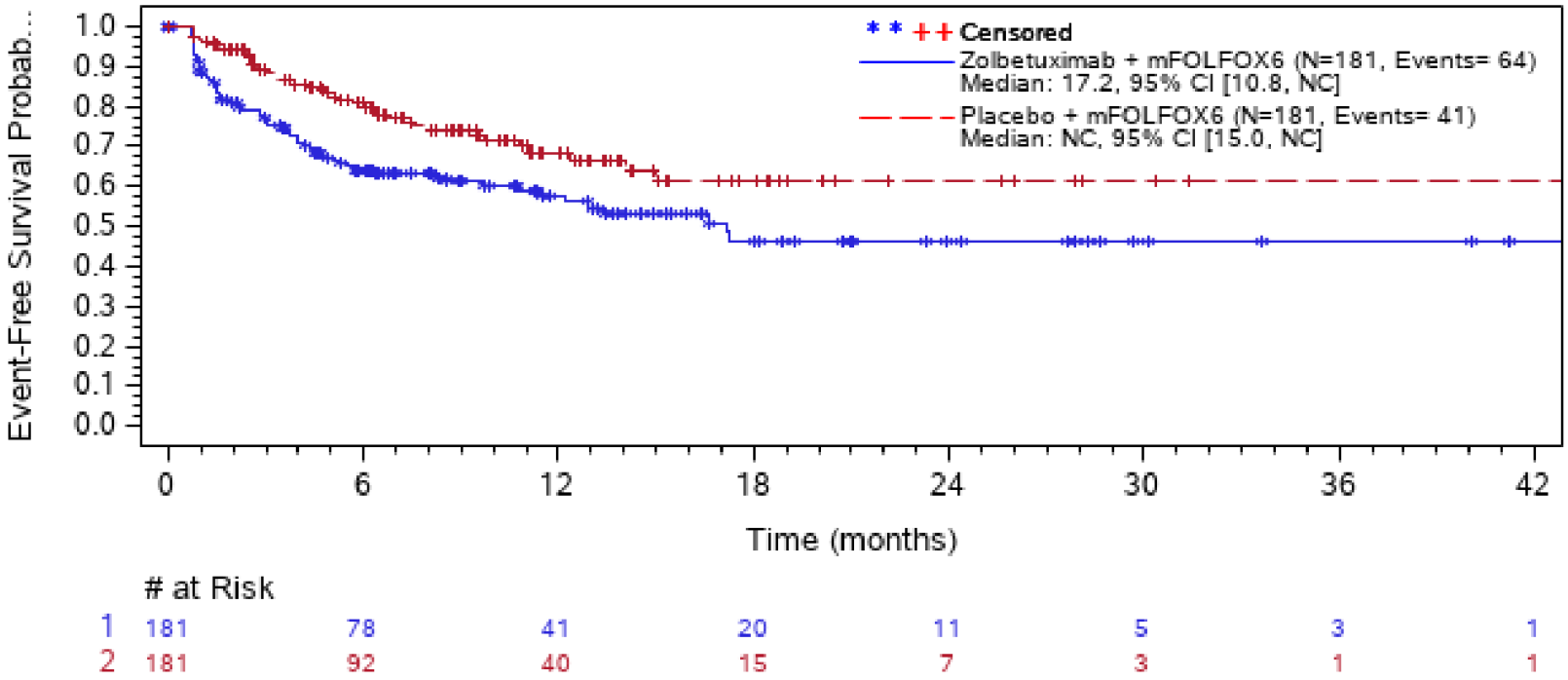
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.31.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

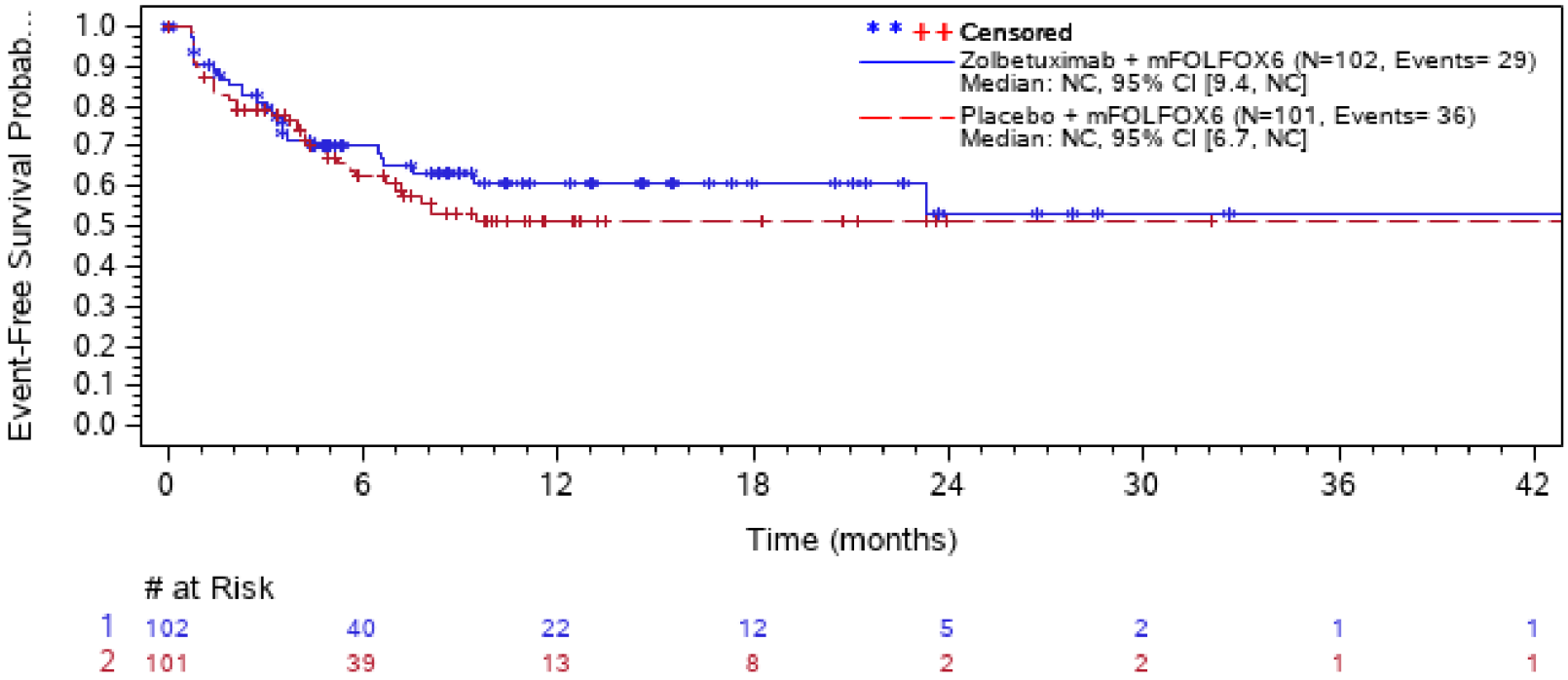
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.31.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Choked When Swallowing Score by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



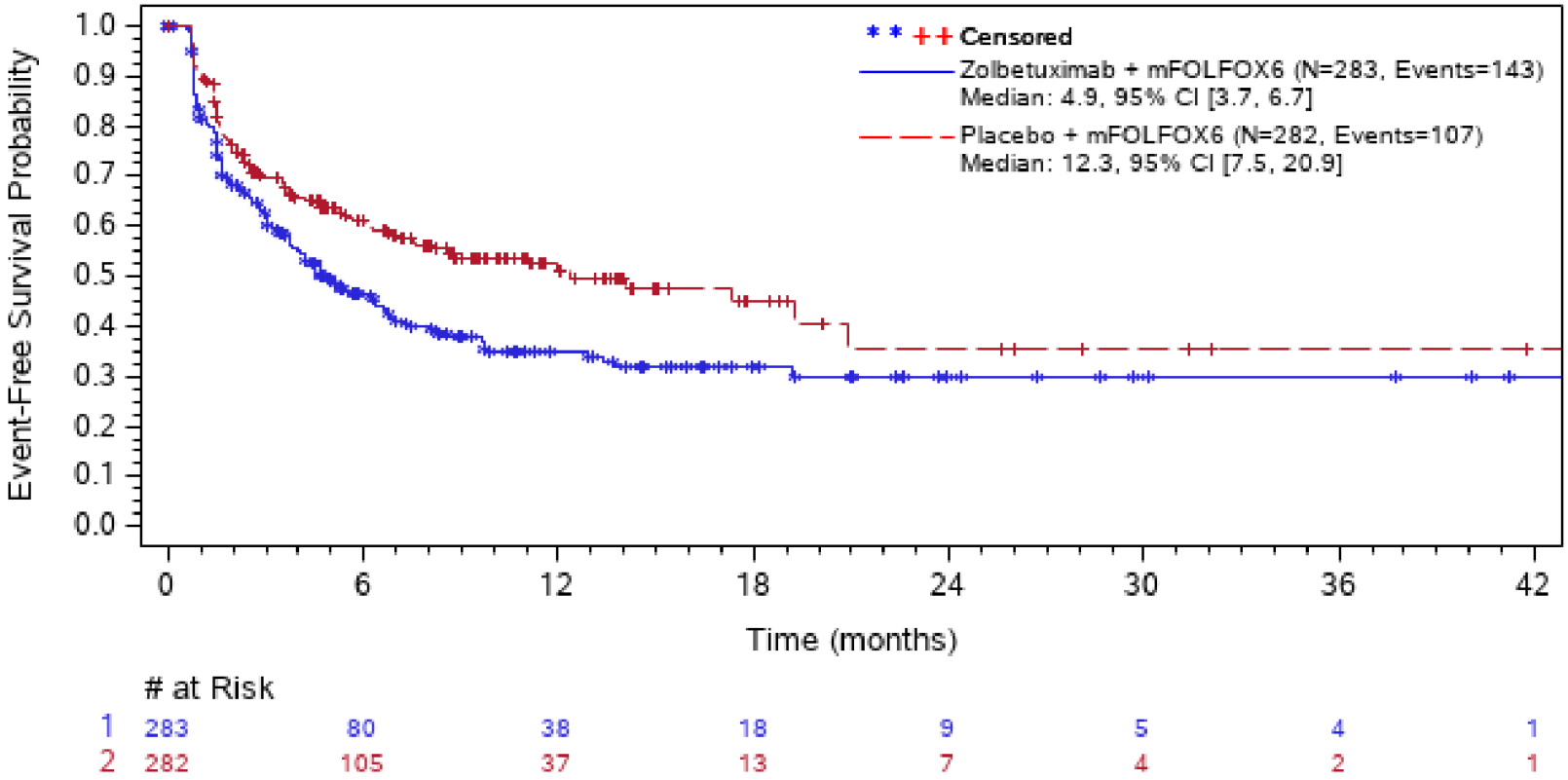
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.32: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble with Coughing (MID=10) - Full Analysis Set



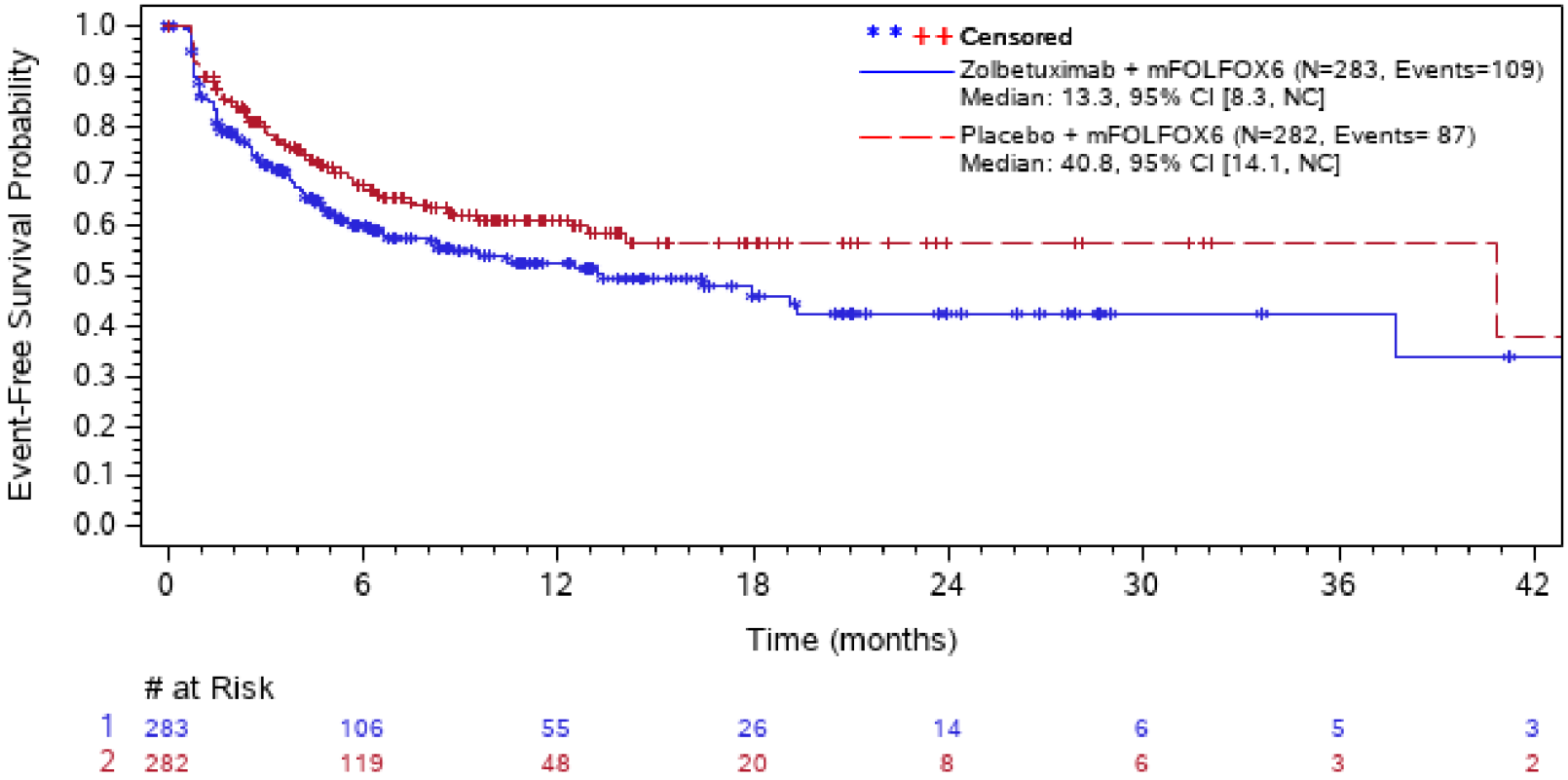
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.33: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

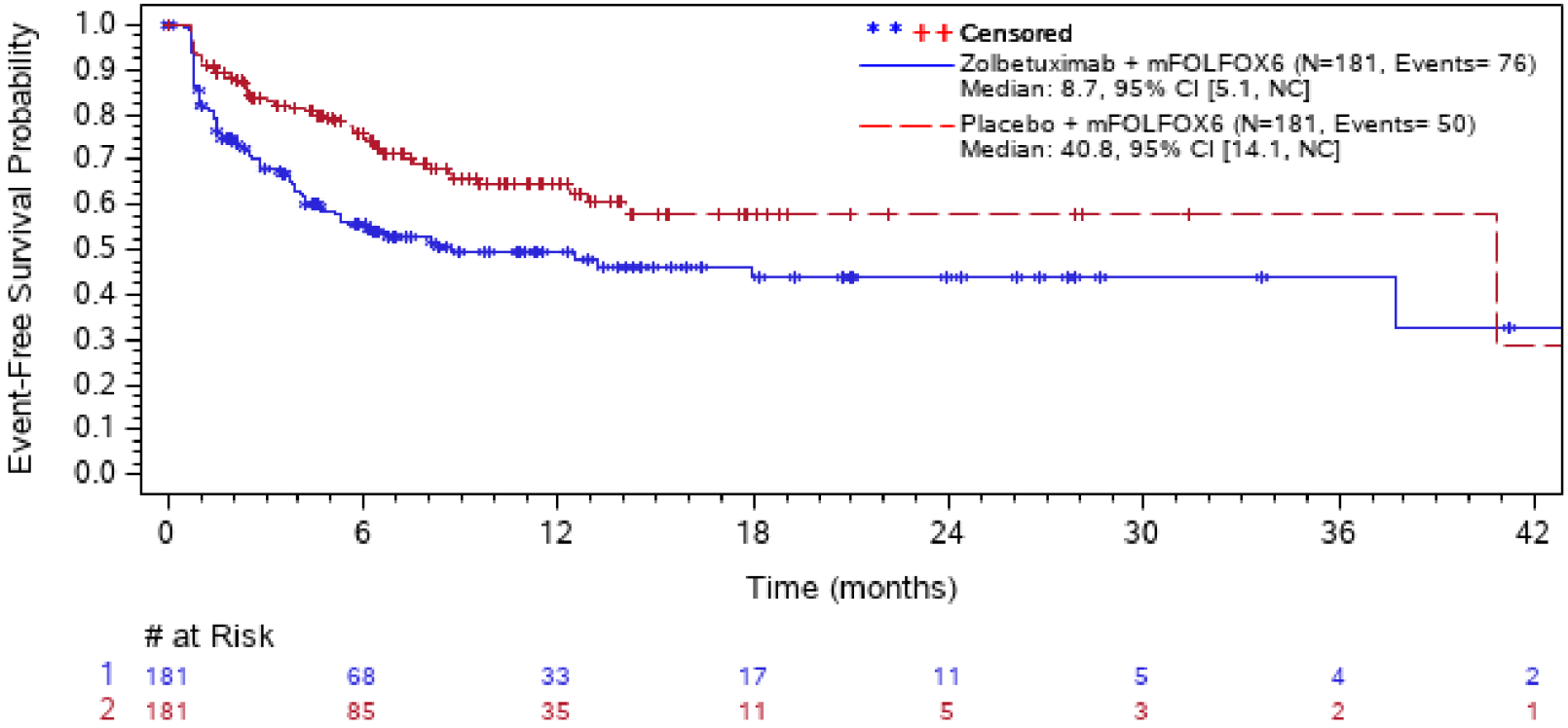
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.33.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: <=65 years



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

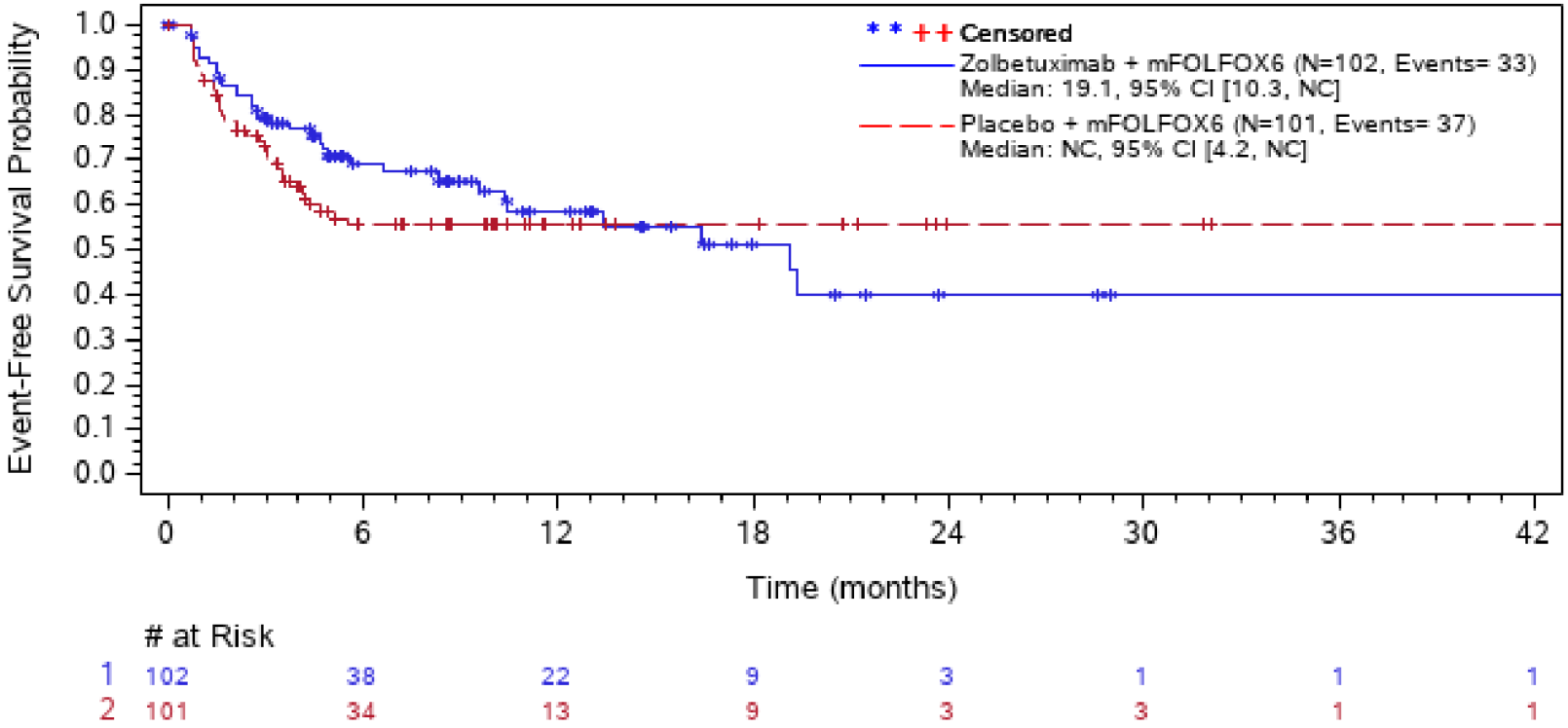
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=10 point increase. Censoring date is date of last available assessment of the parameter.

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: 08SEP23

Figure 301.3.3004.33.1: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Trouble Talking by Age Group 1 (MID=10) - Full Analysis Set

Age Group 1: >65 years



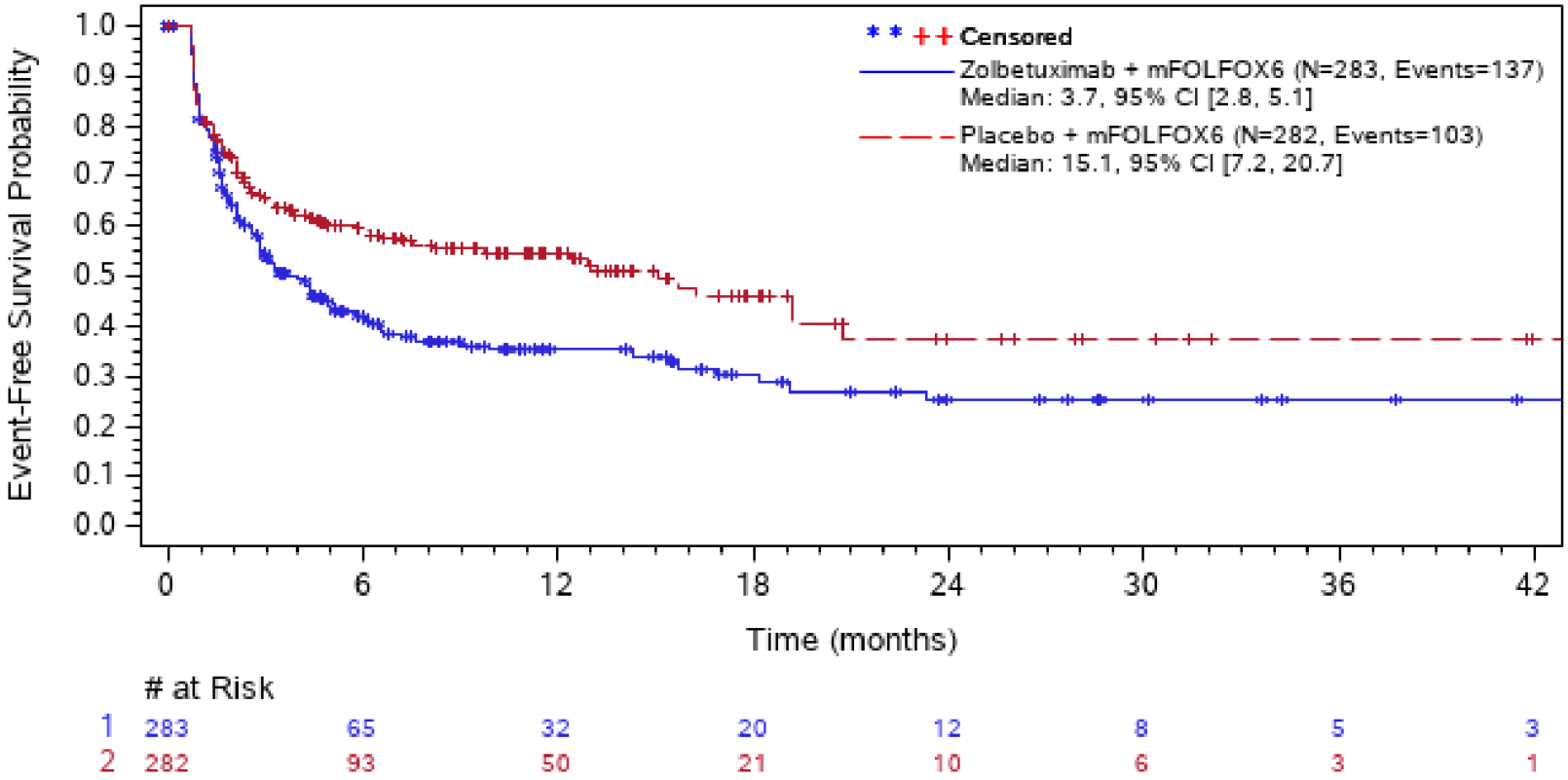
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.34: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Weight Loss (MID=10) - Full Analysis Set



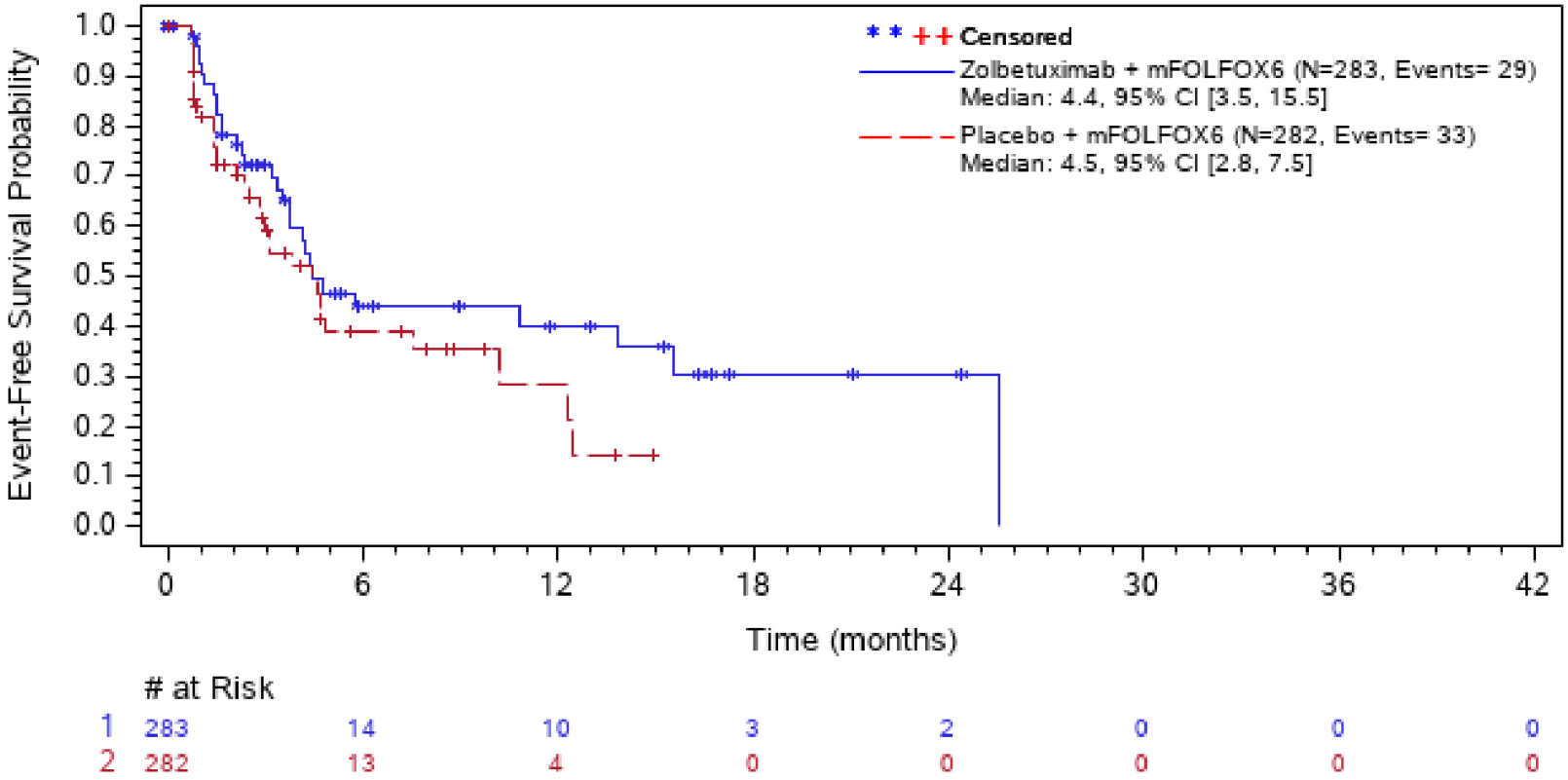
Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; N=number of patients; NC=not calculated.

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.

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: 08SEP23

Figure 301.3.3004.35: EORTC QLQ-OG25 - Kaplan-Meier Plot of Time to First Deterioration of Hair Loss (MID=10) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; MID=minimally important difference; 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.

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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 Schmerzintensität anhand der NRS

1. Rücklaufquoten

Table 301.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	257/279 (92.1%)	257/282 (91.1%)	257/283 (90.8%)	257/278 (92.4%)	257/280 (91.8%)	257/282 (91.1%)
Cycle 1 Day 22	184/257 (71.6%)	185/273 (67.8%)	185/283 (65.4%)	211/266 (79.3%)	211/271 (77.9%)	211/282 (74.8%)
Cycle 2 Day 1	212/244 (86.9%)	212/262 (80.9%)	215/283 (76.0%)	229/263 (87.1%)	230/270 (85.2%)	230/282 (81.6%)
Cycle 2 Day 22	156/222 (70.3%)	157/255 (61.6%)	157/283 (55.5%)	182/243 (74.9%)	183/264 (69.3%)	183/282 (64.9%)
Cycle 3 Day 1	190/215 (88.4%)	196/252 (77.8%)	199/283 (70.3%)	202/228 (88.6%)	202/259 (78.0%)	202/282 (71.6%)
Cycle 3 Day 22	159/204 (77.9%)	160/248 (64.5%)	160/283 (56.5%)	155/219 (70.8%)	155/257 (60.3%)	155/282 (55.0%)
Cycle 4 Day 1	168/192 (87.5%)	173/241 (71.8%)	177/283 (62.5%)	169/202 (83.7%)	169/254 (66.5%)	170/282 (60.3%)
Cycle 4 Day 22	126/179 (70.4%)	126/238 (52.9%)	126/283 (44.5%)	132/185 (71.4%)	132/251 (52.6%)	132/282 (46.8%)
Cycle 5 Day 1	149/172 (86.6%)	155/236 (65.7%)	156/283 (55.1%)	149/172 (86.6%)	149/251 (59.4%)	149/282 (52.8%)
Cycle 5 Day 22	116/156 (74.4%)	117/233 (50.2%)	117/283 (41.3%)	121/155 (78.1%)	122/248 (49.2%)	122/282 (43.3%)
Cycle 6 Day 1	127/144 (88.2%)	131/233 (56.2%)	131/283 (46.3%)	123/144 (85.4%)	125/244 (51.2%)	125/282 (44.3%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	96/128 (75.0%)	96/242 (39.7%)	96/282 (34.0%)
Cycle 7 Day 1	115/130 (88.5%)	119/231 (51.5%)	119/283 (42.0%)	99/114 (86.8%)	99/239 (41.4%)	99/282 (35.1%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	75/105 (71.4%)	75/237 (31.6%)	75/282 (26.6%)
Cycle 8 Day 1	87/110 (79.1%)	88/226 (38.9%)	88/283 (31.1%)	82/ 97 (84.5%)	82/237 (34.6%)	82/282 (29.1%)
Cycle 8 Day 22	76/100 (76.0%)	77/226 (34.1%)	77/283 (27.2%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	81/ 94 (86.2%)	82/224 (36.6%)	82/283 (29.0%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	65/ 84 (77.4%)	65/224 (29.0%)	65/283 (23.0%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	68/ 80 (85.0%)	71/224 (31.7%)	71/283 (25.1%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	60/ 77 (77.9%)	60/224 (26.8%)	60/283 (21.2%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	47/ 67 (70.1%)	48/224 (21.4%)	48/283 (17.0%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	39/ 61 (63.9%)	39/224 (17.4%)	39/283 (13.8%)	26/ 42 (61.9%)	26/230 (11.3%)	26/282 (9.2%)
Cycle 13 Day 1	50/ 60 (83.3%)	50/224 (22.3%)	50/283 (17.7%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	42/ 52 (80.8%)	42/222 (18.9%)	43/283 (15.2%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	29/ 41 (70.7%)	29/222 (13.1%)	29/283 (10.2%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	17/ 20 (85.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	26/ 28 (92.9%)	26/218 (11.9%)	26/283 (9.2%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	10/ 16 (62.5%)	10/218 (4.6%)	10/283 (3.5%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	15/ 16 (93.8%)	15/218 (6.9%)	15/283 (5.3%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.4: Global Pain - Completion Status of PI01 - Pain Intensity - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	147/243 (60.5%)	147/269 (54.6%)	147/283 (51.9%)	165/246 (67.1%)	165/263 (62.7%)	165/282 (58.5%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	93/222 (41.9%)	93/240 (38.8%)	93/282 (33.0%)
90 D SFU Z/P	87/193 (45.1%)	87/222 (39.2%)	87/283 (30.7%)	82/186 (44.1%)	82/205 (40.0%)	83/282 (29.4%)

Abbreviations: FAS=full analysis set; N=number of patients; PRO=patient reported outcome; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

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

Table 301.3.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	257	2.87	2.67	0.0	2.00	10.0						
Cycle 1 Day 22	185	2.50	2.47	0.0	2.00	10.0	175	-0.55	2.85	-10.0	0.00	8.0
Cycle 2 Day 1	215	2.21	2.53	0.0	1.00	10.0	205	-0.75	2.94	-10.0	0.00	9.0
Cycle 2 Day 22	157	2.15	2.42	0.0	1.00	9.0	150	-0.67	3.11	-10.0	0.00	8.0
Cycle 3 Day 1	199	1.82	2.30	0.0	1.00	10.0	189	-0.87	2.88	-10.0	0.00	7.0
Cycle 3 Day 22	160	2.12	2.51	0.0	1.00	9.0	151	-0.62	3.16	-10.0	0.00	8.0
Cycle 4 Day 1	177	1.85	2.20	0.0	1.00	10.0	169	-0.86	2.61	-8.0	0.00	6.0
Cycle 4 Day 22	126	1.98	2.38	0.0	1.00	8.0	122	-0.51	3.02	-8.0	0.00	7.0
Cycle 5 Day 1	156	2.08	2.39	0.0	1.00	10.0	148	-0.53	2.91	-8.0	0.00	8.0
Cycle 5 Day 22	117	1.97	2.42	0.0	1.00	9.0	110	-0.54	2.89	-8.0	0.00	9.0
Cycle 6 Day 1	131	1.98	2.43	0.0	1.00	10.0	122	-0.63	3.13	-8.0	-1.00	9.0
Cycle 6 Day 22	108	1.87	2.47	0.0	0.00	9.0	103	-0.68	2.91	-7.0	0.00	8.0
Cycle 7 Day 1	119	1.86	2.18	0.0	1.00	9.0	113	-0.46	2.87	-7.0	0.00	9.0
Cycle 7 Day 22	87	2.10	2.44	0.0	1.00	8.0	81	-0.31	3.00	-7.0	0.00	8.0
Cycle 8 Day 1	88	1.81	2.31	0.0	0.00	7.0	80	-0.69	2.54	-7.0	0.00	6.0
Cycle 8 Day 22	77	1.84	2.36	0.0	0.00	8.0	71	-0.79	3.28	-7.0	0.00	8.0
Cycle 9 Day 1	82	1.96	2.51	0.0	1.00	9.0	75	-0.71	3.05	-7.0	0.00	8.0
Cycle 9 Day 22	65	1.94	2.26	0.0	1.00	8.0	60	-1.02	2.76	-7.0	0.00	5.0
Cycle 10 Day 1	71	2.21	2.47	0.0	1.00	9.0	65	-0.54	2.84	-6.0	0.00	7.0
Cycle 10 Day 22	60	2.18	2.22	0.0	2.00	9.0	56	-0.50	3.12	-7.0	0.00	6.0
Cycle 11 Day 1	68	2.32	2.66	0.0	1.00	9.0	63	-0.38	3.58	-7.0	0.00	9.0
Cycle 11 Day 22	48	2.21	2.50	0.0	1.50	8.0	44	-0.59	3.27	-7.0	0.00	7.0
Cycle 12 Day 1	58	2.26	2.34	0.0	2.00	8.0	53	-0.30	3.42	-7.0	0.00	8.0
Cycle 12 Day 22	39	2.10	2.07	0.0	2.00	7.0	36	-0.14	2.82	-4.0	0.00	6.0
Cycle 13 Day 1	50	1.86	2.27	0.0	1.00	8.0	47	-0.79	3.51	-7.0	0.00	6.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	43	1.77	2.15	0.0	1.00	8.0	40	-0.63	3.01	-6.0	0.00	6.0
Cycle 14 Day 1	41	2.44	2.60	0.0	1.00	8.0	39	-0.21	2.91	-6.0	0.00	5.0
Cycle 14 Day 22	33	2.12	2.51	0.0	1.00	7.0	32	-0.44	3.70	-7.0	0.00	7.0
Cycle 15 Day 1	36	2.47	2.44	0.0	2.50	7.0	35	0.09	3.49	-6.0	0.00	6.0
Cycle 15 Day 22	29	2.24	2.46	0.0	1.00	7.0	29	-0.38	3.81	-6.0	0.00	7.0
Cycle 16 Day 1	35	2.11	2.63	0.0	1.00	10.0	35	-0.60	3.91	-7.0	0.00	10.0
Cycle 16 Day 22	29	1.97	2.31	0.0	1.00	7.0	29	-0.97	3.23	-7.0	0.00	5.0
Cycle 17 Day 1	30	2.23	2.40	0.0	1.50	8.0	30	-0.03	2.94	-5.0	0.00	6.0
Cycle 17 Day 22	23	2.30	2.38	0.0	1.00	7.0	23	0.22	3.00	-4.0	0.00	7.0
Cycle 18 Day 1	26	2.00	2.43	0.0	0.50	7.0	26	-0.62	3.11	-6.0	0.00	5.0
Cycle 18 Day 22	21	1.48	2.23	0.0	0.00	6.0	21	-1.14	2.87	-5.0	0.00	5.0
Cycle 19 Day 1	23	1.39	2.06	0.0	0.00	6.0	23	-1.04	3.24	-6.0	0.00	5.0
Cycle 19 Day 22	20	1.65	2.01	0.0	1.00	6.0	20	-0.50	2.33	-5.0	0.00	4.0
Cycle 20 Day 1	23	1.74	2.14	0.0	1.00	7.0	23	-0.43	3.26	-6.0	0.00	5.0
Cycle 20 Day 22	18	2.11	2.35	0.0	1.50	7.0	18	-0.17	3.70	-6.0	0.00	7.0
Cycle 21 Day 1	20	1.65	2.37	0.0	0.00	7.0	20	-0.50	3.66	-5.0	0.00	7.0
Cycle 21 Day 22	14	2.14	2.60	0.0	0.50	6.0	14	0.57	2.90	-4.0	0.00	5.0
Cycle 22 Day 1	15	1.73	2.25	0.0	0.00	6.0	15	0.07	3.47	-6.0	0.00	5.0
Cycle 22 Day 22	10	2.30	2.87	0.0	0.50	7.0	10	0.60	3.24	-4.0	0.00	5.0
Cycle 23 Day 1	15	2.93	2.81	0.0	3.00	7.0	15	1.07	4.13	-6.0	0.00	6.0
Cycle 23 Day 22	11	2.91	2.59	0.0	2.00	7.0	11	1.27	4.13	-5.0	0.00	6.0
Cycle 24 Day 1	14	3.21	2.91	0.0	2.50	8.0	14	1.43	4.54	-5.0	0.50	8.0
Cycle 25 Day 1	12	3.67	2.27	0.0	4.50	7.0	12	2.33	3.03	-2.0	3.00	6.0
Cycle 25 Day 22	11	2.82	2.68	0.0	2.00	7.0	11	1.45	3.30	-4.0	1.00	6.0
Cycle 26 Day 1	13	2.77	2.62	0.0	3.00	6.0	13	1.08	3.77	-6.0	0.00	5.0
Cycle 27 Day 1	11	3.00	2.76	0.0	5.00	7.0	11	1.55	3.75	-5.0	3.00	5.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	2.83	2.52	0.0	3.50	6.0	12	1.42	3.55	-5.0	1.50	5.0
Study Disc 1	142	2.90	2.79	0.0	2.00	10.0	134	-0.01	2.80	-7.0	0.00	8.0
30 D SFU Z/P	77	2.87	2.93	0.0	2.00	10.0	72	-0.19	2.99	-8.0	0.00	9.0
90 D SFU Z/P	87	2.43	2.58	0.0	2.00	10.0	84	-0.27	2.94	-8.0	0.00	7.0
Placebo + mFOLFOX6 (N=282)												
Baseline	257	2.96	2.74	0.0	2.00	10.0						
Cycle 1 Day 22	211	2.17	2.28	0.0	1.00	8.0	208	-0.74	2.32	-8.0	0.00	7.0
Cycle 2 Day 1	230	2.09	2.59	0.0	1.00	10.0	223	-0.75	2.98	-9.0	0.00	10.0
Cycle 2 Day 22	183	1.98	2.48	0.0	1.00	10.0	178	-1.01	2.70	-8.0	0.00	9.0
Cycle 3 Day 1	202	1.97	2.46	0.0	1.00	9.0	195	-0.90	2.70	-9.0	0.00	7.0
Cycle 3 Day 22	155	2.08	2.58	0.0	1.00	9.0	148	-0.83	2.60	-8.0	0.00	8.0
Cycle 4 Day 1	170	1.84	2.47	0.0	1.00	9.0	161	-0.66	2.81	-8.0	0.00	9.0
Cycle 4 Day 22	132	1.87	2.33	0.0	1.00	9.0	126	-0.78	2.55	-8.0	0.00	6.0
Cycle 5 Day 1	149	1.77	2.39	0.0	1.00	10.0	144	-0.81	2.91	-8.0	0.00	7.0
Cycle 5 Day 22	122	2.07	2.47	0.0	1.00	9.0	115	-0.84	3.00	-8.0	0.00	9.0
Cycle 6 Day 1	125	2.21	2.76	0.0	1.00	10.0	120	-0.32	3.33	-8.0	0.00	9.0
Cycle 6 Day 22	96	1.47	2.28	0.0	0.00	8.0	92	-0.98	2.52	-8.0	0.00	8.0
Cycle 7 Day 1	99	1.49	2.37	0.0	0.00	9.0	96	-0.86	2.88	-8.0	0.00	9.0
Cycle 7 Day 22	75	1.28	2.13	0.0	0.00	9.0	73	-1.01	2.60	-8.0	0.00	6.0
Cycle 8 Day 1	82	1.54	2.56	0.0	0.00	10.0	81	-0.67	3.17	-8.0	0.00	10.0
Cycle 8 Day 22	67	1.18	2.11	0.0	0.00	10.0	65	-1.09	2.30	-7.0	0.00	6.0
Cycle 9 Day 1	64	1.23	2.02	0.0	0.00	8.0	62	-1.18	2.04	-7.0	-1.00	4.0
Cycle 9 Day 22	57	1.25	1.99	0.0	0.00	9.0	55	-1.13	2.71	-8.0	0.00	6.0
Cycle 10 Day 1	58	1.47	2.27	0.0	0.00	10.0	56	-0.75	2.91	-6.0	-1.00	10.0
Cycle 10 Day 22	44	1.43	2.21	0.0	1.00	9.0	43	-0.74	3.09	-8.0	0.00	9.0
Cycle 11 Day 1	48	1.31	1.99	0.0	0.00	8.0	46	-0.96	2.16	-7.0	0.00	4.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Table 301.3.3002.4: Global Pain - Observed Means and Change from Baseline of PI01 - Pain Intensity - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	1.36	2.42	0.0	0.00	10.0	31	-0.77	1.89	-6.0	0.00	3.0
Cycle 12 Day 1	43	1.51	2.37	0.0	0.00	8.0	41	-0.54	2.81	-8.0	0.00	8.0
Cycle 12 Day 22	26	1.23	2.14	0.0	0.00	8.0	24	-0.88	2.17	-7.0	-0.50	3.0
Cycle 13 Day 1	37	1.41	2.13	0.0	0.00	8.0	35	-0.66	2.52	-8.0	0.00	4.0
Cycle 13 Day 22	22	1.18	1.71	0.0	0.00	5.0	21	-1.19	3.23	-8.0	-1.00	5.0
Cycle 14 Day 1	31	1.58	2.45	0.0	0.00	10.0	30	-0.37	2.46	-7.0	0.00	5.0
Cycle 14 Day 22	20	1.90	2.61	0.0	0.50	8.0	19	-0.84	3.34	-8.0	0.00	5.0
Cycle 15 Day 1	27	1.85	2.81	0.0	0.00	10.0	27	0.22	3.63	-8.0	0.00	10.0
Cycle 15 Day 22	17	1.29	2.26	0.0	0.00	7.0	17	-0.71	3.62	-8.0	0.00	5.0
Cycle 16 Day 1	22	1.32	2.32	0.0	0.00	8.0	22	-0.45	3.66	-8.0	0.00	8.0
Cycle 16 Day 22	14	0.64	1.45	0.0	0.00	4.0	14	-0.71	2.46	-7.0	0.00	4.0
Cycle 17 Day 1	17	0.88	1.73	0.0	0.00	5.0	17	-0.53	2.62	-7.0	0.00	5.0
Cycle 18 Day 1	16	0.88	2.22	0.0	0.00	7.0	16	-0.31	2.91	-7.0	0.00	7.0
Cycle 18 Day 22	11	0.73	0.90	0.0	1.00	3.0	10	-0.40	2.32	-6.0	0.00	3.0
Cycle 19 Day 1	16	0.56	1.26	0.0	0.00	5.0	15	-0.73	2.22	-7.0	0.00	2.0
Cycle 19 Day 22	12	0.75	1.06	0.0	0.00	3.0	11	-0.45	2.34	-7.0	0.00	2.0
Cycle 20 Day 1	16	1.75	2.86	0.0	0.00	9.0	15	0.60	3.07	-7.0	0.00	5.0
Cycle 20 Day 22	11	1.36	2.80	0.0	0.00	9.0	10	-0.20	2.74	-7.0	0.00	4.0
Cycle 21 Day 1	15	0.33	0.82	0.0	0.00	3.0	14	-0.79	2.36	-7.0	0.00	3.0
Cycle 22 Day 1	12	0.83	2.04	0.0	0.00	7.0	12	-0.42	2.78	-7.0	0.00	4.0
Cycle 23 Day 1	13	0.85	1.72	0.0	0.00	6.0	13	-0.54	2.63	-7.0	0.00	3.0
Study Disc 1	153	3.27	2.80	0.0	3.00	10.0	149	0.49	2.99	-8.0	0.00	8.0
Study Disc 2	12	4.50	3.00	0.0	4.00	10.0	11	1.00	2.57	-5.0	2.00	3.0
30 D SFU Z/P	93	3.02	2.73	0.0	3.00	10.0	90	0.39	3.16	-8.0	0.00	8.0
90 D SFU Z/P	83	2.80	2.82	0.0	2.00	9.0	81	0.31	3.12	-7.0	0.00	8.0

Abbreviations: N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc x=study drug discontinuation visit x.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 Schmerzintensität anhand der NRS

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

Table 301.3.3004.4.1: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	131 (46.3%)	130 (46.1%)	
Number of patients censored	152 (53.7%)	152 (53.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.7 [5.1, 11.1]	8.0 [5.5, 10.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.044 [0.817, 1.333]
Log-rank test			
Two-sided stratified log-rank p-value			0.7285

Abbreviations: CI=confidence interval; HR=hazard ratio; MID=minimally important difference; 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 >=2 point increase. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3004.4.2: Global Pain - Summary of Time to First Deterioration of PI01 - Pain Intensity by Subgroups (MID=2) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	86 (47.5)	7.5 [3.7, 12.9]	181	79 (43.6)	8.7 [5.4, 10.9]	1.166 [0.859, 1.584]	0.3259	0.2271
>65 years	102	45 (44.1)	6.7 [4.9, 15.2]	101	51 (50.5)	7.2 [4.2, 10.1]	0.843 [0.564, 1.259]	0.4071	
Sex									
Male	176	78 (44.3)	7.6 [5.5, 14.3]	175	78 (44.6)	9.4 [5.5, 12.3]	1.079 [0.788, 1.478]	0.6352	0.6794
Female	107	53 (49.5)	6.4 [3.5, 11.0]	107	52 (48.6)	6.6 [3.7, 9.7]	0.986 [0.672, 1.447]	0.9463	
Region									
Asia	88	46 (52.3)	6.2 [3.5, 14.3]	89	44 (49.4)	9.3 [5.1, 12.3]	1.119 [0.739, 1.693]	0.5962	0.7515
Non-Asia	195	85 (43.6)	7.6 [5.5, 14.0]	193	86 (44.6)	7.9 [4.6, 10.4]	1.011 [0.749, 1.365]	0.9361	
Number of Organs with Metastatic Sites									
0-2	219	104 (47.5)	6.7 [5.0, 12.9]	219	104 (47.5)	8.7 [5.7, 10.4]	1.089 [0.829, 1.429]	0.5408	0.4561
>=3	64	27 (42.2)	10.1 [3.5, NC]	63	26 (41.3)	4.2 [3.3, NC]	0.871 [0.508, 1.494]	0.6200	

Abbreviations: CI=confidence interval; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; 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 >=2 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 [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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
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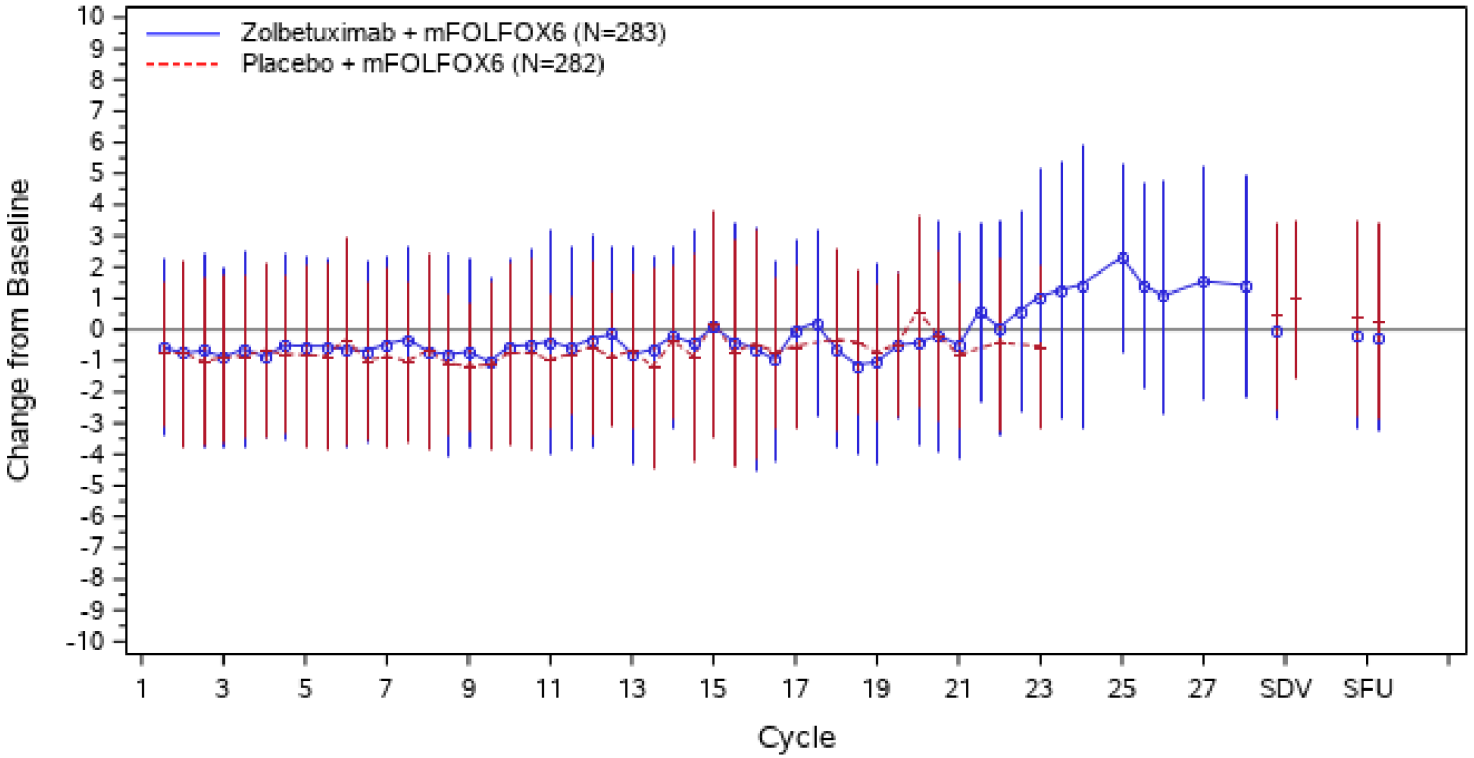
4. Graphische Darstellung des Verlaufs (Mean Change from Baseline)

The SAS System

Figure 301.3.3002.4: Global Pain(GP) - Plot of Mean Change from Baseline of PI01 - Pain Intensity - Full Analysis Set



Abbreviations: N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
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.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
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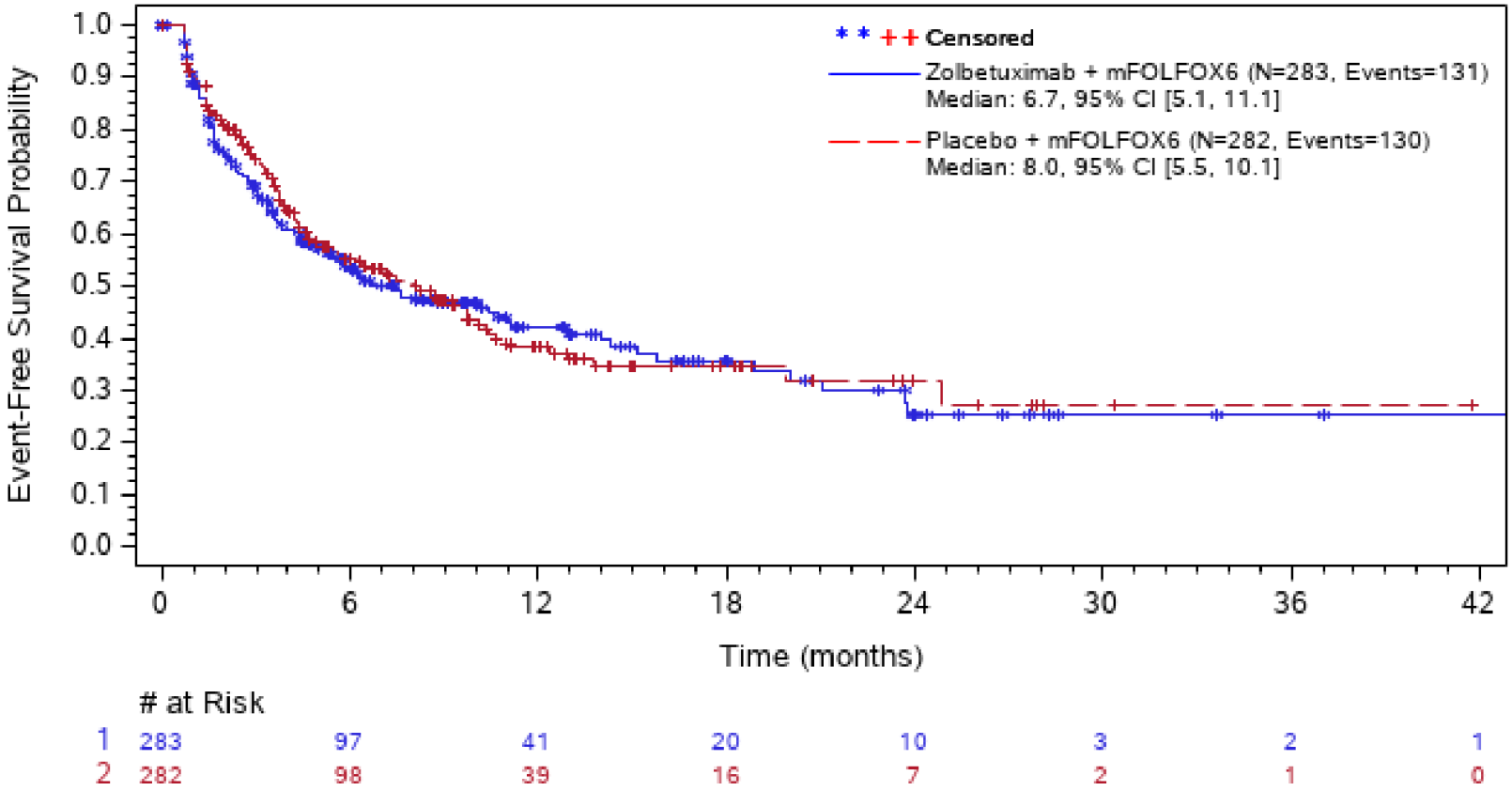
5. Kaplan-Meier-Plots

Figure 301.3.3004.4: Global Pain - Kaplan-Meier Plot of Time to First Deterioration of PI01 - Pain Intensity (MID=2) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; MID=minimally important difference; 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 >=2 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Patientenberichtete Endpunkte

Anhang 4-G4 EQ-5D VAS

1. Rücklaufquoten

Table 301.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Baseline	258/279 (92.5%)	258/282 (91.5%)	258/283 (91.2%)	258/278 (92.8%)	258/280 (92.1%)	258/282 (91.5%)
Cycle 1 Day 22	187/257 (72.8%)	188/273 (68.9%)	188/283 (66.4%)	214/266 (80.5%)	214/271 (79.0%)	214/282 (75.9%)
Cycle 2 Day 1	214/244 (87.7%)	214/262 (81.7%)	217/283 (76.7%)	232/263 (88.2%)	233/270 (86.3%)	233/282 (82.6%)
Cycle 2 Day 22	158/222 (71.2%)	159/255 (62.4%)	159/283 (56.2%)	184/243 (75.7%)	185/264 (70.1%)	185/282 (65.6%)
Cycle 3 Day 1	191/215 (88.8%)	197/252 (78.2%)	200/283 (70.7%)	204/228 (89.5%)	204/259 (78.8%)	204/282 (72.3%)
Cycle 3 Day 22	162/204 (79.4%)	163/248 (65.7%)	163/283 (57.6%)	156/219 (71.2%)	156/257 (60.7%)	156/282 (55.3%)
Cycle 4 Day 1	171/192 (89.1%)	176/241 (73.0%)	180/283 (63.6%)	171/202 (84.7%)	171/254 (67.3%)	172/282 (61.0%)
Cycle 4 Day 22	130/179 (72.6%)	130/238 (54.6%)	130/283 (45.9%)	133/185 (71.9%)	133/251 (53.0%)	133/282 (47.2%)
Cycle 5 Day 1	150/172 (87.2%)	156/236 (66.1%)	157/283 (55.5%)	150/172 (87.2%)	150/251 (59.8%)	150/282 (53.2%)
Cycle 5 Day 22	120/156 (76.9%)	121/233 (51.9%)	121/283 (42.8%)	122/155 (78.7%)	123/248 (49.6%)	123/282 (43.6%)
Cycle 6 Day 1	128/144 (88.9%)	132/233 (56.7%)	132/283 (46.6%)	125/144 (86.8%)	127/244 (52.0%)	127/282 (45.0%)
Cycle 6 Day 22	106/135 (78.5%)	108/231 (46.8%)	108/283 (38.2%)	99/128 (77.3%)	99/242 (40.9%)	99/282 (35.1%)
Cycle 7 Day 1	116/130 (89.2%)	120/231 (51.9%)	120/283 (42.4%)	101/114 (88.6%)	101/239 (42.3%)	101/282 (35.8%)
Cycle 7 Day 22	87/120 (72.5%)	87/229 (38.0%)	87/283 (30.7%)	76/105 (72.4%)	76/237 (32.1%)	76/282 (27.0%)
Cycle 8 Day 1	89/110 (80.9%)	90/226 (39.8%)	90/283 (31.8%)	84/ 97 (86.6%)	84/237 (35.4%)	84/282 (29.8%)
Cycle 8 Day 22	77/100 (77.0%)	78/226 (34.5%)	78/283 (27.6%)	67/ 87 (77.0%)	67/235 (28.5%)	67/282 (23.8%)
Cycle 9 Day 1	82/ 94 (87.2%)	83/224 (37.1%)	83/283 (29.3%)	64/ 75 (85.3%)	64/234 (27.4%)	64/282 (22.7%)
Cycle 9 Day 22	66/ 84 (78.6%)	66/224 (29.5%)	66/283 (23.3%)	57/ 71 (80.3%)	57/234 (24.4%)	57/282 (20.2%)
Cycle 10 Day 1	69/ 80 (86.3%)	72/224 (32.1%)	72/283 (25.4%)	57/ 61 (93.4%)	58/234 (24.8%)	58/282 (20.6%)
Cycle 10 Day 22	61/ 77 (79.2%)	61/224 (27.2%)	61/283 (21.6%)	44/ 55 (80.0%)	44/234 (18.8%)	44/282 (15.6%)
Cycle 11 Day 1	67/ 74 (90.5%)	68/224 (30.4%)	68/283 (24.0%)	48/ 52 (92.3%)	48/234 (20.5%)	48/282 (17.0%)
Cycle 11 Day 22	48/ 67 (71.6%)	49/224 (21.9%)	49/283 (17.3%)	33/ 48 (68.8%)	33/233 (14.2%)	33/282 (11.7%)
Cycle 12 Day 1	56/ 65 (86.2%)	58/224 (25.9%)	58/283 (20.5%)	43/ 46 (93.5%)	43/233 (18.5%)	43/282 (15.2%)
Cycle 12 Day 22	42/ 61 (68.9%)	42/224 (18.8%)	42/283 (14.8%)	28/ 42 (66.7%)	28/230 (12.2%)	28/282 (9.9%)
Cycle 13 Day 1	51/ 60 (85.0%)	51/224 (22.8%)	51/283 (18.0%)	37/ 40 (92.5%)	37/230 (16.1%)	37/282 (13.1%)
Cycle 13 Day 22	44/ 52 (84.6%)	44/222 (19.8%)	45/283 (15.9%)	22/ 37 (59.5%)	22/230 (9.6%)	22/282 (7.8%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 14 Day 1	41/ 45 (91.1%)	41/222 (18.5%)	41/283 (14.5%)	31/ 35 (88.6%)	31/230 (13.5%)	31/282 (11.0%)
Cycle 14 Day 22	33/ 43 (76.7%)	33/222 (14.9%)	33/283 (11.7%)	20/ 33 (60.6%)	20/230 (8.7%)	20/282 (7.1%)
Cycle 15 Day 1	36/ 42 (85.7%)	36/222 (16.2%)	36/283 (12.7%)	27/ 30 (90.0%)	27/230 (11.7%)	27/282 (9.6%)
Cycle 15 Day 22	30/ 41 (73.2%)	30/222 (13.5%)	30/283 (10.6%)	17/ 27 (63.0%)	17/230 (7.4%)	17/282 (6.0%)
Cycle 16 Day 1	34/ 38 (89.5%)	35/222 (15.8%)	35/283 (12.4%)	22/ 25 (88.0%)	22/230 (9.6%)	22/282 (7.8%)
Cycle 16 Day 22	28/ 36 (77.8%)	29/222 (13.1%)	29/283 (10.2%)	14/ 21 (66.7%)	14/230 (6.1%)	14/282 (5.0%)
Cycle 17 Day 1	30/ 32 (93.8%)	30/220 (13.6%)	30/283 (10.6%)	18/ 20 (90.0%)	18/230 (7.8%)	18/282 (6.4%)
Cycle 17 Day 22	23/ 29 (79.3%)	23/219 (10.5%)	23/283 (8.1%)	9/ 19 (47.4%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 18 Day 1	27/ 28 (96.4%)	27/218 (12.4%)	27/283 (9.5%)	16/ 17 (94.1%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 18 Day 22	21/ 26 (80.8%)	21/218 (9.6%)	21/283 (7.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 19 Day 1	23/ 25 (92.0%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 19 Day 22	20/ 24 (83.3%)	20/218 (9.2%)	20/283 (7.1%)	12/ 16 (75.0%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 20 Day 1	23/ 24 (95.8%)	23/218 (10.6%)	23/283 (8.1%)	16/ 16 (100.0%)	16/229 (7.0%)	16/282 (5.7%)
Cycle 20 Day 22	18/ 22 (81.8%)	18/218 (8.3%)	18/283 (6.4%)	11/ 16 (68.8%)	11/229 (4.8%)	11/282 (3.9%)
Cycle 21 Day 1	20/ 21 (95.2%)	20/218 (9.2%)	20/283 (7.1%)	15/ 16 (93.8%)	15/229 (6.6%)	15/282 (5.3%)
Cycle 21 Day 22	14/ 18 (77.8%)	14/218 (6.4%)	14/283 (4.9%)	9/ 15 (60.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 22 Day 1	15/ 17 (88.2%)	15/218 (6.9%)	15/283 (5.3%)	12/ 13 (92.3%)	12/229 (5.2%)	12/282 (4.3%)
Cycle 22 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	8/ 13 (61.5%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 23 Day 1	16/ 16 (100.0%)	16/218 (7.3%)	16/283 (5.7%)	13/ 13 (100.0%)	13/229 (5.7%)	13/282 (4.6%)
Cycle 23 Day 22	11/ 16 (68.8%)	11/218 (5.0%)	11/283 (3.9%)	6/ 11 (54.5%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 24 Day 1	14/ 15 (93.3%)	14/218 (6.4%)	14/283 (4.9%)	9/ 10 (90.0%)	9/229 (3.9%)	9/282 (3.2%)
Cycle 24 Day 22	9/ 13 (69.2%)	9/218 (4.1%)	9/283 (3.2%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 25 Day 1	12/ 13 (92.3%)	12/218 (5.5%)	12/283 (4.2%)	8/ 8 (100.0%)	8/229 (3.5%)	8/282 (2.8%)
Cycle 25 Day 22	11/ 13 (84.6%)	11/218 (5.0%)	11/283 (3.9%)	6/ 8 (75.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 1	13/ 13 (100.0%)	13/218 (6.0%)	13/283 (4.6%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 26 Day 22	7/ 12 (58.3%)	7/218 (3.2%)	7/283 (2.5%)	3/ 6 (50.0%)	3/229 (1.3%)	3/282 (1.1%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Cycle 27 Day 1	11/ 12 (91.7%)	11/218 (5.0%)	11/283 (3.9%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 27 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	4/ 6 (66.7%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 28 Day 1	12/ 12 (100.0%)	12/218 (5.5%)	12/283 (4.2%)	6/ 6 (100.0%)	6/229 (2.6%)	6/282 (2.1%)
Cycle 28 Day 22	9/ 12 (75.0%)	9/218 (4.1%)	9/283 (3.2%)	1/ 5 (20.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 29 Day 1	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	5/ 5 (100.0%)	5/229 (2.2%)	5/282 (1.8%)
Cycle 29 Day 22	6/ 10 (60.0%)	6/218 (2.8%)	6/283 (2.1%)	3/ 5 (60.0%)	3/229 (1.3%)	3/282 (1.1%)
Cycle 30 Day 1	8/ 9 (88.9%)	8/218 (3.7%)	8/283 (2.8%)	4/ 5 (80.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 30 Day 22	6/ 9 (66.7%)	6/218 (2.8%)	6/283 (2.1%)	0/ 4 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 31 Day 1	6/ 7 (85.7%)	6/218 (2.8%)	6/283 (2.1%)	4/ 4 (100.0%)	4/229 (1.7%)	4/282 (1.4%)
Cycle 31 Day 22	5/ 6 (83.3%)	5/218 (2.3%)	5/283 (1.8%)	1/ 3 (33.3%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 32 Day 1	6/ 6 (100.0%)	6/218 (2.8%)	6/283 (2.1%)	2/ 3 (66.7%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 32 Day 22	5/ 5 (100.0%)	5/218 (2.3%)	5/283 (1.8%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 33 Day 1	4/ 4 (100.0%)	4/218 (1.8%)	4/283 (1.4%)	2/ 2 (100.0%)	2/229 (0.9%)	2/282 (0.7%)
Cycle 33 Day 22	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	0/ 2 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 34 Day 1	3/ 3 (100.0%)	3/218 (1.4%)	3/283 (1.1%)	1/ 2 (50.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 34 Day 22	2/ 3 (66.7%)	2/218 (0.9%)	2/283 (0.7%)	0/ 1 (0.0%)	0/229 (0.0%)	0/282 (0.0%)
Cycle 35 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 35 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 36 Day 22	1/ 2 (50.0%)	1/218 (0.5%)	1/283 (0.4%)	1/ 1 (100.0%)	1/229 (0.4%)	1/282 (0.4%)
Cycle 37 Day 1	2/ 2 (100.0%)	2/218 (0.9%)	2/283 (0.7%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 37 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 38 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 1	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)
Cycle 39 Day 22	1/ 1 (100.0%)	1/218 (0.5%)	1/283 (0.4%)	0	0/229 (0.0%)	0/282 (0.0%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3001.3: EQ-5D-5L - Completion Status of Visual Analog Scale - Full Analysis Set

Analysis Visit	Zolbetuximab + mFOLFOX6 (N=283)			Placebo + mFOLFOX6 (N=282)		
	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)	Compliance Rate [1] (based on expected assessments)	Compliance Rate [2] (adjusted for deaths)	Completion Rate [3] (unadjusted)
Study Disc	150/243 (61.7%)	150/269 (55.8%)	150/283 (53.0%)	167/246 (67.9%)	167/263 (63.5%)	167/282 (59.2%)
30 D SFU Z/P	76/220 (34.5%)	76/247 (30.8%)	77/283 (27.2%)	94/222 (42.3%)	94/240 (39.2%)	94/282 (33.3%)
90 D SFU Z/P	89/193 (46.1%)	89/222 (40.1%)	89/283 (31.4%)	84/186 (45.2%)	84/205 (41.0%)	85/282 (30.1%)

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; 30 D SFU Z/P=30 day safety follow up visit - Zolbetuximab/Placebo; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
[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 PRO from FAS 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 the number of subjects with PRO from FAS 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 the number of subjects in the FAS.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

Table 301.3.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Zolbetuximab + mFOLFOX6 (N=283)												
Baseline	258	68.91	19.15	0.0	70.00	100.0						
Cycle 1 Day 22	188	67.32	18.91	0.0	70.00	100.0	178	-3.44	18.53	-87.0	-1.00	61.0
Cycle 2 Day 1	217	70.41	17.66	0.0	74.00	100.0	207	0.05	18.05	-72.0	0.00	40.0
Cycle 2 Day 22	159	70.18	14.99	0.0	71.00	95.0	152	0.63	18.37	-100.0	0.00	39.0
Cycle 3 Day 1	200	72.97	16.23	0.0	74.50	100.0	190	1.16	18.61	-61.0	0.00	52.0
Cycle 3 Day 22	163	69.13	17.49	0.0	70.00	100.0	154	-1.69	18.39	-50.0	0.00	48.0
Cycle 4 Day 1	180	71.43	15.82	26.0	73.00	100.0	172	0.35	17.10	-49.0	0.00	45.0
Cycle 4 Day 22	130	70.35	15.97	15.0	70.00	100.0	125	-1.11	19.16	-44.0	0.00	59.0
Cycle 5 Day 1	157	70.70	17.34	0.0	73.00	100.0	150	-0.54	19.36	-58.0	0.00	61.0
Cycle 5 Day 22	121	71.74	19.01	0.0	76.00	100.0	114	0.37	22.01	-81.0	0.00	50.0
Cycle 6 Day 1	132	71.54	18.35	0.0	75.00	100.0	123	1.28	19.67	-60.0	2.00	52.0
Cycle 6 Day 22	108	73.28	17.05	25.0	77.00	96.0	103	4.33	18.56	-55.0	2.00	49.0
Cycle 7 Day 1	120	72.63	16.26	15.0	78.50	98.0	114	1.32	20.58	-72.0	1.00	50.0
Cycle 7 Day 22	87	73.93	14.45	32.0	79.00	98.0	81	3.51	17.92	-36.0	1.00	52.0
Cycle 8 Day 1	90	75.37	15.66	0.0	79.50	100.0	82	3.77	21.13	-80.0	5.00	53.0
Cycle 8 Day 22	78	73.33	14.70	20.0	76.00	97.0	72	2.71	19.07	-60.0	0.50	45.0
Cycle 9 Day 1	83	74.31	17.12	9.0	80.00	97.0	75	5.05	19.16	-60.0	5.00	45.0
Cycle 9 Day 22	66	72.02	17.91	9.0	78.00	98.0	61	2.44	21.10	-62.0	3.00	54.0
Cycle 10 Day 1	72	72.53	17.64	18.0	75.50	98.0	66	2.52	18.65	-62.0	1.50	44.0
Cycle 10 Day 22	61	75.10	14.36	18.0	79.00	94.0	57	3.23	17.27	-62.0	6.00	44.0
Cycle 11 Day 1	68	75.90	14.67	10.0	80.00	98.0	63	5.10	17.23	-70.0	8.00	36.0
Cycle 11 Day 22	49	75.69	13.05	46.0	76.00	94.0	45	3.96	15.63	-20.0	6.00	37.0
Cycle 12 Day 1	58	74.48	15.35	18.0	79.00	98.0	53	1.06	18.03	-62.0	4.00	48.0
Cycle 12 Day 22	42	72.24	14.94	22.0	71.00	97.0	38	-1.55	17.56	-58.0	-0.50	33.0
Cycle 13 Day 1	51	75.45	15.43	25.0	80.00	100.0	48	3.27	17.64	-55.0	9.00	31.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 08SEP23

Table 301.3.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 13 Day 22	45	74.13	14.19	35.0	77.00	97.0	41	-0.29	18.30	-45.0	5.00	31.0
Cycle 14 Day 1	41	72.66	15.93	31.0	71.00	98.0	39	-0.15	16.81	-30.0	-1.00	34.0
Cycle 14 Day 22	33	72.67	12.27	49.0	71.00	97.0	32	-0.25	18.75	-34.0	2.00	28.0
Cycle 15 Day 1	36	73.44	11.19	50.0	73.50	94.0	35	-0.09	16.90	-30.0	-2.00	28.0
Cycle 15 Day 22	30	69.80	16.82	29.0	70.00	99.0	30	-2.63	23.87	-71.0	5.50	38.0
Cycle 16 Day 1	35	73.94	14.52	39.0	70.00	97.0	35	2.43	16.37	-35.0	6.00	27.0
Cycle 16 Day 22	29	71.41	11.98	49.0	70.00	96.0	29	2.00	15.26	-34.0	1.00	32.0
Cycle 17 Day 1	30	74.17	11.80	39.0	78.50	90.0	30	2.50	16.74	-35.0	0.00	35.0
Cycle 17 Day 22	23	68.78	12.38	41.0	70.00	88.0	23	-2.61	17.26	-35.0	0.00	30.0
Cycle 18 Day 1	27	72.74	12.74	39.0	70.00	93.0	27	2.85	18.61	-32.0	5.00	37.0
Cycle 18 Day 22	21	72.24	14.41	37.0	74.00	93.0	21	0.86	18.74	-32.0	3.00	37.0
Cycle 19 Day 1	23	77.43	12.62	39.0	80.00	97.0	23	5.39	16.57	-24.0	0.00	36.0
Cycle 19 Day 22	20	72.70	13.80	40.0	72.50	98.0	20	-0.25	19.05	-29.0	-3.00	36.0
Cycle 20 Day 1	23	74.48	14.27	40.0	71.00	100.0	23	1.57	21.46	-33.0	-2.00	56.0
Cycle 20 Day 22	18	73.28	12.12	37.0	76.00	90.0	18	0.78	16.00	-21.0	-3.00	36.0
Cycle 21 Day 1	20	75.90	12.51	39.0	74.00	94.0	20	2.80	15.83	-19.0	-0.50	36.0
Cycle 21 Day 22	14	71.71	12.65	39.0	71.50	91.0	14	-4.64	12.29	-22.0	-8.50	20.0
Cycle 22 Day 1	15	74.00	12.41	51.0	72.00	94.0	15	1.33	17.37	-28.0	0.00	22.0
Cycle 22 Day 22	11	66.00	15.94	39.0	68.00	90.0	11	-6.00	19.20	-33.0	-12.00	20.0
Cycle 23 Day 1	16	70.69	16.52	27.0	68.50	91.0	16	-2.25	18.36	-30.0	-5.00	22.0
Cycle 23 Day 22	11	67.64	12.37	37.0	70.00	83.0	11	-3.09	16.57	-31.0	-1.00	20.0
Cycle 24 Day 1	14	68.71	17.54	28.0	68.00	90.0	14	-3.43	18.81	-32.0	-8.00	21.0
Cycle 25 Day 1	12	68.50	16.16	27.0	70.00	92.0	12	-4.08	15.32	-27.0	-5.00	21.0
Cycle 25 Day 22	11	68.27	13.57	36.0	68.00	90.0	11	-4.64	14.43	-22.0	-12.00	20.0
Cycle 26 Day 1	13	74.00	15.09	39.0	73.00	95.0	13	1.69	16.79	-23.0	-3.00	26.0
Cycle 27 Day 1	11	75.91	10.95	62.0	70.00	92.0	11	1.45	17.15	-27.0	-3.00	23.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 08SEP23

Table 301.3.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 28 Day 1	12	75.42	11.17	62.0	70.00	95.0	12	-0.42	17.61	-27.0	-3.50	26.0
Study Disc 1	145	62.66	21.61	0.0	69.00	96.0	137	-6.96	19.86	-64.0	-7.00	48.0
30 D SFU Z/P	77	65.62	18.79	22.0	70.00	100.0	72	-1.33	18.53	-48.0	1.00	39.0
90 D SFU Z/P	89	66.67	19.32	0.0	70.00	95.0	86	-3.79	20.59	-52.0	-1.00	49.0
Placebo + mFOLFOX6 (N=282)												
Baseline	258	67.95	19.78	0.0	70.00	100.0						
Cycle 1 Day 22	214	68.17	18.71	10.0	70.00	100.0	212	-0.21	15.63	-60.0	0.00	61.0
Cycle 2 Day 1	233	72.18	17.92	11.0	73.00	100.0	226	4.10	17.43	-59.0	1.00	79.0
Cycle 2 Day 22	185	70.40	19.39	2.0	71.00	100.0	181	2.25	19.26	-81.0	2.00	50.0
Cycle 3 Day 1	204	73.88	17.10	3.0	79.00	100.0	198	5.57	18.23	-67.0	3.50	58.0
Cycle 3 Day 22	156	72.12	19.03	0.0	78.00	100.0	149	2.73	19.27	-88.0	1.00	52.0
Cycle 4 Day 1	172	73.81	16.83	11.0	78.00	100.0	164	5.89	17.65	-41.0	5.00	54.0
Cycle 4 Day 22	133	70.63	18.27	10.0	71.00	100.0	128	3.39	17.41	-43.0	3.50	49.0
Cycle 5 Day 1	150	73.65	16.95	11.0	75.50	100.0	146	5.14	17.26	-40.0	4.00	53.0
Cycle 5 Day 22	123	71.01	18.54	10.0	73.00	100.0	116	2.29	18.00	-60.0	2.00	53.0
Cycle 6 Day 1	127	72.07	20.06	10.0	75.00	100.0	122	2.48	20.43	-69.0	2.00	58.0
Cycle 6 Day 22	99	75.69	18.60	9.0	80.00	100.0	95	5.21	16.71	-29.0	3.00	54.0
Cycle 7 Day 1	101	76.93	15.88	27.0	79.00	100.0	98	6.15	15.20	-33.0	4.50	48.0
Cycle 7 Day 22	76	75.79	14.89	29.0	79.00	100.0	74	5.14	14.60	-26.0	2.50	48.0
Cycle 8 Day 1	84	78.21	14.80	33.0	80.00	100.0	83	6.60	14.65	-28.0	5.00	48.0
Cycle 8 Day 22	67	77.76	15.41	31.0	80.00	100.0	65	7.65	14.13	-29.0	6.00	48.0
Cycle 9 Day 1	64	77.14	15.16	29.0	79.00	100.0	62	5.24	13.63	-24.0	3.00	48.0
Cycle 9 Day 22	57	76.68	17.16	28.0	78.00	100.0	55	6.42	15.96	-30.0	5.00	48.0
Cycle 10 Day 1	58	77.21	17.49	29.0	80.00	100.0	56	5.86	18.29	-51.0	5.00	48.0
Cycle 10 Day 22	44	76.84	18.27	33.0	81.00	100.0	43	6.72	15.81	-23.0	3.00	48.0
Cycle 11 Day 1	48	78.17	17.23	25.0	82.00	100.0	46	7.33	14.98	-20.0	3.50	48.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation;
90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 08SEP23

Table 301.3.3002.3: EQ-5D-5L - Observed Means and Change from Baseline of Visual Analog Scale - Full Analysis Set

Treatment Group Analysis Visit	Value						Change from Baseline					
	n	Mean	SD	Min	Med	Max	n	Mean	SD	Min	Med	Max
Cycle 11 Day 22	33	75.15	20.01	29.0	80.00	100.0	31	5.58	15.74	-21.0	3.00	48.0
Cycle 12 Day 1	43	74.63	19.63	16.0	80.00	100.0	41	3.95	17.66	-40.0	1.00	48.0
Cycle 12 Day 22	28	74.93	21.08	10.0	80.50	100.0	26	3.69	16.11	-40.0	2.00	48.0
Cycle 13 Day 1	37	74.35	19.92	31.0	80.00	100.0	35	3.34	17.40	-24.0	-1.00	48.0
Cycle 13 Day 22	22	72.36	23.60	6.0	79.00	100.0	21	1.67	17.02	-44.0	2.00	27.0
Cycle 14 Day 1	31	76.29	16.82	32.0	80.00	100.0	30	5.83	13.93	-19.0	7.00	29.0
Cycle 14 Day 22	20	72.50	21.76	29.0	78.50	100.0	19	3.53	14.98	-25.0	3.00	28.0
Cycle 15 Day 1	27	77.41	17.50	31.0	80.00	100.0	27	7.11	14.91	-20.0	6.00	48.0
Cycle 15 Day 22	17	74.94	21.18	27.0	73.00	100.0	17	2.29	17.85	-33.0	0.00	48.0
Cycle 16 Day 1	22	74.95	18.85	27.0	79.00	100.0	22	3.86	15.94	-21.0	4.00	38.0
Cycle 16 Day 22	14	79.21	17.53	30.0	80.00	100.0	14	0.36	12.34	-30.0	2.00	20.0
Cycle 17 Day 1	18	78.89	16.47	40.0	80.00	100.0	18	1.72	14.90	-20.0	0.00	28.0
Cycle 18 Day 1	16	80.50	15.05	40.0	82.50	100.0	16	2.69	12.72	-22.0	0.50	25.0
Cycle 18 Day 22	11	82.18	9.88	67.0	81.00	100.0	10	2.90	12.08	-13.0	3.00	24.0
Cycle 19 Day 1	16	80.69	13.88	40.0	81.50	100.0	15	3.33	14.11	-20.0	2.00	31.0
Cycle 19 Day 22	12	82.67	9.84	68.0	81.00	100.0	11	3.73	10.36	-10.0	3.00	23.0
Cycle 20 Day 1	16	81.06	13.66	50.0	81.00	100.0	15	3.67	13.97	-19.0	3.00	27.0
Cycle 20 Day 22	11	87.73	9.49	70.0	90.00	100.0	10	7.00	14.24	-10.0	3.00	31.0
Cycle 21 Day 1	15	82.47	11.49	67.0	80.00	100.0	14	4.00	15.06	-19.0	1.50	28.0
Cycle 22 Day 1	12	80.58	12.12	60.0	80.50	99.0	12	4.25	16.19	-21.0	2.00	29.0
Cycle 23 Day 1	13	81.08	13.63	50.0	80.00	100.0	13	5.31	17.77	-21.0	5.00	38.0
Study Disc 1	155	64.55	21.21	0.0	70.00	100.0	149	-2.62	21.46	-78.0	-1.00	51.0
Study Disc 2	12	57.75	15.44	34.0	60.00	81.0	12	-8.50	23.80	-42.0	-7.50	29.0
30 D SFU Z/P	94	64.48	18.38	15.0	68.00	98.0	92	-2.07	17.67	-45.0	-2.00	41.0
90 D SFU Z/P	85	63.18	21.21	10.0	68.00	100.0	83	-4.84	19.73	-68.0	-3.00	59.0

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Max=maximum; Med=median; Min=minimum; SD=standard deviation; 90 D FU Z/P=90 day follow up visit Zolbetuximab/Placebo; Study Disc=study drug discontinuation visit.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

Table 301.3.3004.3.1: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	283 (100.0%)	282 (100.0%)	
Number of patients with events	127 (44.9%)	120 (42.6%)	
Number of patients censored	156 (55.1%)	162 (57.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	6.5 [4.6, 9.9]	9.7 [6.8, 15.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.180 [0.917, 1.517]
Log-rank test			
Two-sided stratified log-rank p-value			0.1998

Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; MID=minimally important difference; 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 >=15 point decrease. Censoring date is date of last available assessment of the parameter.
[a] Based on the Brookmeyer-Crowley Method.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3004.3.2: EQ-5D-5L - Summary of Time to First Deterioration of Visual Analog Scale by Subgroups (MID=15) - Full Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	181	82 (45.3)	6.4 [4.2, 21.3]	181	76 (42.0)	9.7 [6.7, 15.7]	1.184 [0.866, 1.619]	0.2893	0.9390
>65 years	102	45 (44.1)	6.9 [3.7, 17.9]	101	44 (43.6)	9.4 [5.2, 19.3]	1.160 [0.765, 1.759]	0.4884	
Sex									
Male	176	72 (40.9)	7.6 [4.7, NC]	175	73 (41.7)	10.4 [7.2, 18.2]	1.125 [0.812, 1.558]	0.4834	0.6756
Female	107	55 (51.4)	5.3 [2.4, 9.9]	107	47 (43.9)	8.5 [4.7, 13.9]	1.239 [0.839, 1.831]	0.2814	
Region									
Asia	88	53 (60.2)	4.4 [2.2, 6.9]	89	47 (52.8)	6.7 [4.9, 13.9]	1.245 [0.839, 1.848]	0.2776	0.6749
Non-Asia	195	74 (37.9)	9.9 [5.0, NC]	193	73 (37.8)	11.1 [7.2, NC]	1.120 [0.810, 1.548]	0.4972	
Number of Organs with Metastatic Sites									
0-2	219	101 (46.1)	6.3 [3.7, 9.5]	219	93 (42.5)	11.1 [6.8, 18.2]	1.238 [0.933, 1.641]	0.1394	0.4577
>=3	64	26 (40.6)	8.9 [4.4, NC]	63	27 (42.9)	9.2 [4.4, NC]	0.967 [0.564, 1.659]	0.9031	

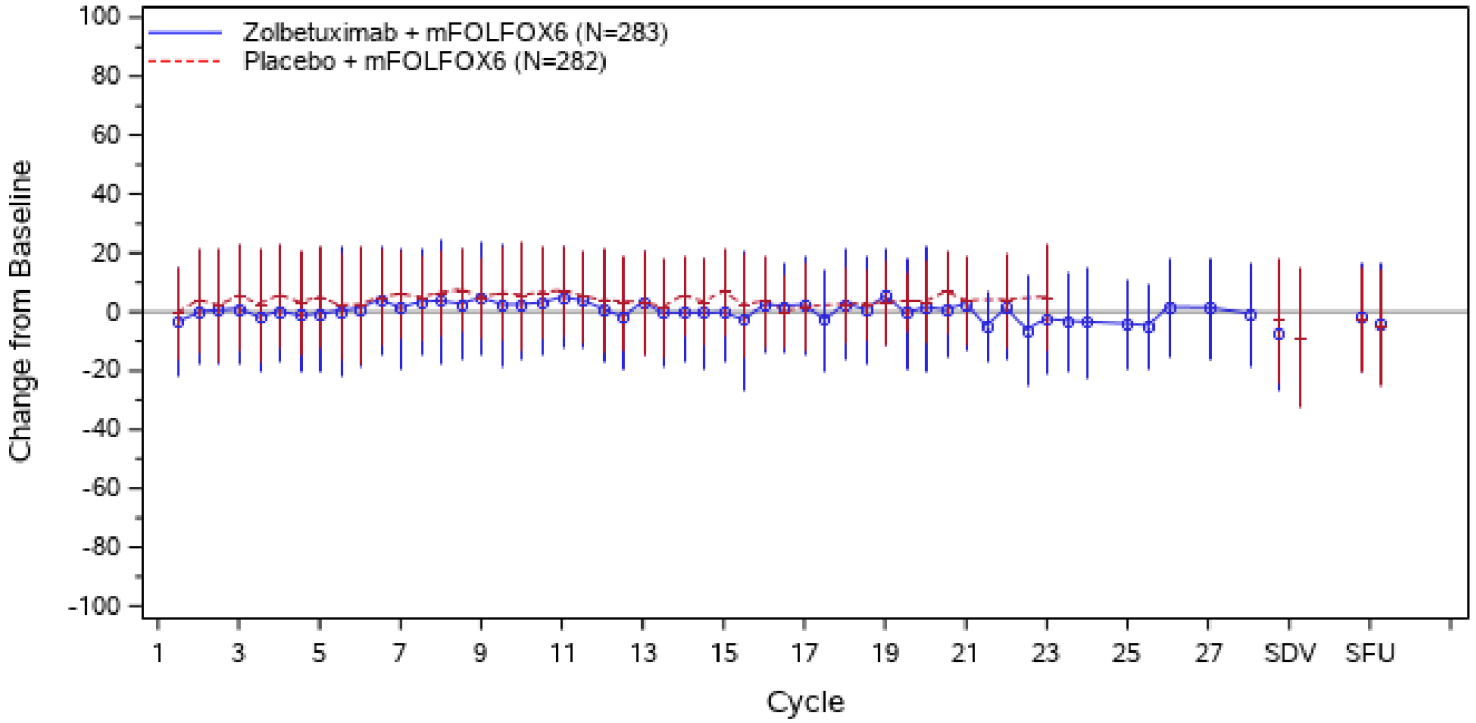
Abbreviations: CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; HR=hazard ratio; KME=kaplan-meier estimate of time to event (months); MID=minimally important difference; N=number of patients; n=number of patients with event; NC=not calculated.
Note: Time to first deterioration is defined as the time from randomization to the first observation with a >=15 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 [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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

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

The SAS System

Figure 301.3.3002.3: EQ-5D-5L - Plot of Mean Change from Baseline of Visual Analog Scale - Full Analysis Set

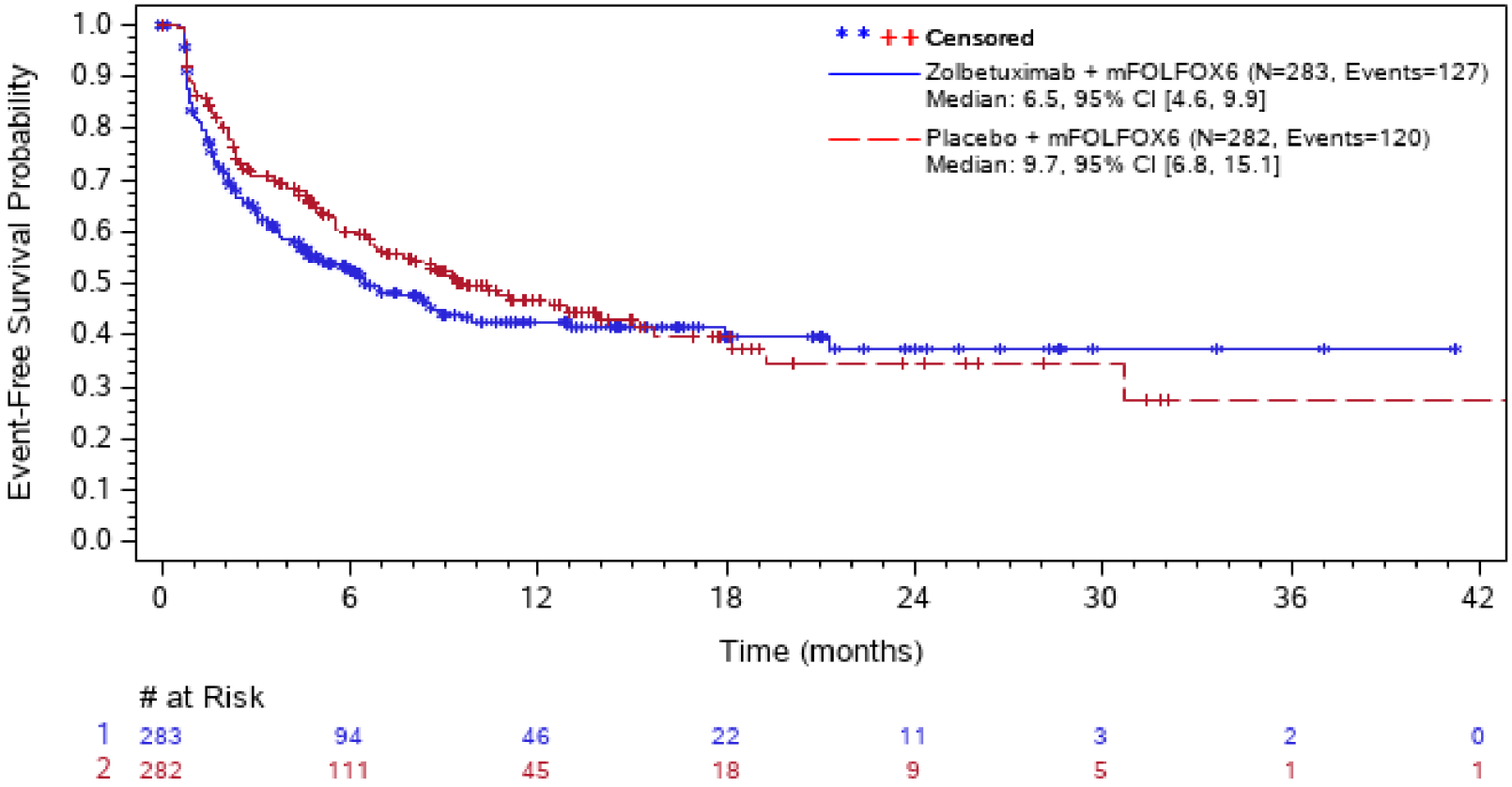


Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; SD=standard deviation; SDV=study discontinuation visits; SFU=safety follow up.
Vertical bars indicate Mean +/- SD and are only provided for the treatment arm for the visit if that arm has at least 10 subjects at that visit. Baseline is the last available measurement before the visit dose.
SDV contains both Study Discontinuation Visit 1(left) and Visit 2 (right). SFU contains both 30 Day Safety Follow Up Visit - Zolbetuximab/Placebo (left) and 90 Day Safety Follow Up Visit - Zolbetuximab/Placebo (right).
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Patientenberichtete Endpunkte
Anhang 4-G4 EQ-5D VAS

5. Kaplan-Meier-Plots

Figure 301.3.3004.3: EQ-5D-5L - Kaplan-Meier Plot of Time to First Deterioration of Visual Analog Scale (MID=15) - Full Analysis Set



Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; EQ-5D-5L=european quality of life 5 dimensions 5 level; MID=minimally important difference; 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 >=15 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Sicherheit

Anhang 4-G4 Unerwünschte Ereignisse

1. Time-to Event-Analysen

Table 301.3.2001.1.1: Summary and Results of TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	278 (99.6%)	277 (99.6%)	
Number of patients censored	1 (0.4%)	1 (0.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.1 [0.1, 0.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.650 [1.385, 1.967]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 08SEP23

Table 301.3.2001.1.2: Summary and Results of TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	178 (100.0)	0.0 [NC, NC]	177	176 (99.4)	0.1 [0.1, 0.1]	1.761 [1.421, 2.183]	<.0001	0.4905
>65 years	101	100 (99.0)	0.0 [NC, NC]	101	101 (100.0)	0.1 [0.1, 0.1]	1.505 [1.136, 1.993]	0.0122	
Sex									
Male	174	173 (99.4)	0.0 [NC, NC]	173	172 (99.4)	0.1 [0.1, 0.1]	1.488 [1.200, 1.845]	0.0014	0.3405
Female	105	105 (100.0)	0.0 [NC, NC]	105	105 (100.0)	0.1 [0.1, 0.1]	2.143 [1.617, 2.839]	<.0001	
Region									
Asia	87	87 (100.0)	0.0 [NC, NC]	88	87 (98.9)	0.1 [0.1, 0.1]	1.951 [1.435, 2.654]	<.0001	0.1628
Non-Asia	192	191 (99.5)	0.0 [NC, NC]	190	190 (100.0)	0.1 [0.1, 0.1]	1.503 [1.224, 1.845]	0.0021	
Number of Organs with Metastatic Sites									
0-2	216	215 (99.5)	0.0 [NC, NC]	216	215 (99.5)	0.1 [0.1, 0.1]	1.808 [1.488, 2.196]	<.0001	0.1164
>=3	63	63 (100.0)	0.0 [NC, NC]	62	62 (100.0)	0.1 [0.0, 0.2]	1.202 [0.839, 1.723]	0.5691	

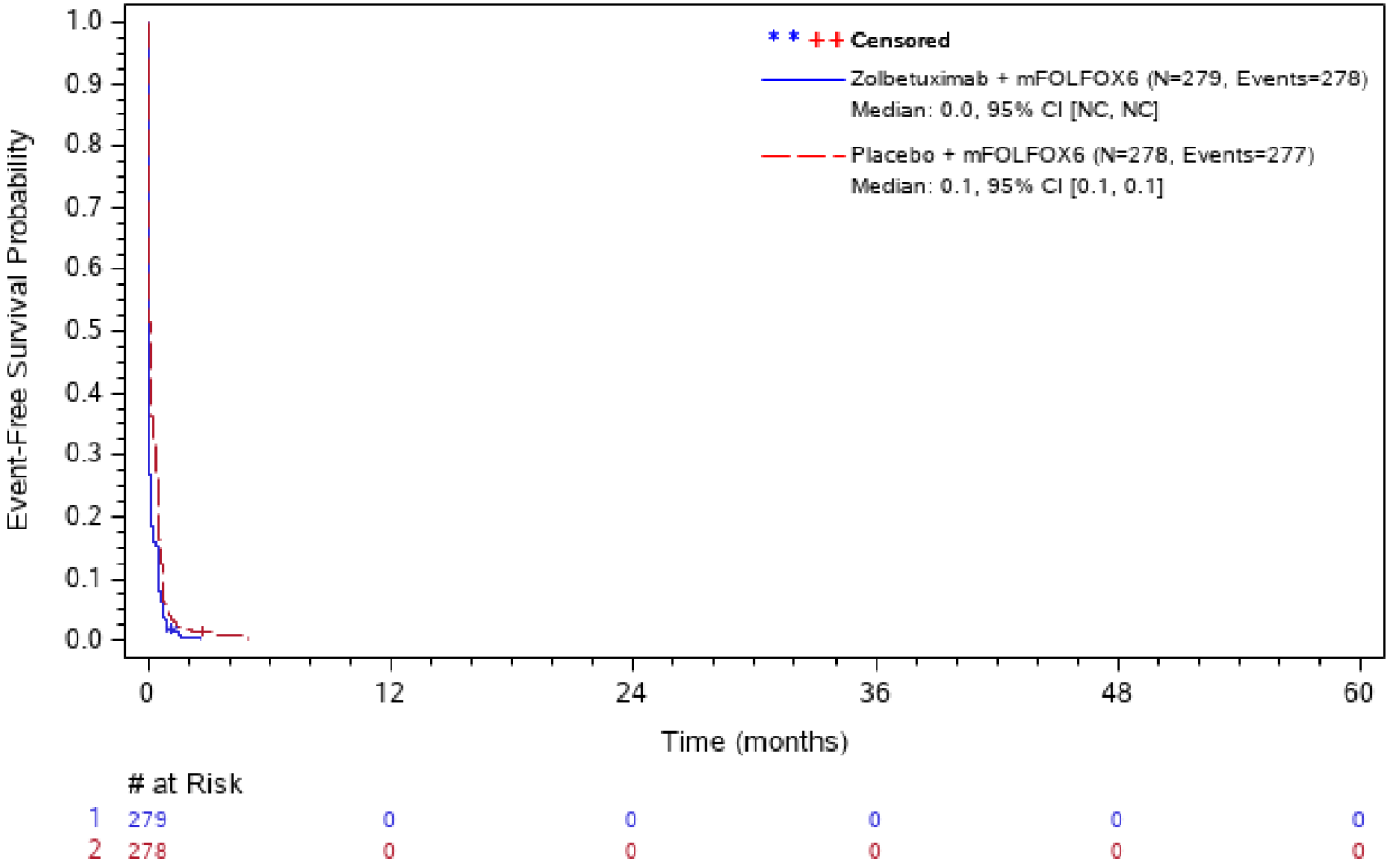
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of studytreatment + 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.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.1: 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 301.3.2001.3.1: Summary and Results of Severe TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	244 (87.5%)	219 (78.8%)	
Number of patients censored	35 (12.5%)	59 (21.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.1 [0.8, 1.4]	2.2 [1.9, 2.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.519 [1.262, 1.829]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 08SEP23

Table 301.3.2001.3.2: Summary and Results of Severe TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	156 (87.6)	0.9 [0.7, 1.4]	177	140 (79.1)	2.2 [1.6, 2.8]	1.477 [1.175, 1.858]	0.0010	0.9913
>65 years	101	88 (87.1)	1.3 [0.9, 1.4]	101	79 (78.2)	2.1 [1.5, 2.8]	1.513 [1.115, 2.053]	0.0075	
Sex									
Male	174	147 (84.5)	1.3 [1.0, 2.0]	173	134 (77.5)	2.7 [2.1, 3.4]	1.430 [1.130, 1.810]	0.0030	0.5595
Female	105	97 (92.4)	0.8 [0.6, 1.2]	105	85 (81.0)	1.9 [1.0, 2.2]	1.604 [1.197, 2.148]	0.0016	
Region									
Asia	87	71 (81.6)	1.4 [1.0, 2.2]	88	66 (75.0)	2.1 [1.4, 3.7]	1.183 [0.844, 1.657]	0.3212	0.0975
Non-Asia	192	173 (90.1)	0.9 [0.7, 1.4]	190	153 (80.5)	2.3 [1.7, 2.8]	1.681 [1.351, 2.091]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	185 (85.6)	1.0 [0.8, 1.4]	216	169 (78.2)	2.2 [1.9, 2.6]	1.454 [1.180, 1.793]	0.0005	0.6416
>=3	63	59 (93.7)	1.1 [0.7, 1.4]	62	50 (80.6)	2.1 [0.8, 3.2]	1.640 [1.118, 2.406]	0.0099	

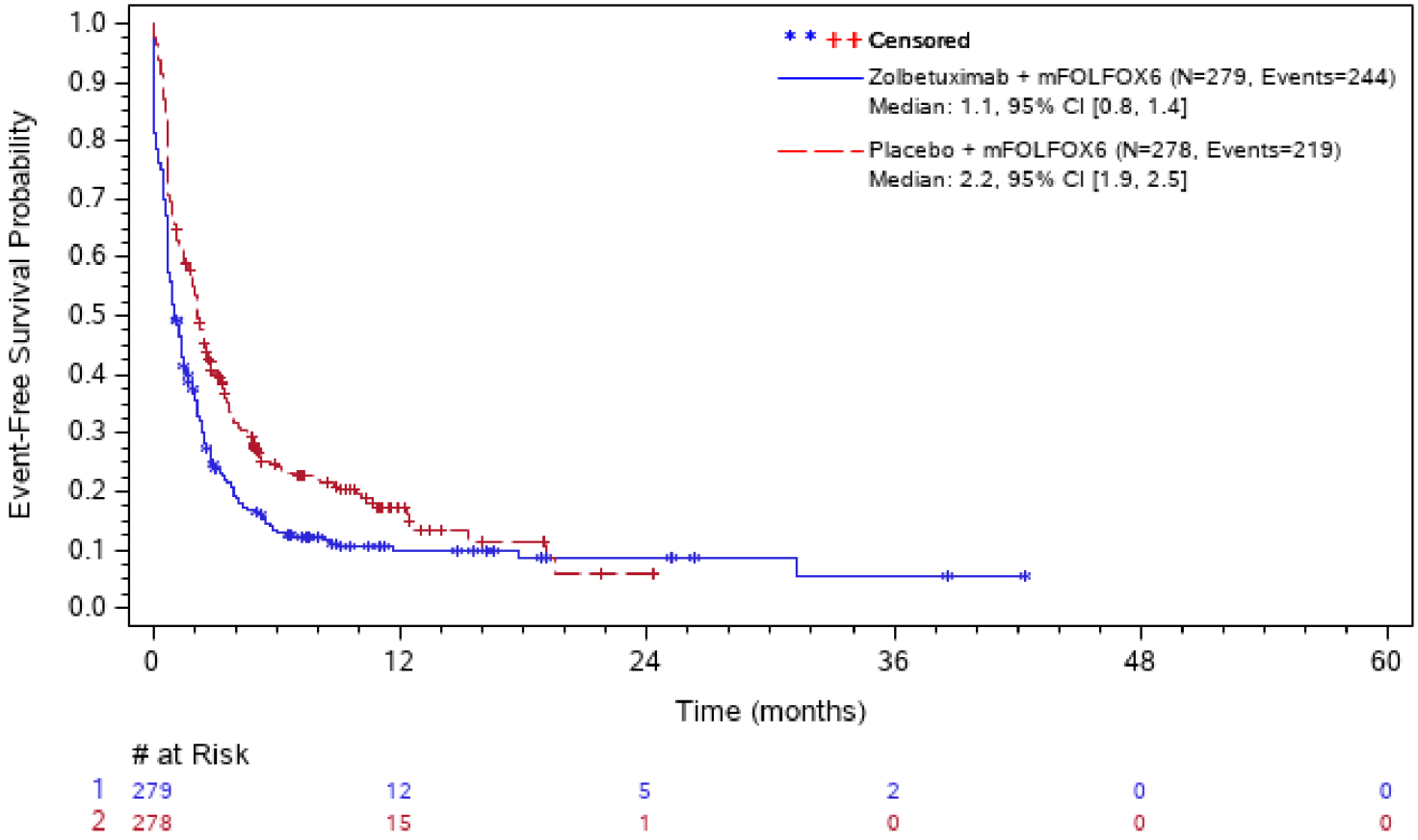
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of studytreatment + 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.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.3: 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse

1. Time-to-Event-Analysen

Table 301.3.2001.4.1: Summary and Results of TESAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	133 (47.7%)	129 (46.4%)	
Number of patients censored	146 (52.3%)	149 (53.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	15.3 [8.1, 24.5]	11.6 [9.1, 15.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.108 [0.868, 1.414]
Log-rank test			
Two-sided stratified log-rank p-value			0.4181

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 08SEP23

Table 301.3.2001.4.2: Summary and Results of TESAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	85 (47.8)	16.7 [7.1, 28.9]	177	82 (46.3)	11.8 [7.6, 15.3]	1.091 [0.804, 1.479]	0.5843	0.6883
>65 years	101	48 (47.5)	12.0 [6.6, NC]	101	47 (46.5)	11.5 [8.8, 19.1]	0.976 [0.650, 1.464]	0.9023	
Sex									
Male	174	81 (46.6)	15.3 [7.2, 24.5]	173	82 (47.4)	11.8 [8.7, 15.4]	0.983 [0.722, 1.337]	0.9086	0.5483
Female	105	52 (49.5)	13.3 [4.9, 30.2]	105	47 (44.8)	11.5 [7.6, NC]	1.172 [0.788, 1.744]	0.4425	
Region									
Asia	87	31 (35.6)	29.2 [16.7, NC]	88	29 (33.0)	15.4 [10.2, NC]	0.910 [0.545, 1.520]	0.7192	0.5221
Non-Asia	192	102 (53.1)	7.3 [4.7, 15.3]	190	100 (52.6)	10.4 [7.5, 15.1]	1.129 [0.857, 1.489]	0.3966	
Number of Organs with Metastatic Sites									
0-2	216	97 (44.9)	18.1 [10.2, 28.9]	216	93 (43.1)	13.3 [10.3, 18.9]	1.053 [0.791, 1.401]	0.7276	0.8170
>=3	63	36 (57.1)	4.7 [2.4, NC]	62	36 (58.1)	6.2 [3.0, 24.9]	1.067 [0.671, 1.696]	0.7886	

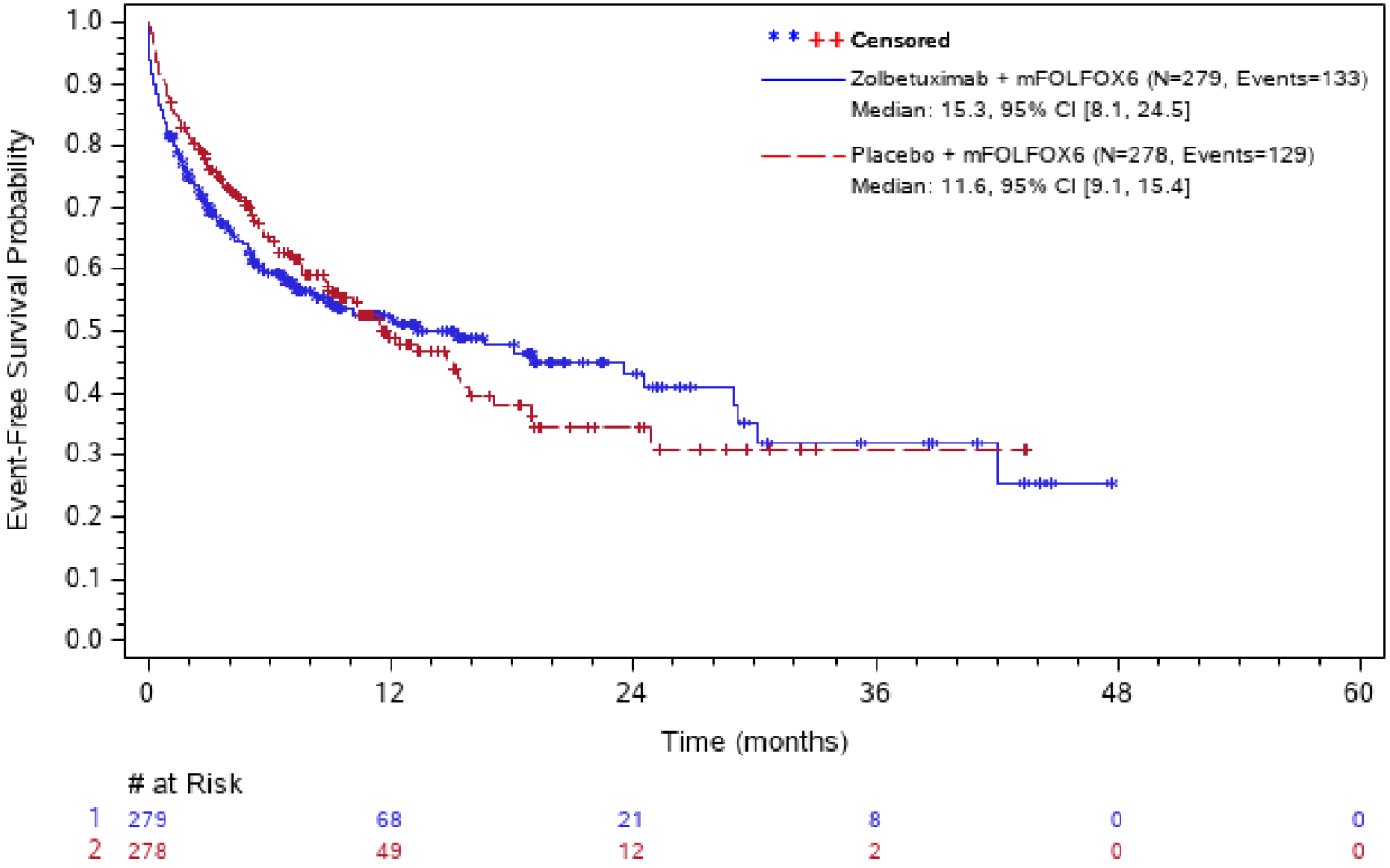
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of studytreatment + 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.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.4: 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

1. Time-to-Event-Analysen

Table 301.3.2001.5.1: Summary and Results of Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	125 (44.8%)	107 (38.5%)	
Number of patients censored	154 (55.2%)	171 (61.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.8 [6.9, 22.4]	24.1 [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.173 [0.905, 1.522]
Log-rank test			
Two-sided stratified log-rank p-value			0.2274

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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: 08SEP23

Table 301.3.2001.5.2: Summary and Results of Permanent Treatment Discontinuation due to TEAEs by Subgroups - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	75 (42.1)	15.2 [7.8, NC]	177	62 (35.0)	NC [14.5, NC]	1.218 [0.870, 1.705]	0.2508	0.7187
>65 years	101	50 (49.5)	6.9 [5.1, 22.4]	101	45 (44.6)	9.5 [5.5, NC]	1.103 [0.737, 1.652]	0.6364	
Sex									
Male	174	78 (44.8)	10.8 [6.4, NC]	173	62 (35.8)	24.1 [14.8, NC]	1.284 [0.920, 1.793]	0.1410	0.3807
Female	105	47 (44.8)	10.2 [5.5, NC]	105	45 (42.9)	9.5 [5.3, NC]	1.030 [0.684, 1.550]	0.8933	
Region									
Asia	87	33 (37.9)	NC [7.6, NC]	88	31 (35.2)	14.8 [6.5, NC]	0.953 [0.582, 1.561]	0.8463	0.2968
Non-Asia	192	92 (47.9)	7.9 [5.8, 16.4]	190	76 (40.0)	24.1 [6.9, NC]	1.286 [0.949, 1.743]	0.1036	
Number of Organs with Metastatic Sites									
0-2	216	95 (44.0)	12.0 [6.9, NC]	216	82 (38.0)	24.1 [14.5, NC]	1.140 [0.848, 1.531]	0.3856	0.6969
>=3	63	30 (47.6)	6.7 [4.5, NC]	62	25 (40.3)	10.4 [6.0, NC]	1.281 [0.751, 2.186]	0.3613	

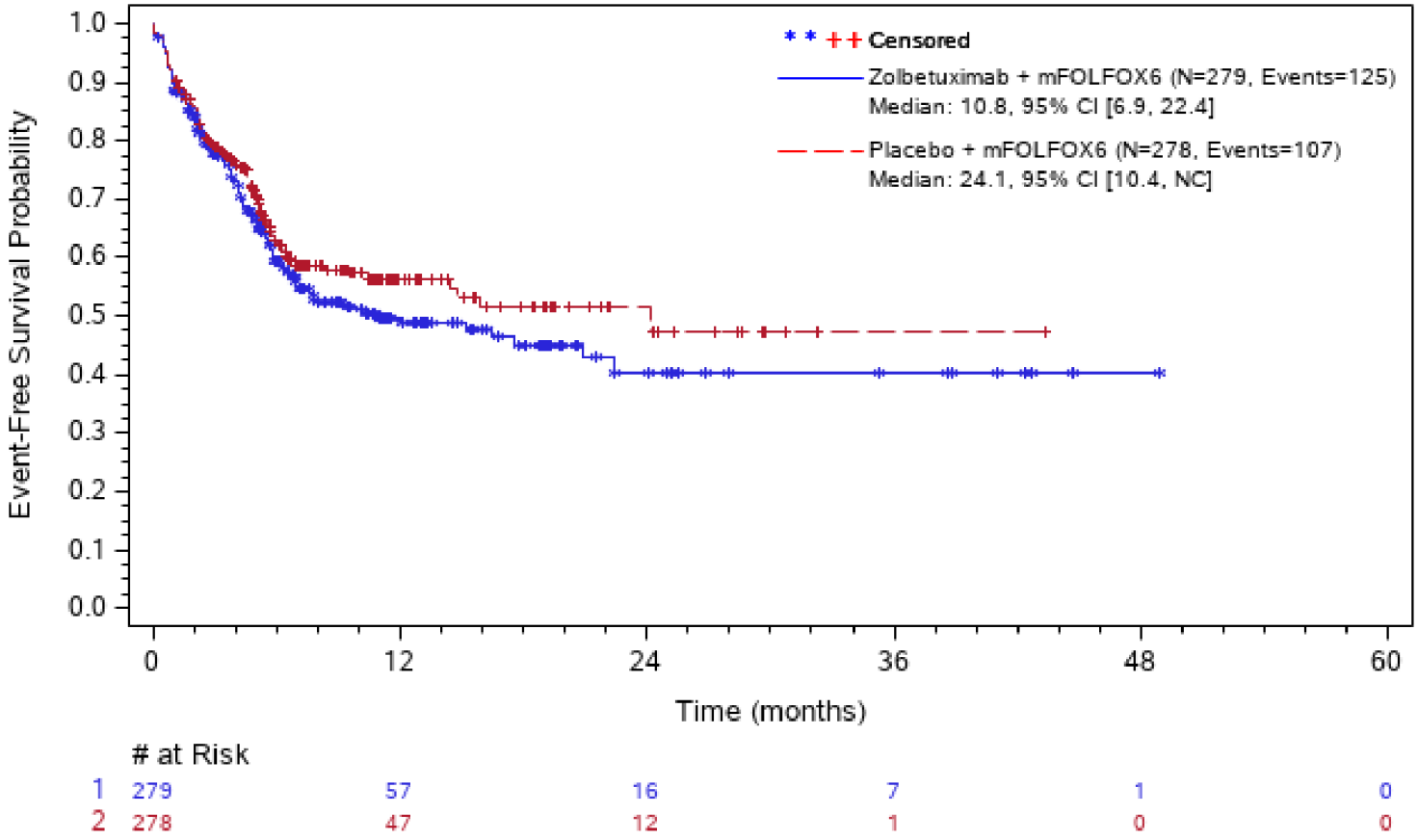
Abbreviations: CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.
Time to event duration is defined as date of first exposure to treatment to start date of first AE + 1 day. Censoring date is defined as min(date of last dose of studytreatment + 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.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruch der Studienmedikation aufgrund unerwünschter Ereignisse

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.5: 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.3.2001.6.1: Summary and Results of TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	171 (61.3%)	169 (60.8%)	
Number of patients censored	108 (38.7%)	109 (39.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.8 [2.1, 3.9]	3.0 [2.1, 4.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.989 [0.798, 1.225]
Log-rank test			
Two-sided stratified log-rank p-value			0.9414

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.7.1: Summary and Results of TEAEs - Anaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	106 (38.0%)	107 (38.5%)	
Number of patients censored	173 (62.0%)	171 (61.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	34.3 [12.6, NC]	27.4 [11.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.945 [0.720, 1.240]
Log-rank test			
Two-sided stratified log-rank p-value			0.6915

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.8.1: Summary and Results of TEAEs - Leukocytosis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.115 [0.538, 8.305]
Log-rank test			
Two-sided stratified log-rank p-value			0.2726

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.9.1: Summary and Results of TEAEs - Leukopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	13 (4.7%)	
Number of patients censored	262 (93.9%)	265 (95.3%)	
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			1.330 [0.644, 2.744]
Log-rank test			
Two-sided stratified log-rank p-value			0.4432

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.10.1: Summary and Results of TEAEs - Neutropenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	102 (36.6%)	94 (33.8%)	
Number of patients censored	177 (63.4%)	184 (66.2%)	
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			1.155 [0.872, 1.530]
Log-rank test			
Two-sided stratified log-rank p-value			0.3068

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.11.1: Summary and Results of TEAEs - Thrombocytopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	29 (10.4%)	45 (16.2%)	
Number of patients censored	250 (89.6%)	233 (83.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.644 [0.404, 1.027]
Log-rank test			
Two-sided stratified log-rank p-value			0.0629

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.12.1: Summary and Results of TEAEs - Cardiac Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	26 (9.3%)	23 (8.3%)	
Number of patients censored	253 (90.7%)	255 (91.7%)	
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			1.171 [0.668, 2.055]
Log-rank test			
Two-sided stratified log-rank p-value			0.5806

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.13.1: Summary and Results of TEAEs - Palpitations (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.517 [0.494, 4.658]
Log-rank test			
Two-sided stratified log-rank p-value			0.4634

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.14.1: Summary and Results of TEAEs - Tachycardia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	2 (0.7%)	
Number of patients censored	269 (96.4%)	276 (99.3%)	
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			4.836 [1.056, 22.146]
Log-rank test			
Two-sided stratified log-rank p-value			0.0249

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.14.2: Summary and Results of TEAEs by Subgroups - Tachycardia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	5 (2.8)		177	1 (0.6)				
>65 years	101	5 (5.0)		101	1 (1.0)				
Sex									
Male	174	7 (4.0)		173	2 (1.2)				
Female	105	3 (2.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.3145	0.9938
Non-Asia	192	9 (4.7)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	4.501 [0.971, 20.875]	0.0352	
Number of Organs with Metastatic Sites									
0-2	216	7 (3.2)		216	2 (0.9)				
>=3	63	3 (4.8)		62	0 (0.0)				

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.15.1: Summary and Results of TEAEs - Ear and Labyrinth Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.770 [0.330, 1.797]
Log-rank test			
Two-sided stratified log-rank p-value			0.5440

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.16.1: Summary and Results of TEAEs - Tinnitus (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.231 [0.385, 3.936]
Log-rank test			
Two-sided stratified log-rank p-value			0.7255

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.17.1: Summary and Results of TEAEs - Endocrine Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	7 (2.5%)	
Number of patients censored	269 (96.4%)	271 (97.5%)	
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			1.309 [0.494, 3.471]
Log-rank test			
Two-sided stratified log-rank p-value			0.5868

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.18.1: Summary and Results of TEAEs - Hypothyroidism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.474 [0.476, 4.561]
Log-rank test			
Two-sided stratified log-rank p-value			0.4984

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.19.1: Summary and Results of TEAEs - Eye Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	28 (10.1%)	
Number of patients censored	257 (92.1%)	250 (89.9%)	
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			0.715 [0.405, 1.265]
Log-rank test			
Two-sided stratified log-rank p-value			0.2466

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.20.1: Summary and Results of TEAEs - Dry Eye (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	8 (2.9%)	
Number of patients censored	275 (98.6%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.364 [0.096, 1.379]
Log-rank test			
Two-sided stratified log-rank p-value			0.1211

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.21.1: Summary and Results of TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	264 (94.6%)	252 (90.6%)	
Number of patients censored	15 (5.4%)	26 (9.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [NC, NC]	0.3 [0.2, 0.4]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.853 [1.547, 2.220]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.21.2: Summary and Results of TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	171 (96.1)	0.0 [NC, NC]	177	163 (92.1)	0.2 [0.1, 0.4]	1.880 [1.512, 2.338]	<.0001	0.9860
>65 years	101	93 (92.1)	0.0 [0.0, 0.1]	101	89 (88.1)	0.4 [0.2, 0.6]	1.816 [1.353, 2.436]	0.0004	
Sex									
Male	174	162 (93.1)	0.0 [NC, NC]	173	160 (92.5)	0.4 [0.2, 0.5]	1.665 [1.335, 2.077]	0.0001	0.2112
Female	105	102 (97.1)	0.0 [NC, NC]	105	92 (87.6)	0.2 [0.1, 0.4]	2.309 [1.732, 3.078]	<.0001	
Region									
Asia	87	85 (97.7)	0.0 [0.0, 0.1]	88	77 (87.5)	0.1 [0.1, 0.6]	2.298 [1.676, 3.151]	<.0001	0.1394
Non-Asia	192	179 (93.2)	0.0 [NC, NC]	190	175 (92.1)	0.4 [0.2, 0.5]	1.668 [1.351, 2.060]	0.0002	
Number of Organs with Metastatic Sites									
0-2	216	205 (94.9)	0.0 [NC, NC]	216	195 (90.3)	0.3 [0.1, 0.5]	1.995 [1.635, 2.434]	<.0001	0.2949
>=3	63	59 (93.7)	0.0 [0.0, 0.1]	62	57 (91.9)	0.4 [0.2, 0.5]	1.483 [1.025, 2.146]	0.0904	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.22.1: Summary and Results of TEAEs - Abdominal Discomfort (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	8 (2.9%)	
Number of patients censored	270 (96.8%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.958 [0.358, 2.567]
Log-rank test			
Two-sided stratified log-rank p-value			0.9323

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.23.1: Summary and Results of TEAEs - Abdominal Distension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	23 (8.3%)	
Number of patients censored	262 (93.9%)	255 (91.7%)	
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			0.737 [0.393, 1.381]
Log-rank test			
Two-sided stratified log-rank p-value			0.3383

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.24.1: Summary and Results of TEAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	70 (25.1%)	87 (31.3%)	
Number of patients censored	209 (74.9%)	191 (68.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	19.8 [14.5, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.826 [0.602, 1.134]
Log-rank test			
Two-sided stratified log-rank p-value			0.2270

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.25.1: Summary and Results of TEAEs - Abdominal Pain Upper (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	47 (16.8%)	34 (12.2%)	
Number of patients censored	232 (83.2%)	244 (87.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.429 [0.917, 2.227]
Log-rank test			
Two-sided stratified log-rank p-value			0.1145

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.26.1: Summary and Results of TEAEs - Ascites (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	12 (4.3%)	
Number of patients censored	274 (98.2%)	266 (95.7%)	
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			0.386 [0.133, 1.123]
Log-rank test			
Two-sided stratified log-rank p-value			0.0708

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.27.1: Summary and Results of TEAEs - Constipation (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	101 (36.2%)	113 (40.6%)	
Number of patients censored	178 (63.8%)	165 (59.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	23.9 [13.6, NC]	NC [10.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.796 [0.606, 1.045]
Log-rank test			
Two-sided stratified log-rank p-value			0.0995

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.28.1: Summary and Results of TEAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	114 (40.9%)	125 (45.0%)	
Number of patients censored	165 (59.1%)	153 (55.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	20.3 [10.7, NC]	13.2 [7.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.834 [0.646, 1.077]
Log-rank test			
Two-sided stratified log-rank p-value			0.1631

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.29.1: Summary and Results of TEAEs - Dry Mouth (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	10 (3.6%)	
Number of patients censored	265 (95.0%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.391 [0.617, 3.135]
Log-rank test			
Two-sided stratified log-rank p-value			0.4219

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.30.1: Summary and Results of TEAEs - Dyspepsia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	28 (10.0%)	20 (7.2%)	
Number of patients censored	251 (90.0%)	258 (92.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.423 [0.799, 2.536]
Log-rank test			
Two-sided stratified log-rank p-value			0.2289

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.31.1: Summary and Results of TEAEs - Dysphagia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	23 (8.2%)	22 (7.9%)	
Number of patients censored	256 (91.8%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.052 [0.584, 1.894]
Log-rank test			
Two-sided stratified log-rank p-value			0.8671

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.32.1: Summary and Results of TEAEs - Flatulence (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	8 (2.9%)	
Number of patients censored	271 (97.1%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.981 [0.367, 2.618]
Log-rank test			
Two-sided stratified log-rank p-value			0.9692

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.33.1: Summary and Results of TEAEs - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	16 (5.8%)	
Number of patients censored	265 (95.0%)	262 (94.2%)	
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			0.878 [0.428, 1.803]
Log-rank test			
Two-sided stratified log-rank p-value			0.7230

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.34.1: Summary and Results of TEAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	9 (3.2%)	
Number of patients censored	271 (97.1%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.863 [0.332, 2.245]
Log-rank test			
Two-sided stratified log-rank p-value			0.7617

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.35.1: Summary and Results of TEAEs - Mouth Ulceration (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.075 [0.529, 8.135]
Log-rank test			
Two-sided stratified log-rank p-value			0.2848

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.36.1: Summary and Results of TEAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	230 (82.4%)	171 (61.5%)	
Number of patients censored	49 (17.6%)	107 (38.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	2.0 [0.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.149 [1.755, 2.630]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.36.2: Summary and Results of TEAEs by Subgroups - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	146 (82.0)	0.0 [0.0, 0.1]	177	119 (67.2)	1.0 [0.6, 2.2]	1.913 [1.499, 2.441]	<.0001	0.0868
>65 years	101	84 (83.2)	0.1 [0.0, 0.4]	101	52 (51.5)	3.5 [1.5, NC]	2.762 [1.947, 3.918]	<.0001	
Sex									
Male	174	137 (78.7)	0.1 [0.0, 0.4]	173	107 (61.8)	2.0 [0.8, 3.3]	1.869 [1.449, 2.410]	<.0001	0.1032
Female	105	93 (88.6)	0.0 [0.0, 0.1]	105	64 (61.0)	2.1 [0.7, 5.0]	2.860 [2.069, 3.952]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.1]	88	60 (68.2)	1.1 [0.5, 2.4]	2.029 [1.442, 2.857]	<.0001	0.5163
Non-Asia	192	155 (80.7)	0.0 [0.0, 0.1]	190	111 (58.4)	2.4 [0.9, 4.8]	2.253 [1.762, 2.880]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	182 (84.3)	0.0 [0.0, 0.1]	216	134 (62.0)	1.6 [0.9, 3.3]	2.285 [1.824, 2.861]	<.0001	0.4459
>=3	63	48 (76.2)	0.1 [0.0, 0.7]	62	37 (59.7)	2.2 [0.5, NC]	1.827 [1.187, 2.812]	0.0119	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.37.1: Summary and Results of TEAEs - Retching (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.350 [0.607, 9.095]
Log-rank test			
Two-sided stratified log-rank p-value			0.2020

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.38.1: Summary and Results of TEAEs - Salivary Hypersecretion (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	2 (0.7%)	
Number of patients censored	267 (95.7%)	276 (99.3%)	
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			6.303 [1.410, 28.170]
Log-rank test			
Two-sided stratified log-rank p-value			0.0057

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.38.2: Summary and Results of TEAEs by Subgroups - Salivary Hypersecretion (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	8 (4.5)		177	1 (0.6)				
>65 years	101	4 (4.0)		101	1 (1.0)				
Sex									
Male	174	7 (4.0)		173	1 (0.6)				
Female	105	5 (4.8)		105	1 (1.0)				
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.99E7 [0.000, NC]	0.3145	0.9936
Non-Asia	192	11 (5.7)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	5.684 [1.259, 25.653]	0.0106	
Number of Organs with Metastatic Sites									
0-2	216	11 (5.1)	NC [NC, NC]	216	2 (0.9)	NC [NC, NC]	5.458 [1.209, 24.648]	0.0132	0.9940
>=3	63	1 (1.6)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.15E7 [0.000, NC]	0.3023	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.39.1: Summary and Results of TEAEs - Stomatitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	60 (21.5%)	60 (21.6%)	
Number of patients censored	219 (78.5%)	218 (78.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [36.7, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.998 [0.697, 1.429]
Log-rank test			
Two-sided stratified log-rank p-value			0.9946

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.40.1: Summary and Results of TEAEs - Toothache (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	7 (2.5%)	
Number of patients censored	275 (98.6%)	271 (97.5%)	
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			0.396 [0.101, 1.549]
Log-rank test			
Two-sided stratified log-rank p-value			0.1682

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.41.1: Summary and Results of TEAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	188 (67.4%)	101 (36.3%)	
Number of patients censored	91 (32.6%)	177 (63.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.7 [0.3, 1.4]	NC [16.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.887 [2.257, 3.693]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.41.2: Summary and Results of TEAEs by Subgroups - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	127 (71.3)	0.5 [0.0, 0.9]	177	73 (41.2)	25.9 [12.0, NC]	2.672 [2.000, 3.568]	<.0001	0.5421
>65 years	101	61 (60.4)	1.6 [0.7, 5.9]	101	28 (27.7)	NC [NC, NC]	3.081 [1.967, 4.826]	<.0001	
Sex									
Male	174	111 (63.8)	0.9 [0.5, 2.9]	173	57 (32.9)	NC [16.6, NC]	2.830 [2.053, 3.900]	<.0001	0.7974
Female	105	77 (73.3)	0.2 [0.0, 1.1]	105	44 (41.9)	NC [5.2, NC]	2.731 [1.883, 3.962]	<.0001	
Region									
Asia	87	54 (62.1)	1.2 [0.1, 12.2]	88	29 (33.0)	16.6 [13.2, NC]	2.430 [1.541, 3.834]	0.0002	0.6828
Non-Asia	192	134 (69.8)	0.5 [0.1, 1.2]	190	72 (37.9)	NC [25.9, NC]	2.919 [2.188, 3.894]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	148 (68.5)	0.7 [0.1, 1.1]	216	76 (35.2)	NC [16.6, NC]	2.971 [2.249, 3.923]	<.0001	0.2746
>=3	63	40 (63.5)	1.4 [0.2, 5.1]	62	25 (40.3)	NC [3.1, NC]	2.157 [1.307, 3.560]	0.0031	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.42.1: Summary and Results of TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	209 (74.9%)	207 (74.5%)	
Number of patients censored	70 (25.1%)	71 (25.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.4 [1.0, 1.8]	2.1 [1.5, 2.9]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.179 [0.970, 1.432]
Log-rank test			
Two-sided stratified log-rank p-value			0.1006

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.43.1: Summary and Results of TEAEs - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	74 (26.5%)	64 (23.0%)	
Number of patients censored	205 (73.5%)	214 (77.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [31.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.170 [0.835, 1.639]
Log-rank test			
Two-sided stratified log-rank p-value			0.3584

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.44.1: Summary and Results of TEAEs - Chest Discomfort (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			1.167 [0.422, 3.224]
Log-rank test			
Two-sided stratified log-rank p-value			0.7657

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.45.1: Summary and Results of TEAEs - Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	6 (2.2%)	
Number of patients censored	270 (96.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.543 [0.546, 4.356]
Log-rank test			
Two-sided stratified log-rank p-value			0.4107

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.46.1: Summary and Results of TEAEs - Chills (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	10 (3.6%)	
Number of patients censored	262 (93.9%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.697 [0.776, 3.710]
Log-rank test			
Two-sided stratified log-rank p-value			0.1793

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.47.1: Summary and Results of TEAEs - Fatigue (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	83 (29.7%)	94 (33.8%)	
Number of patients censored	196 (70.3%)	184 (66.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [25.1, NC]	NC [23.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.872 [0.649, 1.173]
Log-rank test			
Two-sided stratified log-rank p-value			0.3616

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.48.1: Summary and Results of TEAEs - General Physical Health Deterioration (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	7 (2.5%)	
Number of patients censored	276 (98.9%)	271 (97.5%)	
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			0.365 [0.093, 1.435]
Log-rank test			
Two-sided stratified log-rank p-value			0.1335

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.49.1: Summary and Results of TEAEs - Influenza Like Illness (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	7 (2.5%)	
Number of patients censored	272 (97.5%)	271 (97.5%)	
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			1.038 [0.355, 3.039]
Log-rank test			
Two-sided stratified log-rank p-value			0.9454

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.50.1: Summary and Results of TEAEs - Malaise (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	9 (3.2%)	
Number of patients censored	258 (92.5%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.469 [1.130, 5.397]
Log-rank test			
Two-sided stratified log-rank p-value			0.0191

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.50.2: Summary and Results of TEAEs by Subgroups - Malaise (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	12 (6.7)	NC [NC, NC]	177	5 (2.8)	NC [NC, NC]	2.491 [0.877, 7.072]	0.0761	0.9157
>65 years	101	9 (8.9)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	2.330 [0.717, 7.565]	0.1473	
Sex									
Male	174	12 (6.9)	NC [NC, NC]	173	5 (2.9)	NC [NC, NC]	2.485 [0.875, 7.057]	0.0770	0.9281
Female	105	9 (8.6)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	2.340 [0.721, 7.599]	0.1449	
Region									
Asia	87	16 (18.4)	NC [NC, NC]	88	8 (9.1)	NC [NC, NC]	2.099 [0.898, 4.908]	0.0801	0.4392
Non-Asia	192	5 (2.6)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	5.181 [0.605, 44.365]	0.0937	
Number of Organs with Metastatic Sites									
0-2	216	19 (8.8)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	3.349 [1.337, 8.388]	0.0061	0.1170
>=3	63	2 (3.2)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.715 [0.119, 4.288]	0.7119	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.51.1: Summary and Results of TEAEs - Mucosal Inflammation (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	14 (5.0%)	
Number of patients censored	273 (97.8%)	264 (95.0%)	
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			0.401 [0.154, 1.047]
Log-rank test			
Two-sided stratified log-rank p-value			0.0536

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.52.1: Summary and Results of TEAEs - Non-Cardiac Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	13 (4.7%)	
Number of patients censored	269 (96.4%)	265 (95.3%)	
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			0.744 [0.325, 1.703]
Log-rank test			
Two-sided stratified log-rank p-value			0.4826

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.53.1: Summary and Results of TEAEs - Oedema (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	2 (0.7%)	
Number of patients censored	271 (97.1%)	276 (99.3%)	
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			3.231 [0.674, 15.482]
Log-rank test			
Two-sided stratified log-rank p-value			0.1219

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.54.1: Summary and Results of TEAEs - Oedema Peripheral (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	52 (18.6%)	27 (9.7%)	
Number of patients censored	227 (81.4%)	251 (90.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [34.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.137 [1.339, 3.408]
Log-rank test			
Two-sided stratified log-rank p-value			0.0011

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.54.2: Summary and Results of TEAEs by Subgroups - Oedema Peripheral (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	32 (18.0)	NC [34.5, NC]	177	11 (6.2)	NC [NC, NC]	3.050 [1.535, 6.058]	0.0008	0.0632
>65 years	101	20 (19.8)	NC [NC, NC]	101	16 (15.8)	NC [NC, NC]	1.289 [0.668, 2.490]	0.4483	
Sex									
Male	174	32 (18.4)	NC [34.5, NC]	173	19 (11.0)	NC [NC, NC]	1.699 [0.961, 3.005]	0.0652	0.3828
Female	105	20 (19.0)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	2.713 [1.194, 6.164]	0.0131	
Region									
Asia	87	10 (11.5)	NC [34.5, NC]	88	1 (1.1)	NC [NC, NC]	9.726 [1.241, 76.251]	0.0079	0.1248
Non-Asia	192	42 (21.9)	NC [NC, NC]	190	26 (13.7)	NC [NC, NC]	1.779 [1.090, 2.903]	0.0195	
Number of Organs with Metastatic Sites									
0-2	216	35 (16.2)	NC [34.5, NC]	216	20 (9.3)	NC [NC, NC]	1.812 [1.045, 3.143]	0.0317	0.5087
>=3	63	17 (27.0)	NC [18.2, NC]	62	7 (11.3)	NC [NC, NC]	2.619 [1.080, 6.347]	0.0270	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.55.1: Summary and Results of TEAEs - Pyrexia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	59 (21.1%)	50 (18.0%)	
Number of patients censored	220 (78.9%)	228 (82.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [27.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.109 [0.758, 1.623]
Log-rank test			
Two-sided stratified log-rank p-value			0.5929

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.56.1: Summary and Results of TEAEs - Temperature Intolerance (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	10 (3.6%)	
Number of patients censored	271 (97.1%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.806 [0.318, 2.042]
Log-rank test			
Two-sided stratified log-rank p-value			0.6492

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.57.1: Summary and Results of TEAEs - Hepatobiliary Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	22 (7.9%)	
Number of patients censored	254 (91.0%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.082 [0.605, 1.933]
Log-rank test			
Two-sided stratified log-rank p-value			0.7926

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.58.1: Summary and Results of TEAEs - Immune System Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	12 (4.3%)	
Number of patients censored	272 (97.5%)	266 (95.7%)	
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			0.530 [0.207, 1.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.1787

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.59.1: Summary and Results of TEAEs - Drug Hypersensitivity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	6 (2.2%)	
Number of patients censored	275 (98.6%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.644 [0.181, 2.290]
Log-rank test			
Two-sided stratified log-rank p-value			0.4933

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.60.1: Summary and Results of TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	118 (42.3%)	103 (37.1%)	
Number of patients censored	161 (57.7%)	175 (62.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	13.8 [10.2, 18.6]	14.0 [11.0, 19.1]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.093 [0.836, 1.429]
Log-rank test			
Two-sided stratified log-rank p-value			0.5172

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.61.1: Summary and Results of TEAEs - Conjunctivitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.012 [0.306, 3.352]
Log-rank test			
Two-sided stratified log-rank p-value			0.9840

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.62.1: Summary and Results of TEAEs - Covid-19 (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	25 (9.0%)	
Number of patients censored	255 (91.4%)	253 (91.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [29.0, NC]	NC [30.1, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.720 [0.396, 1.310]
Log-rank test			
Two-sided stratified log-rank p-value			0.2797

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.63.1: Summary and Results of TEAEs - Nasopharyngitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	9 (3.2%)	
Number of patients censored	271 (97.1%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.709 [0.270, 1.863]
Log-rank test			
Two-sided stratified log-rank p-value			0.4831

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.64.1: Summary and Results of TEAEs - Oral Candidiasis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	14 (5.0%)	
Number of patients censored	274 (98.2%)	264 (95.0%)	
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			0.361 [0.130, 1.003]
Log-rank test			
Two-sided stratified log-rank p-value			0.0414

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.64.2: Summary and Results of TEAEs by Subgroups - Oral Candidiasis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)	NC [NC, NC]	177	10 (5.6)	NC [NC, NC]	0.192 [0.042, 0.875]	0.0172	0.2311
>65 years	101	3 (3.0)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	0.754 [0.169, 3.372]	0.7113	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	0.324 [0.088, 1.198]	0.0751	0.8437
Female	105	2 (1.9)	NC [NC, NC]	105	5 (4.8)	NC [NC, NC]	0.396 [0.077, 2.044]	0.2519	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	0.829 [0.052, 13.284]	0.8941	0.4813
Non-Asia	192	4 (2.1)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	0.308 [0.101, 0.946]	0.0295	
Number of Organs with Metastatic Sites									
0-2	216	5 (2.3)	NC [NC, NC]	216	12 (5.6)	NC [NC, NC]	0.405 [0.142, 1.149]	0.0788	0.9917
>=3	63	0 (0.0)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.000 [0.000, NC]	0.1655	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.65.1: Summary and Results of TEAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	14 (5.0%)	
Number of patients censored	264 (94.6%)	264 (95.0%)	
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			0.828 [0.395, 1.737]
Log-rank test			
Two-sided stratified log-rank p-value			0.6177

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.66.1: Summary and Results of TEAEs - Urinary Tract Infection (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	9 (3.2%)	
Number of patients censored	262 (93.9%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.982 [0.877, 4.480]
Log-rank test			
Two-sided stratified log-rank p-value			0.0943

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.67.1: Summary and Results of TEAEs - Urinary Tract Infection Bacterial (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	6 (2.2%)	
Number of patients censored	275 (98.6%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.599 [0.168, 2.135]
Log-rank test			
Two-sided stratified log-rank p-value			0.4247

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.68.1: Summary and Results of TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	50 (17.9%)	41 (14.7%)	
Number of patients censored	229 (82.1%)	237 (85.3%)	
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			1.228 [0.810, 1.863]
Log-rank test			
Two-sided stratified log-rank p-value			0.3327

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.69.1: Summary and Results of TEAEs - Fall (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	9 (3.2%)	
Number of patients censored	267 (95.7%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.390 [0.585, 3.304]
Log-rank test			
Two-sided stratified log-rank p-value			0.4541

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.70.1: Summary and Results of TEAEs - Infusion Related Reaction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.409 [0.447, 4.441]
Log-rank test			
Two-sided stratified log-rank p-value			0.5569

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.71.1: Summary and Results of TEAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	184 (65.9%)	175 (62.9%)	
Number of patients censored	95 (34.1%)	103 (37.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.5 [1.8, 3.7]	2.8 [2.1, 3.7]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.120 [0.908, 1.382]
Log-rank test			
Two-sided stratified log-rank p-value			0.2900

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.72.1: Summary and Results of TEAEs - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	35 (12.5%)	50 (18.0%)	
Number of patients censored	244 (87.5%)	228 (82.0%)	
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			0.672 [0.435, 1.039]
Log-rank test			
Two-sided stratified log-rank p-value			0.0718

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.73.1: Summary and Results of TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	50 (17.9%)	47 (16.9%)	
Number of patients censored	229 (82.1%)	231 (83.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.054 [0.706, 1.573]
Log-rank test			
Two-sided stratified log-rank p-value			0.8007

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.74.1: Summary and Results of TEAEs - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	26 (9.4%)	
Number of patients censored	258 (92.5%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.771 [0.431, 1.378]
Log-rank test			
Two-sided stratified log-rank p-value			0.3791

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.75.1: Summary and Results of TEAEs - Blood Bilirubin Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	15 (5.4%)	
Number of patients censored	272 (97.5%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.405 [0.162, 1.010]
Log-rank test			
Two-sided stratified log-rank p-value			0.0457

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.75.2: Summary and Results of TEAEs by Subgroups - Blood Bilirubin Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	7 (3.9)	NC [NC, NC]	177	10 (5.6)	NC [NC, NC]	0.595 [0.226, 1.570]	0.2891	0.9917
>65 years	101	0 (0.0)	NC [NC, NC]	101	5 (5.0)	NC [23.9, NC]	0.000 [0.000, NC]	0.0108	
Sex									
Male	174	6 (3.4)	NC [NC, NC]	173	10 (5.8)	NC [NC, NC]	0.473 [0.171, 1.308]	0.1401	0.3638
Female	105	1 (1.0)	NC [NC, NC]	105	5 (4.8)	NC [NC, NC]	0.180 [0.021, 1.545]	0.0782	
Region									
Asia	87	3 (3.4)	NC [NC, NC]	88	4 (4.5)	NC [NC, NC]	0.453 [0.099, 2.080]	0.2970	0.7525
Non-Asia	192	4 (2.1)	NC [NC, NC]	190	11 (5.8)	NC [NC, NC]	0.350 [0.111, 1.102]	0.0606	
Number of Organs with Metastatic Sites									
0-2	216	6 (2.8)	NC [NC, NC]	216	10 (4.6)	NC [NC, NC]	0.474 [0.172, 1.311]	0.1416	0.3584
>=3	63	1 (1.6)	NC [NC, NC]	62	5 (8.1)	NC [NC, NC]	0.199 [0.023, 1.713]	0.1029	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.76.1: Summary and Results of TEAEs - Blood Creatinine Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			0.968 [0.346, 2.713]
Log-rank test			
Two-sided stratified log-rank p-value			0.9512

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.77.1: Summary and Results of TEAEs - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	6 (2.2%)	
Number of patients censored	270 (96.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.519 [0.539, 4.280]
Log-rank test			
Two-sided stratified log-rank p-value			0.4258

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.78.1: Summary and Results of TEAEs - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	8 (2.9%)	
Number of patients censored	271 (97.1%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.047 [0.391, 2.799]
Log-rank test			
Two-sided stratified log-rank p-value			0.9274

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.79.1: Summary and Results of TEAEs - Lymphocyte Count Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.436 [0.404, 5.095]
Log-rank test			
Two-sided stratified log-rank p-value			0.5738

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.80.1: Summary and Results of TEAEs - Neutrophil Count Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	96 (34.4%)	91 (32.7%)	
Number of patients censored	183 (65.6%)	187 (67.3%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [36.1, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.055 [0.790, 1.407]
Log-rank test			
Two-sided stratified log-rank p-value			0.6934

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.81.1: Summary and Results of TEAEs - Platelet Count Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	41 (14.7%)	49 (17.6%)	
Number of patients censored	238 (85.3%)	229 (82.4%)	
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			0.833 [0.549, 1.263]
Log-rank test			
Two-sided stratified log-rank p-value			0.3886

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.82.1: Summary and Results of TEAEs - Weight Decreased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	57 (20.4%)	56 (20.1%)	
Number of patients censored	222 (79.6%)	222 (79.9%)	
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			1.006 [0.694, 1.457]
Log-rank test			
Two-sided stratified log-rank p-value			0.9768

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.83.1: Summary and Results of TEAEs - Weight Increased (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	9 (3.2%)	
Number of patients censored	270 (96.8%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.952 [0.376, 2.409]
Log-rank test			
Two-sided stratified log-rank p-value			0.9166

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.84.1: Summary and Results of TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	51 (18.3%)	46 (16.5%)	
Number of patients censored	228 (81.7%)	232 (83.5%)	
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			1.099 [0.737, 1.640]
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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.85.1: Summary and Results of TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	195 (69.9%)	163 (58.6%)	
Number of patients censored	84 (30.1%)	115 (41.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.8 [1.1, 2.2]	3.6 [2.9, 5.6]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.436 [1.162, 1.773]
Log-rank test			
Two-sided stratified log-rank p-value			0.0008

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.85.2: Summary and Results of TEAEs by Subgroups - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	118 (66.3)	2.0 [1.3, 3.5]	177	97 (54.8)	4.5 [3.3, 10.4]	1.447 [1.104, 1.895]	0.0074	0.7971
>65 years	101	77 (76.2)	1.4 [0.6, 2.1]	101	66 (65.3)	2.6 [1.4, 4.8]	1.359 [0.977, 1.890]	0.0652	
Sex									
Male	174	121 (69.5)	2.1 [1.1, 3.3]	173	97 (56.1)	3.9 [3.3, 13.2]	1.479 [1.131, 1.934]	0.0040	0.6456
Female	105	74 (70.5)	1.4 [0.6, 1.9]	105	66 (62.9)	3.2 [1.5, 5.7]	1.326 [0.950, 1.850]	0.0992	
Region									
Asia	87	65 (74.7)	0.7 [0.5, 3.9]	88	51 (58.0)	3.5 [2.1, 13.2]	1.407 [0.970, 2.042]	0.0745	0.9752
Non-Asia	192	130 (67.7)	1.9 [1.4, 2.2]	190	112 (58.9)	3.9 [2.8, 6.5]	1.427 [1.108, 1.839]	0.0058	
Number of Organs with Metastatic Sites									
0-2	216	150 (69.4)	2.0 [1.4, 3.1]	216	126 (58.3)	4.0 [3.0, 7.4]	1.378 [1.086, 1.749]	0.0084	0.6763
>=3	63	45 (71.4)	0.9 [0.5, 2.0]	62	37 (59.7)	2.9 [1.2, 10.4]	1.506 [0.973, 2.330]	0.0648	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.86.1: Summary and Results of TEAEs - Decreased Appetite (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	136 (48.7%)	97 (34.9%)	
Number of patients censored	143 (51.3%)	181 (65.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	8.5 [4.0, 21.2]	NC [16.9, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.615 [1.242, 2.100]
Log-rank test			
Two-sided stratified log-rank p-value			0.0003

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.86.2: Summary and Results of TEAEs by Subgroups - Decreased Appetite (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	76 (42.7)	21.2 [5.3, NC]	177	56 (31.6)	NC [21.3, NC]	1.524 [1.078, 2.154]	0.0167	0.6648
>65 years	101	60 (59.4)	3.0 [1.1, 7.9]	101	41 (40.6)	16.9 [5.5, NC]	1.718 [1.154, 2.559]	0.0067	
Sex									
Male	174	89 (51.1)	5.8 [2.9, 21.2]	173	59 (34.1)	NC [16.9, NC]	1.780 [1.280, 2.476]	0.0005	0.3129
Female	105	47 (44.8)	21.2 [4.7, 35.9]	105	38 (36.2)	NC [9.1, NC]	1.360 [0.886, 2.089]	0.1628	
Region									
Asia	87	49 (56.3)	3.1 [0.6, NC]	88	35 (39.8)	13.2 [5.8, NC]	1.594 [1.029, 2.468]	0.0371	0.9133
Non-Asia	192	87 (45.3)	14.0 [5.3, 21.2]	190	62 (32.6)	NC [21.3, NC]	1.638 [1.182, 2.269]	0.0028	
Number of Organs with Metastatic Sites									
0-2	216	103 (47.7)	15.9 [4.3, 35.9]	216	76 (35.2)	NC [16.9, NC]	1.532 [1.138, 2.062]	0.0048	0.5392
>=3	63	33 (52.4)	4.7 [1.8, NC]	62	21 (33.9)	NC [10.4, NC]	1.789 [1.034, 3.096]	0.0346	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.87.1: Summary and Results of TEAEs - Dehydration (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	9 (3.2%)	
Number of patients censored	268 (96.1%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.260 [0.522, 3.045]
Log-rank test			
Two-sided stratified log-rank p-value			0.6063

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.88.1: Summary and Results of TEAEs - Hyperglycaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	12 (4.3%)	
Number of patients censored	264 (94.6%)	266 (95.7%)	
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			1.114 [0.514, 2.411]
Log-rank test			
Two-sided stratified log-rank p-value			0.7835

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.89.1: Summary and Results of TEAEs - Hyperkalaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	2 (0.7%)	
Number of patients censored	271 (97.1%)	276 (99.3%)	
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			3.751 [0.785, 17.912]
Log-rank test			
Two-sided stratified log-rank p-value			0.0759

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.90.1: Summary and Results of TEAEs - Hypoalbuminaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	46 (16.5%)	18 (6.5%)	
Number of patients censored	233 (83.5%)	260 (93.5%)	
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			2.768 [1.604, 4.779]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.90.2: Summary and Results of TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	29 (16.3)	NC [NC, NC]	177	13 (7.3)	NC [NC, NC]	2.373 [1.233, 4.567]	0.0077	0.5308
>65 years	101	17 (16.8)	NC [NC, NC]	101	5 (5.0)	NC [NC, NC]	3.388 [1.248, 9.193]	0.0109	
Sex									
Male	174	32 (18.4)	NC [NC, NC]	173	7 (4.0)	NC [NC, NC]	4.872 [2.149, 11.042]	<.0001	0.0224
Female	105	14 (13.3)	NC [NC, NC]	105	11 (10.5)	NC [NC, NC]	1.250 [0.566, 2.759]	0.5805	
Region									
Asia	87	14 (16.1)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	2.757 [0.991, 7.672]	0.0430	0.9954
Non-Asia	192	32 (16.7)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	2.658 [1.394, 5.066]	0.0020	
Number of Organs with Metastatic Sites									
0-2	216	36 (16.7)	NC [NC, NC]	216	16 (7.4)	NC [NC, NC]	2.312 [1.282, 4.168]	0.0041	0.3347
>=3	63	10 (15.9)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	5.312 [1.163, 24.257]	0.0158	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.91.1: Summary and Results of TEAEs - Hypocalcaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	31 (11.1%)	9 (3.2%)	
Number of patients censored	248 (88.9%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.531 [1.676, 7.439]
Log-rank test			
Two-sided stratified log-rank p-value			0.0004

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.91.2: Summary and Results of TEAEs by Subgroups - Hypocalcaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	16 (9.0)	NC [NC, NC]	177	3 (1.7)	NC [NC, NC]	5.451 [1.587, 18.724]	0.0025	0.3193
>65 years	101	15 (14.9)	NC [NC, NC]	101	6 (5.9)	NC [NC, NC]	2.411 [0.932, 6.235]	0.0610	
Sex									
Male	174	19 (10.9)	NC [NC, NC]	173	6 (3.5)	NC [NC, NC]	3.232 [1.289, 8.108]	0.0082	0.7554
Female	105	12 (11.4)	NC [28.3, NC]	105	3 (2.9)	NC [NC, NC]	3.909 [1.100, 13.889]	0.0230	
Region									
Asia	87	10 (11.5)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	9.125 [1.160, 71.763]	0.0109	0.2966
Non-Asia	192	21 (10.9)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	2.774 [1.228, 6.268]	0.0105	
Number of Organs with Metastatic Sites									
0-2	216	21 (9.7)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	3.413 [1.374, 8.478]	0.0049	0.9599
>=3	63	10 (15.9)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	3.476 [0.954, 12.658]	0.0443	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.92.1: Summary and Results of TEAEs - Hypoglycaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.434 [0.464, 4.437]
Log-rank test			
Two-sided stratified log-rank p-value			0.5294

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.93.1: Summary and Results of TEAEs - Hypokalaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	51 (18.3%)	42 (15.1%)	
Number of patients censored	228 (81.7%)	236 (84.9%)	
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			1.232 [0.815, 1.862]
Log-rank test			
Two-sided stratified log-rank p-value			0.3204

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.94.1: Summary and Results of TEAEs - Hypomagnesaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	11 (4.0%)	
Number of patients censored	266 (95.3%)	267 (96.0%)	
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			1.228 [0.549, 2.747]
Log-rank test			
Two-sided stratified log-rank p-value			0.6175

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.95.1: Summary and Results of TEAEs - Hyponatraemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	12 (4.3%)	
Number of patients censored	264 (94.6%)	266 (95.7%)	
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			1.156 [0.537, 2.489]
Log-rank test			
Two-sided stratified log-rank p-value			0.7106

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.96.1: Summary and Results of TEAEs - Hypophosphataemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	14 (5.0%)	
Number of patients censored	261 (93.5%)	264 (95.0%)	
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			1.200 [0.589, 2.447]
Log-rank test			
Two-sided stratified log-rank p-value			0.6138

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.97.1: Summary and Results of TEAEs - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	85 (30.5%)	93 (33.5%)	
Number of patients censored	194 (69.5%)	185 (66.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	33.7 [20.1, NC]	19.1 [12.6, 26.8]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.841 [0.624, 1.133]
Log-rank test			
Two-sided stratified log-rank p-value			0.2526

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.98.1: Summary and Results of TEAEs - Arthralgia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	25 (9.0%)	
Number of patients censored	257 (92.1%)	253 (91.0%)	
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			0.747 [0.417, 1.340]
Log-rank test			
Two-sided stratified log-rank p-value			0.3265

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.99.1: Summary and Results of TEAEs - Back Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	36 (12.9%)	34 (12.2%)	
Number of patients censored	243 (87.1%)	244 (87.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	37.3 [26.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.975 [0.607, 1.567]
Log-rank test			
Two-sided stratified log-rank p-value			0.9170

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.100.1: Summary and Results of TEAEs - Flank Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	2 (0.7%)	9 (3.2%)	
Number of patients censored	277 (99.3%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.207 [0.044, 0.960]
Log-rank test			
Two-sided stratified log-rank p-value			0.0263

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.100.2: Summary and Results of TEAEs by Subgroups - Flank Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	7 (4.0)				
>65 years	101	1 (1.0)		101	2 (2.0)				
Sex									
Male	174	1 (0.6)		173	8 (4.6)				
Female	105	1 (1.0)		105	1 (1.0)				
Region									
Asia	87	1 (1.1)		88	5 (5.7)				
Non-Asia	192	1 (0.5)		190	4 (2.1)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)	NC [NC, NC]	216	8 (3.7)	NC [NC, NC]	0.223 [0.047, 1.052]	0.0378	0.9944
>=3	63	0 (0.0)	NC [NC, NC]	62	1 (1.6)	NC [NC, NC]	0.000 [0.000, NC]	0.2909	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.101.1: Summary and Results of TEAEs - Muscular Weakness (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	2 (0.7%)	
Number of patients censored	270 (96.8%)	276 (99.3%)	
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			4.328 [0.929, 20.155]
Log-rank test			
Two-sided stratified log-rank p-value			0.0420

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.101.2: Summary and Results of TEAEs by Subgroups - Muscular Weakness (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	6 (3.4)		177	1 (0.6)				
>65 years	101	3 (3.0)		101	1 (1.0)				
Sex									
Male	174	4 (2.3)		173	0 (0.0)				
Female	105	5 (4.8)		105	2 (1.9)				
Region									
Asia	87	3 (3.4)		88	0 (0.0)				
Non-Asia	192	6 (3.1)		190	2 (1.1)				
Number of Organs with Metastatic Sites									
0-2	216	8 (3.7)		216	0 (0.0)				
>=3	63	1 (1.6)		62	2 (3.2)				

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.102.1: Summary and Results of TEAEs - Musculoskeletal Chest Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	8 (2.9%)	
Number of patients censored	269 (96.4%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.310 [0.515, 3.336]
Log-rank test			
Two-sided stratified log-rank p-value			0.5696

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.103.1: Summary and Results of TEAEs - Myalgia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	13 (4.7%)	
Number of patients censored	267 (95.7%)	265 (95.3%)	
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			0.879 [0.400, 1.932]
Log-rank test			
Two-sided stratified log-rank p-value			0.7483

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.104.1: Summary and Results of TEAEs - Pain In Extremity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	15 (5.4%)	
Number of patients censored	269 (96.4%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.669 [0.300, 1.496]
Log-rank test			
Two-sided stratified log-rank p-value			0.3246

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.105.1: Summary and Results of TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	24 (8.6%)	
Number of patients censored	255 (91.4%)	254 (91.4%)	
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			0.957 [0.540, 1.694]
Log-rank test			
Two-sided stratified log-rank p-value			0.8795

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.106.1: Summary and Results of TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.876 [0.378, 2.033]
Log-rank test			
Two-sided stratified log-rank p-value			0.7579

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.107.1: Summary and Results of TEAEs - Nervous System Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	210 (75.3%)	210 (75.5%)	
Number of patients censored	69 (24.7%)	68 (24.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.9 [1.5, 2.3]	1.9 [1.2, 2.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.926 [0.763, 1.122]
Log-rank test			
Two-sided stratified log-rank p-value			0.4561

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.108.1: Summary and Results of TEAEs - Dizziness (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	37 (13.3%)	28 (10.1%)	
Number of patients censored	242 (86.7%)	250 (89.9%)	
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			1.316 [0.801, 2.164]
Log-rank test			
Two-sided stratified log-rank p-value			0.2768

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.109.1: Summary and Results of TEAEs - Dysaesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	13 (4.7%)	
Number of patients censored	271 (97.1%)	265 (95.3%)	
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			0.611 [0.253, 1.474]
Log-rank test			
Two-sided stratified log-rank p-value			0.2682

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.110.1: Summary and Results of TEAEs - Dysgeusia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	44 (15.8%)	40 (14.4%)	
Number of patients censored	235 (84.2%)	238 (85.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.145 [0.746, 1.759]
Log-rank test			
Two-sided stratified log-rank p-value			0.5335

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.111.1: Summary and Results of TEAEs - Headache (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	34 (12.2%)	35 (12.6%)	
Number of patients censored	245 (87.8%)	243 (87.4%)	
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			0.920 [0.573, 1.477]
Log-rank test			
Two-sided stratified log-rank p-value			0.7298

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.112.1: Summary and Results of TEAEs - Hypoaesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	11 (4.0%)	
Number of patients censored	268 (96.1%)	267 (96.0%)	
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			0.940 [0.407, 2.173]
Log-rank test			
Two-sided stratified log-rank p-value			0.8854

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.113.1: Summary and Results of TEAEs - Neuropathy Peripheral (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	23 (8.2%)	22 (7.9%)	
Number of patients censored	256 (91.8%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.058 [0.590, 1.900]
Log-rank test			
Two-sided stratified log-rank p-value			0.8476

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.114.1: Summary and Results of TEAEs - Neurotoxicity (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	12 (4.3%)	
Number of patients censored	267 (95.7%)	266 (95.7%)	
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			1.026 [0.461, 2.285]
Log-rank test			
Two-sided stratified log-rank p-value			0.9482

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.115.1: Summary and Results of TEAEs - Paraesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	44 (15.8%)	47 (16.9%)	
Number of patients censored	235 (84.2%)	231 (83.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.894 [0.590, 1.354]
Log-rank test			
Two-sided stratified log-rank p-value			0.5978

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.116.1: Summary and Results of TEAEs - Peripheral Motor Neuropathy (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	7 (2.5%)	
Number of patients censored	274 (98.2%)	271 (97.5%)	
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			0.703 [0.223, 2.217]
Log-rank test			
Two-sided stratified log-rank p-value			0.5451

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.117.1: Summary and Results of TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	107 (38.4%)	119 (42.8%)	
Number of patients censored	172 (61.6%)	159 (57.2%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [7.1, NC]	15.9 [5.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.831 [0.640, 1.080]
Log-rank test			
Two-sided stratified log-rank p-value			0.1721

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.118.1: Summary and Results of TEAEs - Syncope (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	7 (2.5%)	
Number of patients censored	273 (97.8%)	271 (97.5%)	
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			0.902 [0.303, 2.686]
Log-rank test			
Two-sided stratified log-rank p-value			0.8529

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.119.1: Summary and Results of TEAEs - Taste Disorder (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.509 [0.425, 5.349]
Log-rank test			
Two-sided stratified log-rank p-value			0.5214

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.120.1: Summary and Results of TEAEs - Psychiatric Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	51 (18.3%)	44 (15.8%)	
Number of patients censored	228 (81.7%)	234 (84.2%)	
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			1.159 [0.774, 1.737]
Log-rank test			
Two-sided stratified log-rank p-value			0.4756

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.121.1: Summary and Results of TEAEs - Anxiety (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	8 (2.9%)	
Number of patients censored	265 (95.0%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.731 [0.724, 4.137]
Log-rank test			
Two-sided stratified log-rank p-value			0.2114

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.122.1: Summary and Results of TEAEs - Depression (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	9 (3.2%)	
Number of patients censored	269 (96.4%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.041 [0.421, 2.575]
Log-rank test			
Two-sided stratified log-rank p-value			0.9304

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.123.1: Summary and Results of TEAEs - Insomnia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	31 (11.1%)	25 (9.0%)	
Number of patients censored	248 (88.9%)	253 (91.0%)	
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			1.199 [0.707, 2.034]
Log-rank test			
Two-sided stratified log-rank p-value			0.5007

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.124.1: Summary and Results of TEAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	41 (14.7%)	35 (12.6%)	
Number of patients censored	238 (85.3%)	243 (87.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.086 [0.689, 1.713]
Log-rank test			
Two-sided stratified log-rank p-value			0.7214

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.125.1: Summary and Results of TEAEs - Dysuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	12 (4.3%)	
Number of patients censored	274 (98.2%)	266 (95.7%)	
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			0.360 [0.125, 1.034]
Log-rank test			
Two-sided stratified log-rank p-value			0.0481

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.125.2: Summary and Results of TEAEs by Subgroups - Dysuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	5 (2.8)	NC [NC, NC]	177	9 (5.1)	NC [NC, NC]	0.503 [0.168, 1.505]	0.2102	0.9895
>65 years	101	0 (0.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	0.000 [0.000, NC]	0.0852	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	0.349 [0.092, 1.322]	0.1052	0.7929
Female	105	2 (1.9)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	0.424 [0.077, 2.330]	0.3094	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	0.210 [0.021, 2.062]	0.1416	0.6617
Non-Asia	192	4 (2.1)	NC [NC, NC]	190	9 (4.7)	NC [NC, NC]	0.446 [0.137, 1.450]	0.1680	
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)	NC [NC, NC]	216	9 (4.2)	NC [NC, NC]	0.398 [0.122, 1.296]	0.1132	0.8017
>=3	63	1 (1.6)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.269 [0.027, 2.641]	0.2285	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.126.1: Summary and Results of TEAEs - Haematuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	9 (3.2%)	
Number of patients censored	269 (96.4%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.077 [0.434, 2.672]
Log-rank test			
Two-sided stratified log-rank p-value			0.8710

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.127.1: Summary and Results of TEAEs - Proteinuria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	11 (3.9%)	6 (2.2%)	
Number of patients censored	268 (96.1%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.924 [0.711, 5.204]
Log-rank test			
Two-sided stratified log-rank p-value			0.1895

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.128.1: Summary and Results of TEAEs - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	13 (4.7%)	
Number of patients censored	273 (97.8%)	265 (95.3%)	
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			0.450 [0.171, 1.186]
Log-rank test			
Two-sided stratified log-rank p-value			0.0974

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.129.1: Summary and Results of TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	110 (39.4%)	114 (41.0%)	
Number of patients censored	169 (60.6%)	164 (59.0%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	18.3 [12.6, NC]	15.3 [7.4, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.962 [0.739, 1.251]
Log-rank test			
Two-sided stratified log-rank p-value			0.7663

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.130.1: Summary and Results of TEAEs - Cough (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	30 (10.8%)	30 (10.8%)	
Number of patients censored	249 (89.2%)	248 (89.2%)	
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			0.982 [0.591, 1.632]
Log-rank test			
Two-sided stratified log-rank p-value			0.9431

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.131.1: Summary and Results of TEAEs - Dyspnoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	33 (11.9%)	
Number of patients censored	258 (92.5%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.660 [0.381, 1.142]
Log-rank test			
Two-sided stratified log-rank p-value			0.1343

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.132.1: Summary and Results of TEAEs - Epistaxis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	26 (9.4%)	
Number of patients censored	265 (95.0%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.530 [0.276, 1.020]
Log-rank test			
Two-sided stratified log-rank p-value			0.0532

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.133.1: Summary and Results of TEAEs - Hiccups (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	12 (4.3%)	
Number of patients censored	262 (93.9%)	266 (95.7%)	
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			1.419 [0.675, 2.981]
Log-rank test			
Two-sided stratified log-rank p-value			0.3538

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.134.1: Summary and Results of TEAEs - Oropharyngeal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	3 (1.1%)	14 (5.0%)	
Number of patients censored	276 (98.9%)	264 (95.0%)	
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			0.212 [0.061, 0.739]
Log-rank test			
Two-sided stratified log-rank p-value			0.0072

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.134.2: Summary and Results of TEAEs by Subgroups - Oropharyngeal Pain (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)	NC [NC, NC]	177	11 (6.2)	NC [NC, NC]	0.169 [0.037, 0.765]	0.0088	0.6708
>65 years	101	1 (1.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	0.333 [0.035, 3.199]	0.3163	
Sex									
Male	174	3 (1.7)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	0.370 [0.098, 1.396]	0.1265	0.9896
Female	105	0 (0.0)	NC [NC, NC]	105	6 (5.7)	NC [NC, NC]	0.000 [0.000, NC]	0.0088	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	0.191 [0.022, 1.633]	0.0908	0.8227
Non-Asia	192	2 (1.0)	NC [NC, NC]	190	9 (4.7)	NC [NC, NC]	0.220 [0.048, 1.021]	0.0339	
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)	NC [NC, NC]	216	12 (5.6)	NC [NC, NC]	0.154 [0.034, 0.689]	0.0049	0.4317
>=3	63	1 (1.6)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.505 [0.046, 5.575]	0.5699	

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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and 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: 08SEP23

Table 301.3.2001.135.1: Summary and Results of TEAEs - Pleural Effusion (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	7 (2.5%)	
Number of patients censored	275 (98.6%)	271 (97.5%)	
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			0.605 [0.177, 2.070]
Log-rank test			
Two-sided stratified log-rank p-value			0.4187

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.136.1: Summary and Results of TEAEs - Productive Cough (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	13 (4.7%)	8 (2.9%)	
Number of patients censored	266 (95.3%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.519 [0.627, 3.681]
Log-rank test			
Two-sided stratified log-rank p-value			0.3542

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.137.1: Summary and Results of TEAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	12 (4.3%)	
Number of patients censored	262 (93.9%)	266 (95.7%)	
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			1.459 [0.696, 3.059]
Log-rank test			
Two-sided stratified log-rank p-value			0.3152

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.138.1: Summary and Results of TEAEs - Rhinorrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	6 (2.2%)	
Number of patients censored	269 (96.4%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.644 [0.595, 4.542]
Log-rank test			
Two-sided stratified log-rank p-value			0.3324

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.139.1: Summary and Results of TEAEs - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	128 (45.9%)	118 (42.4%)	
Number of patients censored	151 (54.1%)	160 (57.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	10.4 [7.8, 14.3]	12.2 [7.6, 23.2]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.037 [0.805, 1.336]
Log-rank test			
Two-sided stratified log-rank p-value			0.7758

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.140.1: Summary and Results of TEAEs - Alopecia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	21 (7.6%)	
Number of patients censored	258 (92.5%)	257 (92.4%)	
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			0.985 [0.536, 1.812]
Log-rank test			
Two-sided stratified log-rank p-value			0.9630

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.141.1: Summary and Results of TEAEs - Dry Skin (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	22 (7.9%)	13 (4.7%)	
Number of patients censored	257 (92.1%)	265 (95.3%)	
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			1.694 [0.852, 3.370]
Log-rank test			
Two-sided stratified log-rank p-value			0.1292

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.142.1: Summary and Results of TEAEs - Erythema (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	10 (3.6%)	
Number of patients censored	272 (97.5%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.706 [0.268, 1.859]
Log-rank test			
Two-sided stratified log-rank p-value			0.4789

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.143.1: Summary and Results of TEAEs - Hyperhidrosis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	5 (1.8%)	
Number of patients censored	270 (96.8%)	273 (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			1.880 [0.630, 5.615]
Log-rank test			
Two-sided stratified log-rank p-value			0.2503

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.144.1: Summary and Results of TEAEs - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	22 (7.9%)	
Number of patients censored	254 (91.0%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.169 [0.658, 2.078]
Log-rank test			
Two-sided stratified log-rank p-value			0.5949

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.145.1: Summary and Results of TEAEs - Pruritus (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	26 (9.4%)	
Number of patients censored	255 (91.4%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.732 [0.411, 1.302]
Log-rank test			
Two-sided stratified log-rank p-value			0.2860

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.146.1: Summary and Results of TEAEs - Rash (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	23 (8.3%)	
Number of patients censored	261 (93.5%)	255 (91.7%)	
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			0.708 [0.380, 1.318]
Log-rank test			
Two-sided stratified log-rank p-value			0.2736

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.147.1: Summary and Results of TEAEs - Rash Maculo-Papular (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	15 (5.4%)	
Number of patients censored	271 (97.1%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.464 [0.193, 1.116]
Log-rank test			
Two-sided stratified log-rank p-value			0.0795

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.148.1: Summary and Results of TEAEs - Urticaria (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	10 (3.6%)	
Number of patients censored	275 (98.6%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [36.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.345 [0.108, 1.108]
Log-rank test			
Two-sided stratified log-rank p-value			0.0614

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.149.1: Summary and Results of TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	82 (29.4%)	68 (24.5%)	
Number of patients censored	197 (70.6%)	210 (75.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [31.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.265 [0.915, 1.749]
Log-rank test			
Two-sided stratified log-rank p-value			0.1632

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.150.1: Summary and Results of TEAEs - Deep Vein Thrombosis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	12 (4.3%)	
Number of patients censored	265 (95.0%)	266 (95.7%)	
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			1.198 [0.552, 2.596]
Log-rank test			
Two-sided stratified log-rank p-value			0.6477

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.151.1: Summary and Results of TEAEs - Flushing (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.472 [0.467, 4.641]
Log-rank test			
Two-sided stratified log-rank p-value			0.5071

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.152.1: Summary and Results of TEAEs - Hot Flush (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	5 (1.8%)	
Number of patients censored	273 (97.8%)	273 (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			1.142 [0.347, 3.758]
Log-rank test			
Two-sided stratified log-rank p-value			0.8257

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.153.1: Summary and Results of TEAEs - Hypertension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	33 (11.8%)	22 (7.9%)	
Number of patients censored	246 (88.2%)	256 (92.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.556 [0.906, 2.673]
Log-rank test			
Two-sided stratified log-rank p-value			0.1123

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.154.1: Summary and Results of TEAEs - Hypotension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	15 (5.4%)	
Number of patients censored	265 (95.0%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.895 [0.429, 1.867]
Log-rank test			
Two-sided stratified log-rank p-value			0.7668

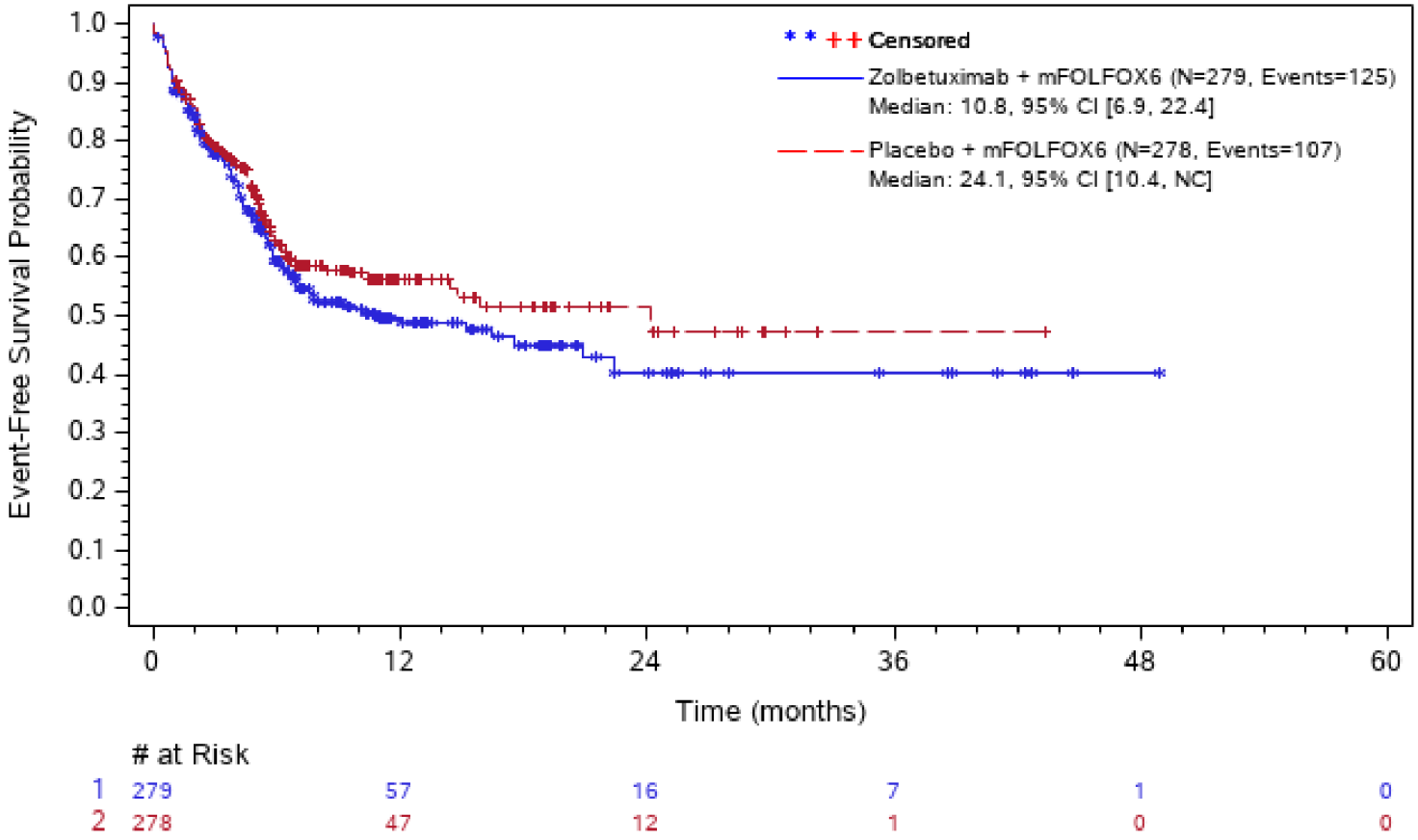
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 10% of subjects in at least one treatment group; OR 2) occurring in at least 10 subjects overall and at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.5: Kaplan-Meier Plot of Time to Permanent Treatment Discontinuation due to TEAEs - Safety Analysis Set

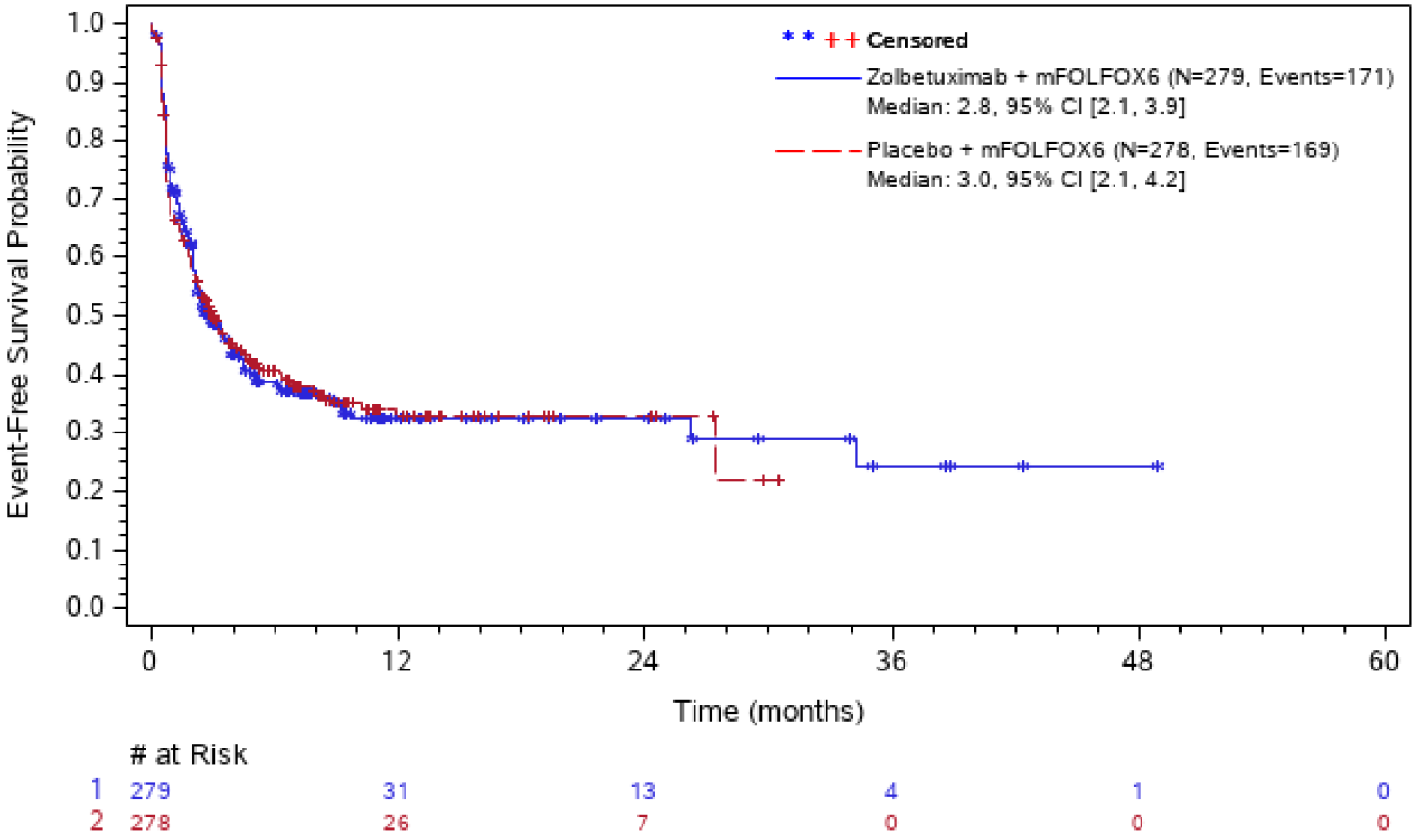


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; TE(S) AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.6: Kaplan-Meier Plot of Time to first TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

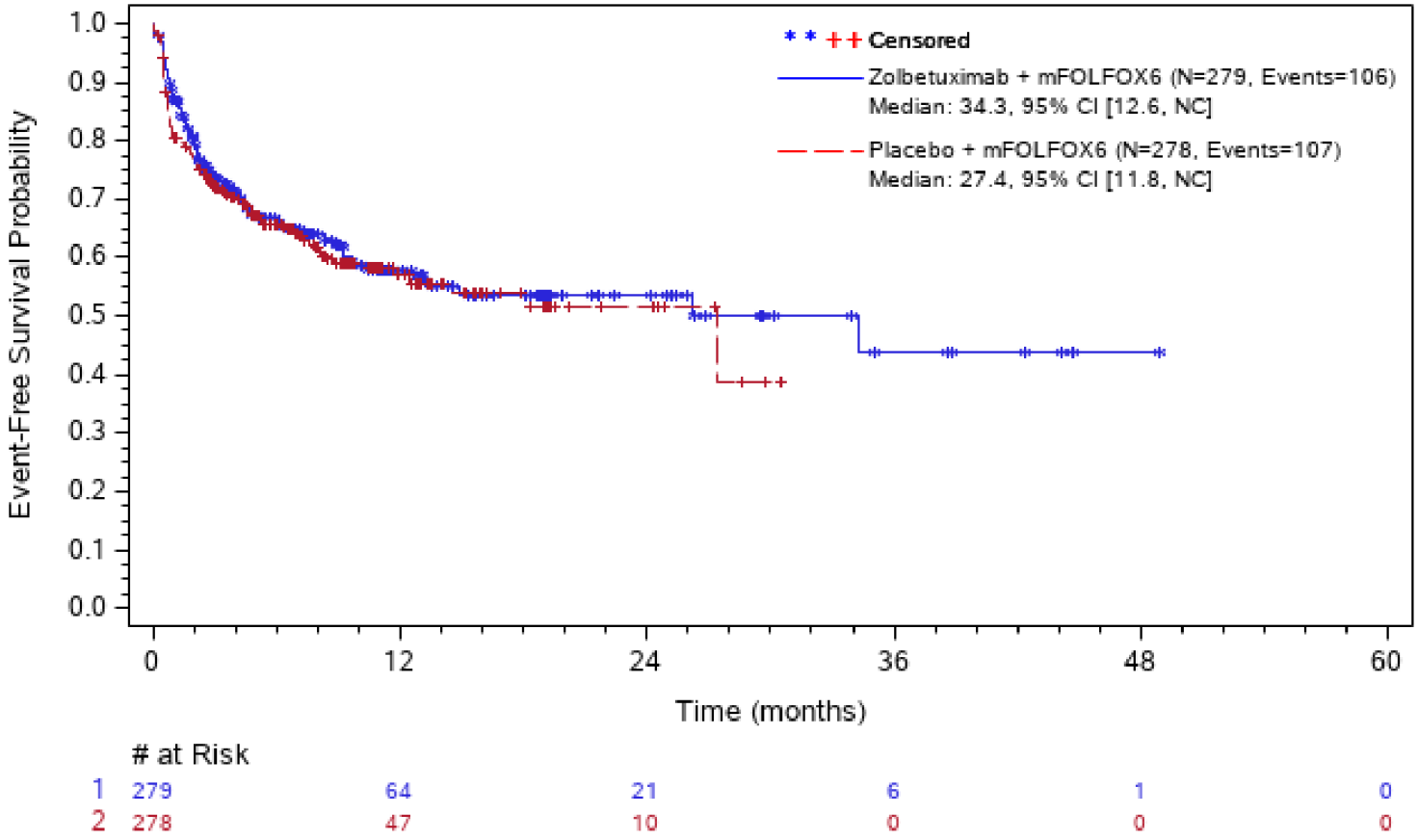


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.7: Kaplan-Meier Plot of Time to first TEAE - Anaemia (PT) - Safety Analysis Set

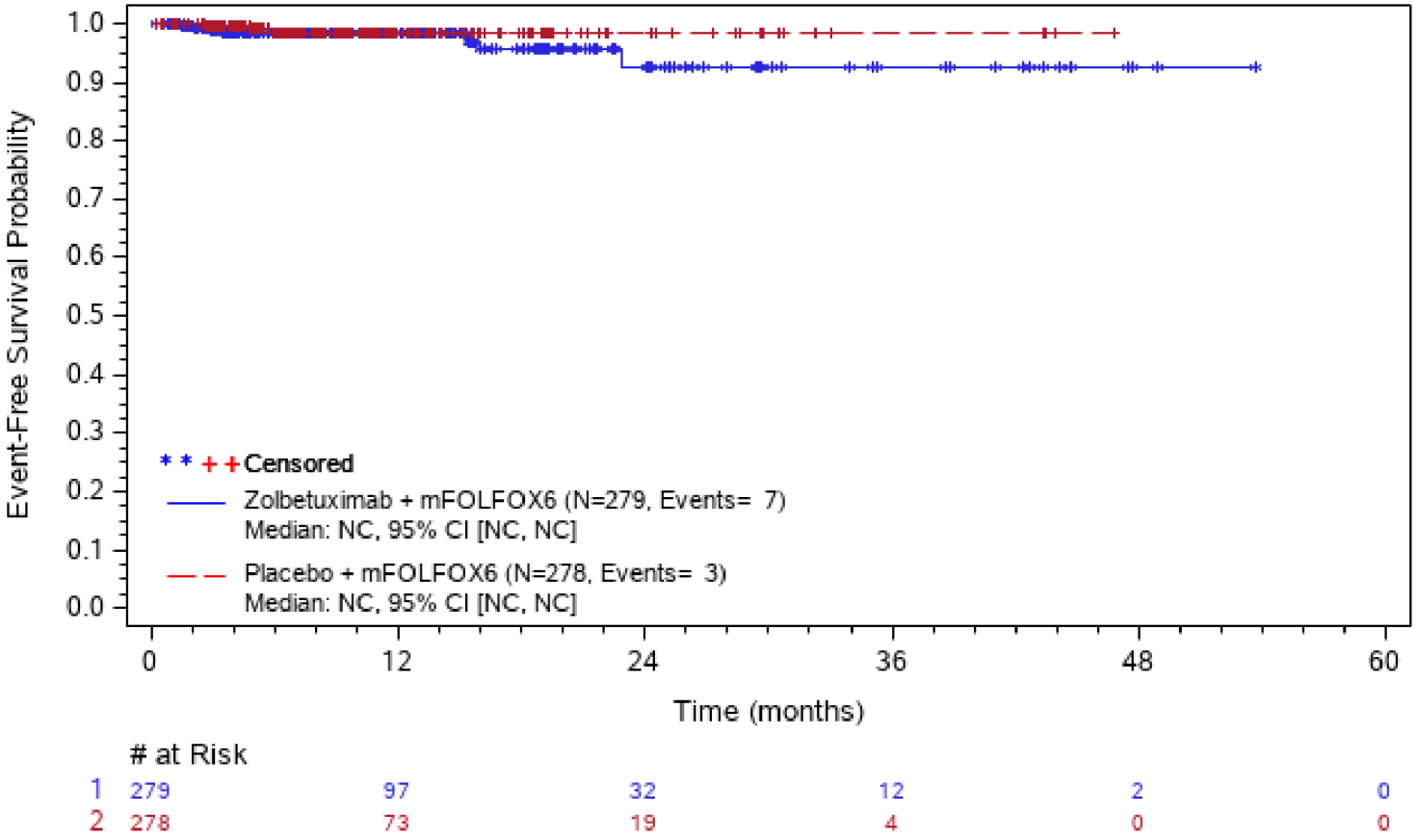


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.8: Kaplan-Meier Plot of Time to first TEAE - Leukocytosis (PT) - Safety Analysis Set

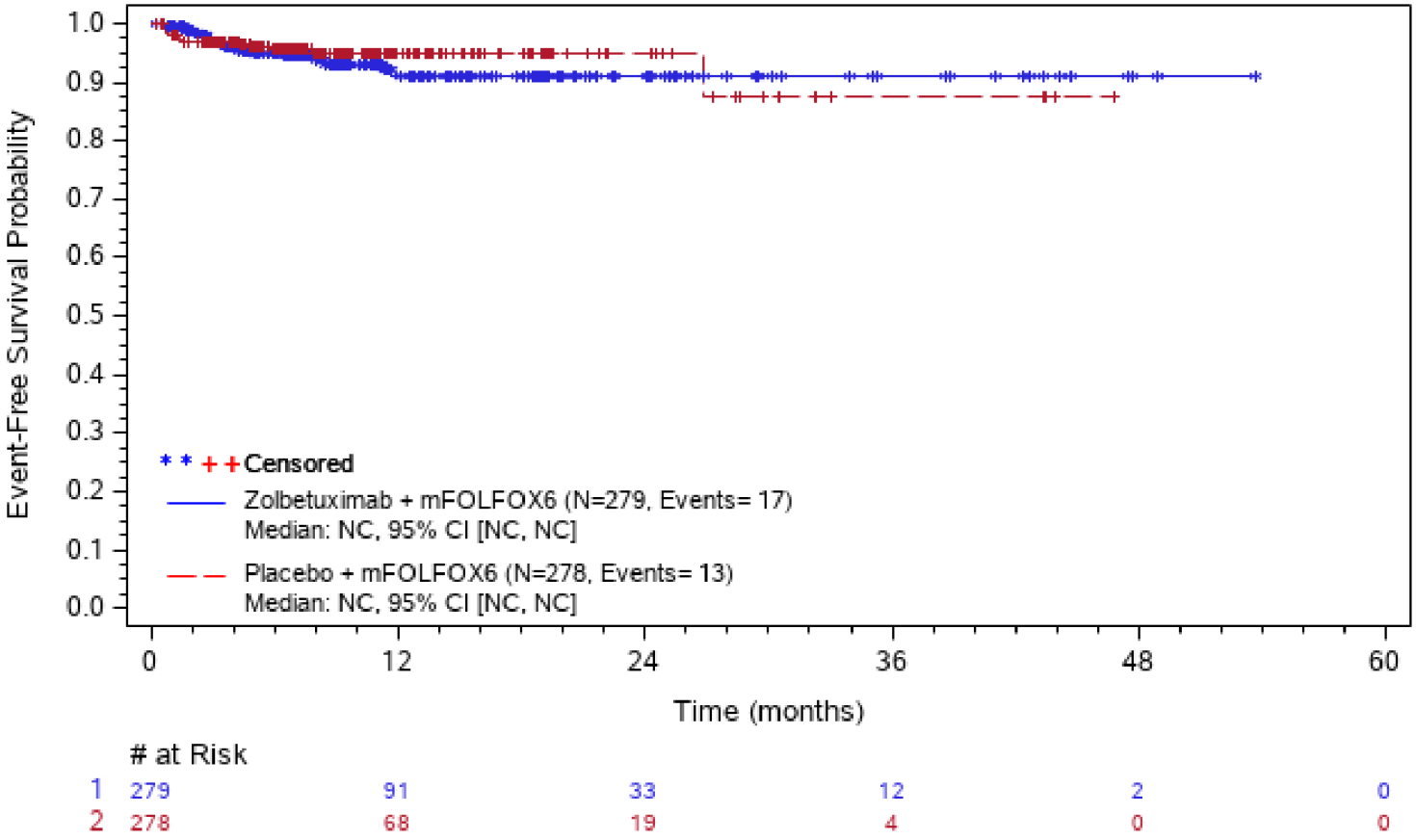


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.9: 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: 08SEP23

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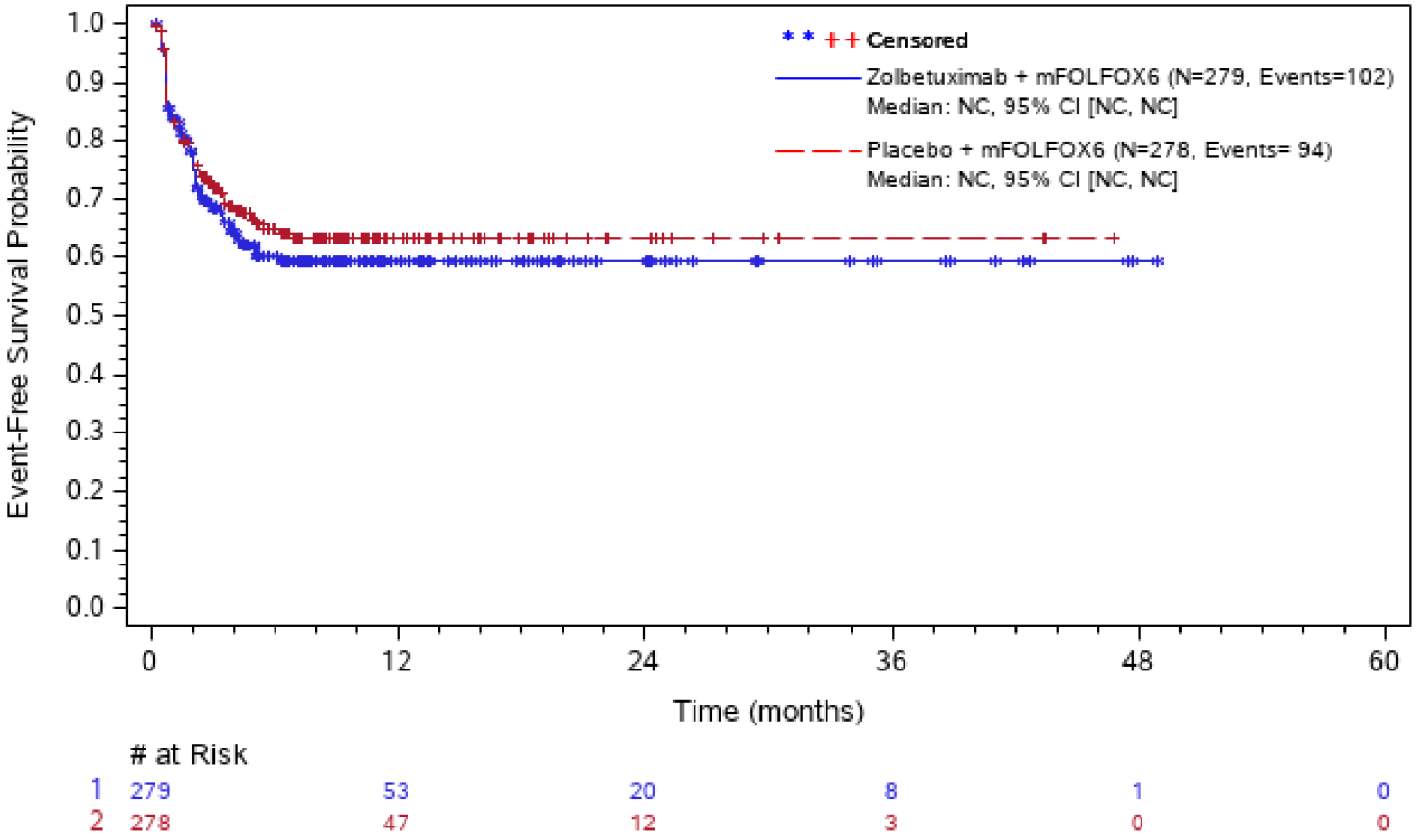
Figure 301.3.2001.10: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (PT) - Safety Analysis Set

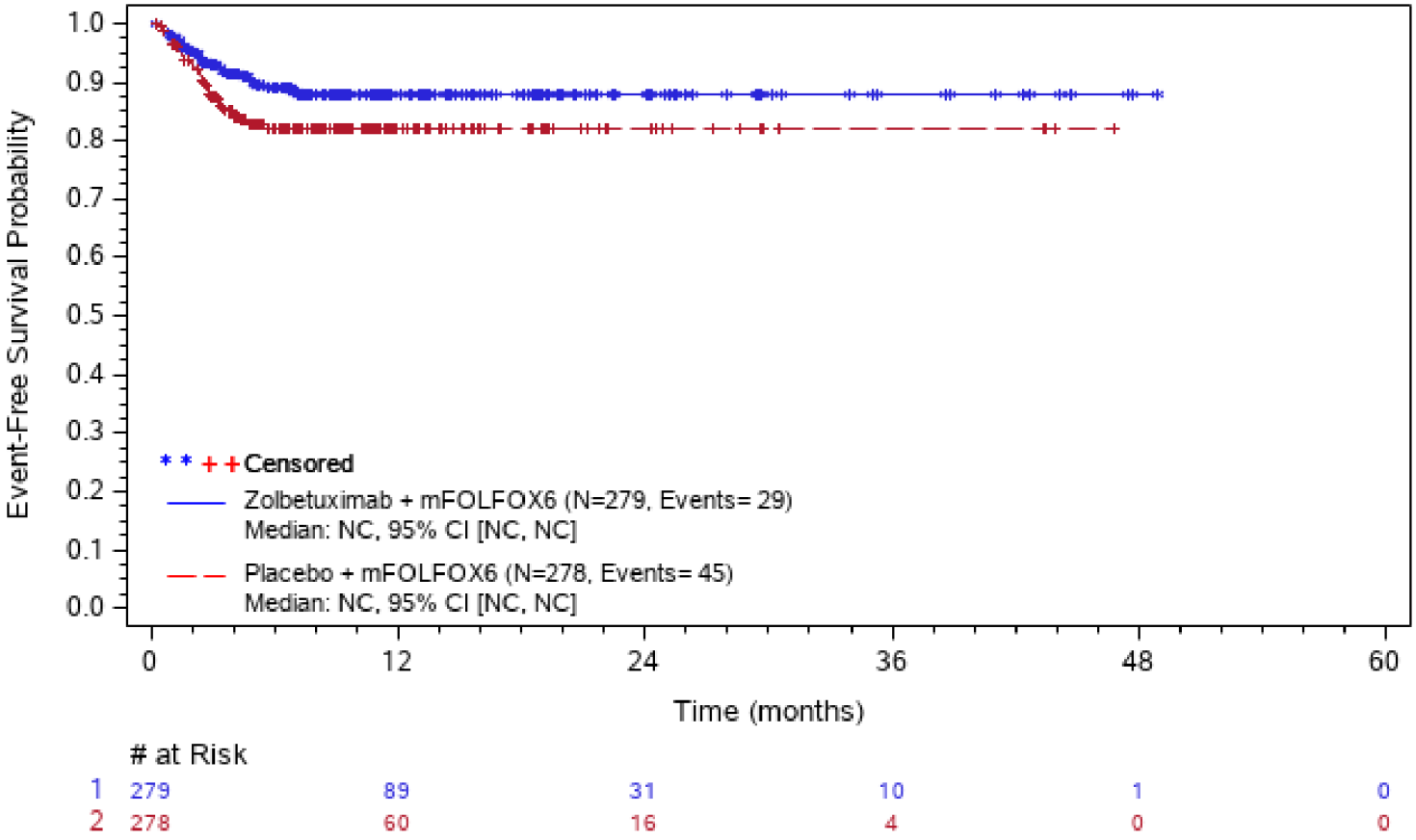


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.11: Kaplan-Meier Plot of Time to first TEAE - Thrombocytopenia (PT) - Safety Analysis Set

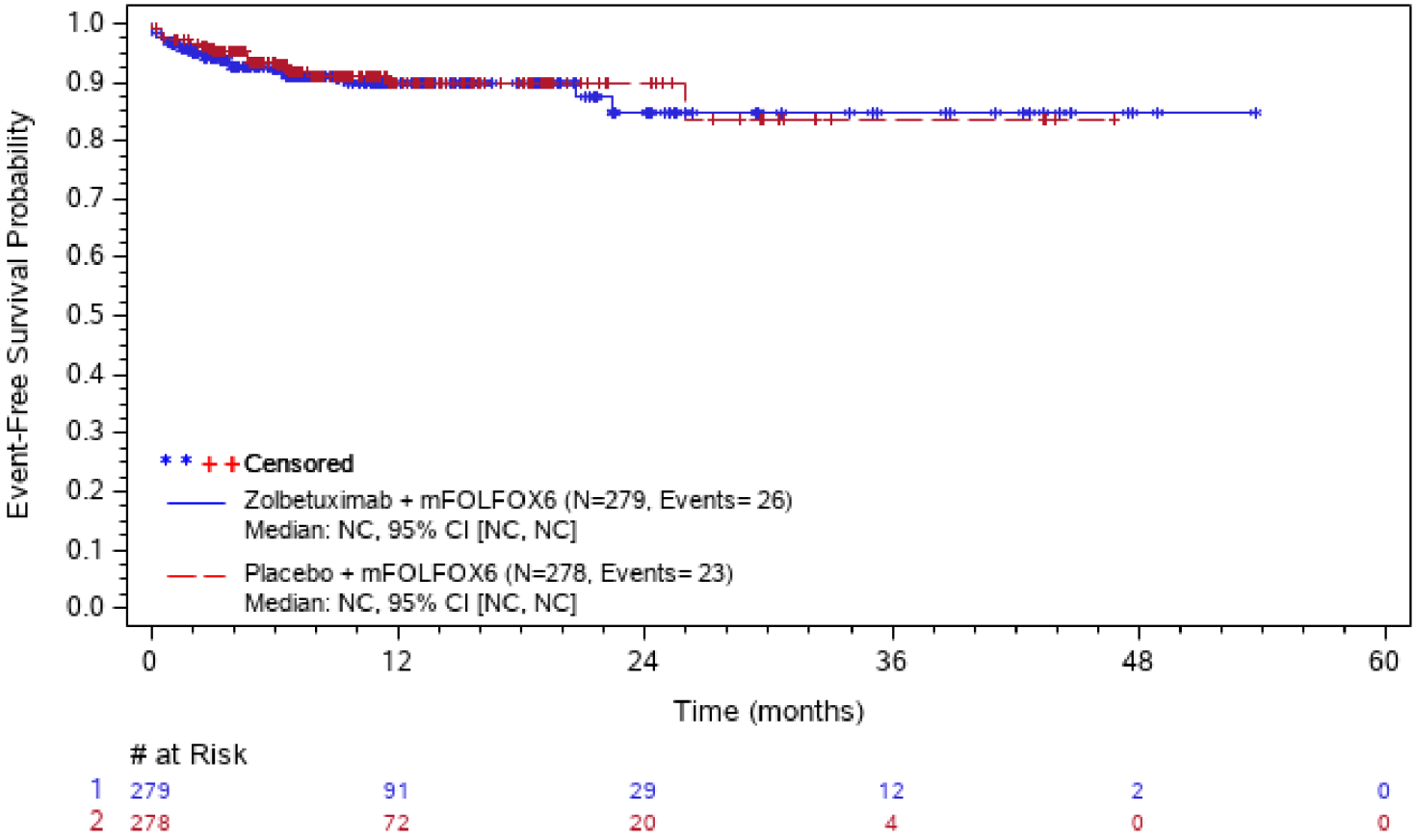


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.12: Kaplan-Meier Plot of Time to first TEAE - Cardiac Disorders (SOC) - Safety Analysis Set

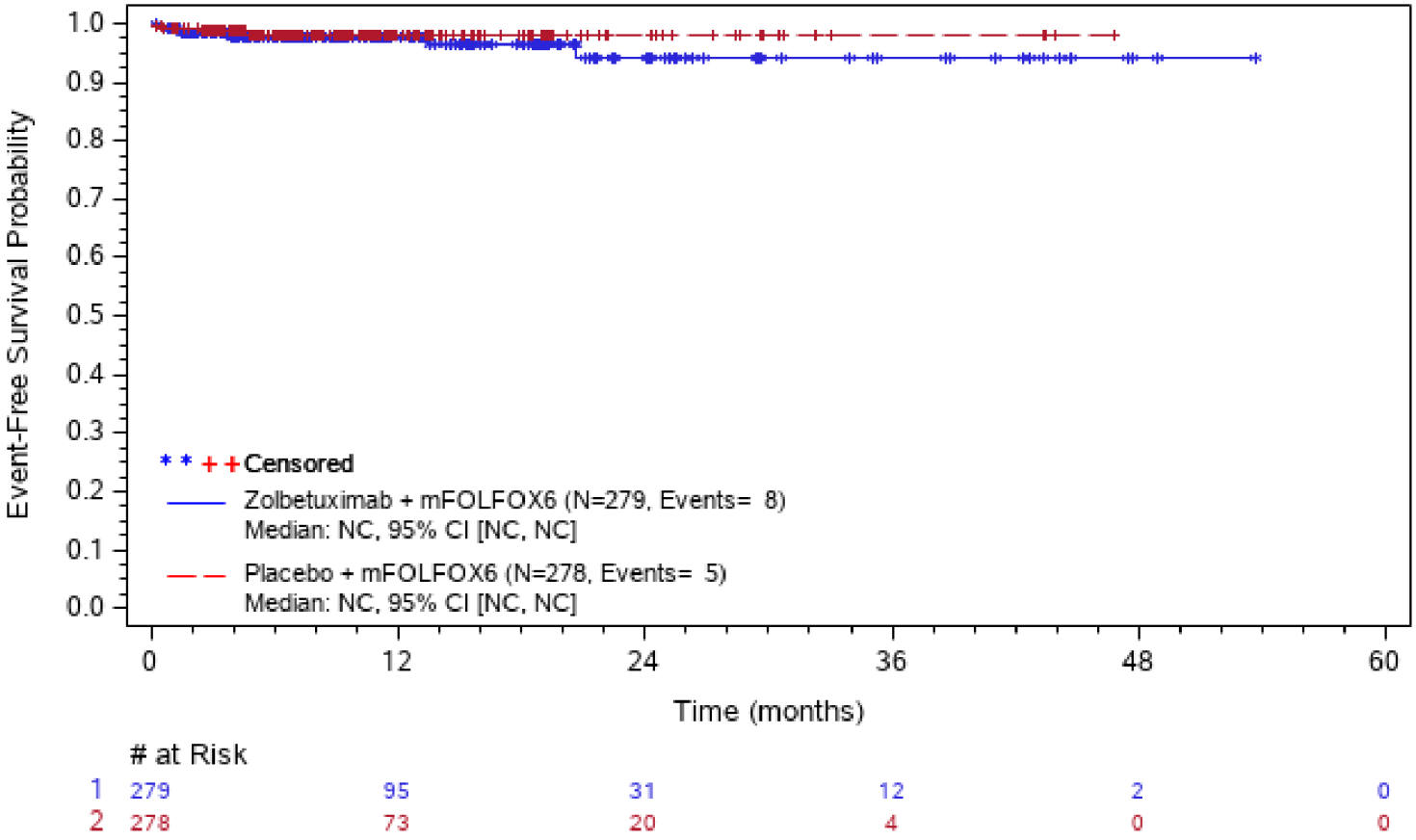


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.13: Kaplan-Meier Plot of Time to first TEAE - Palpitations (PT) - Safety Analysis Set

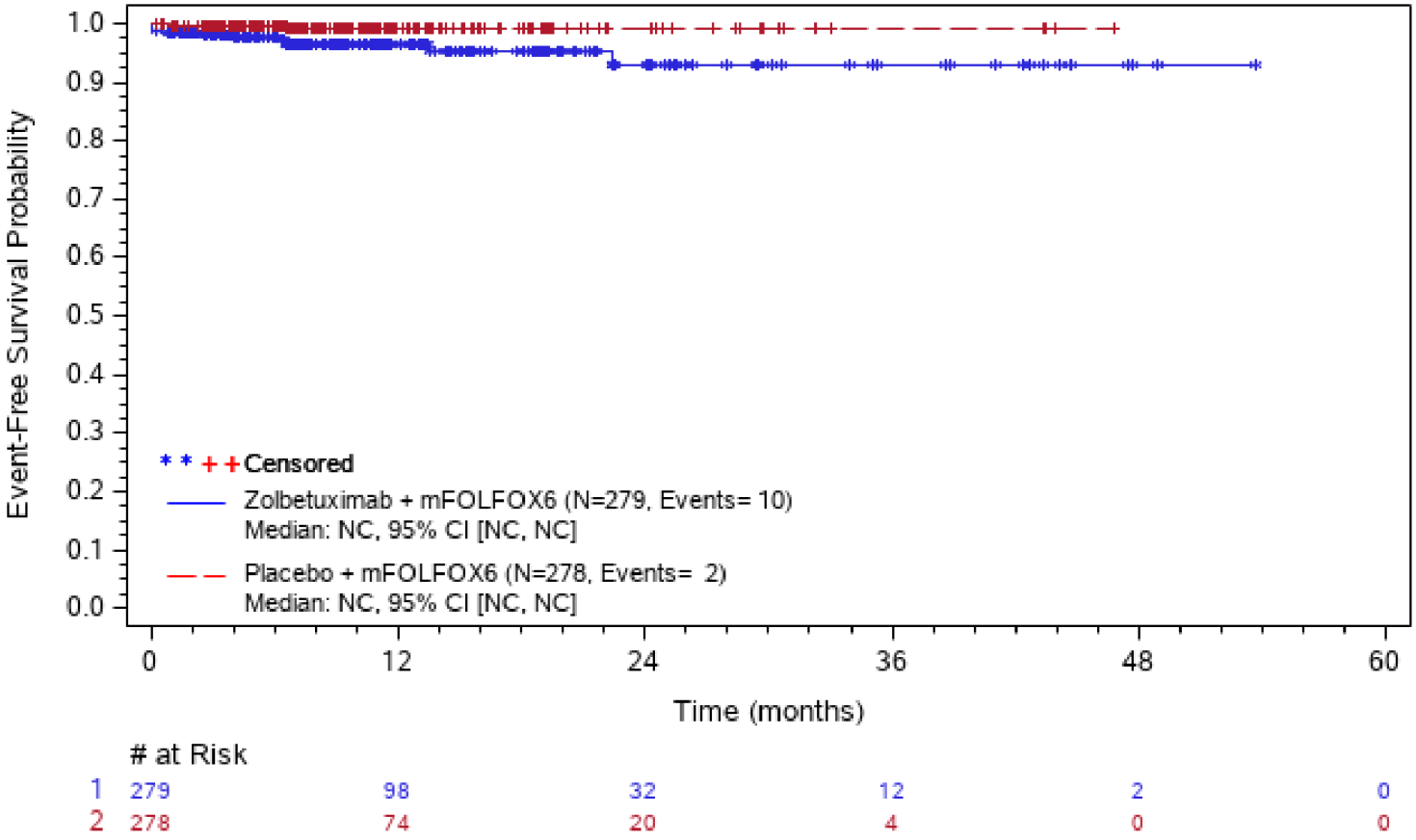


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.14: Kaplan-Meier Plot of Time to first TEAE - Tachycardia (PT) - Safety Analysis Set

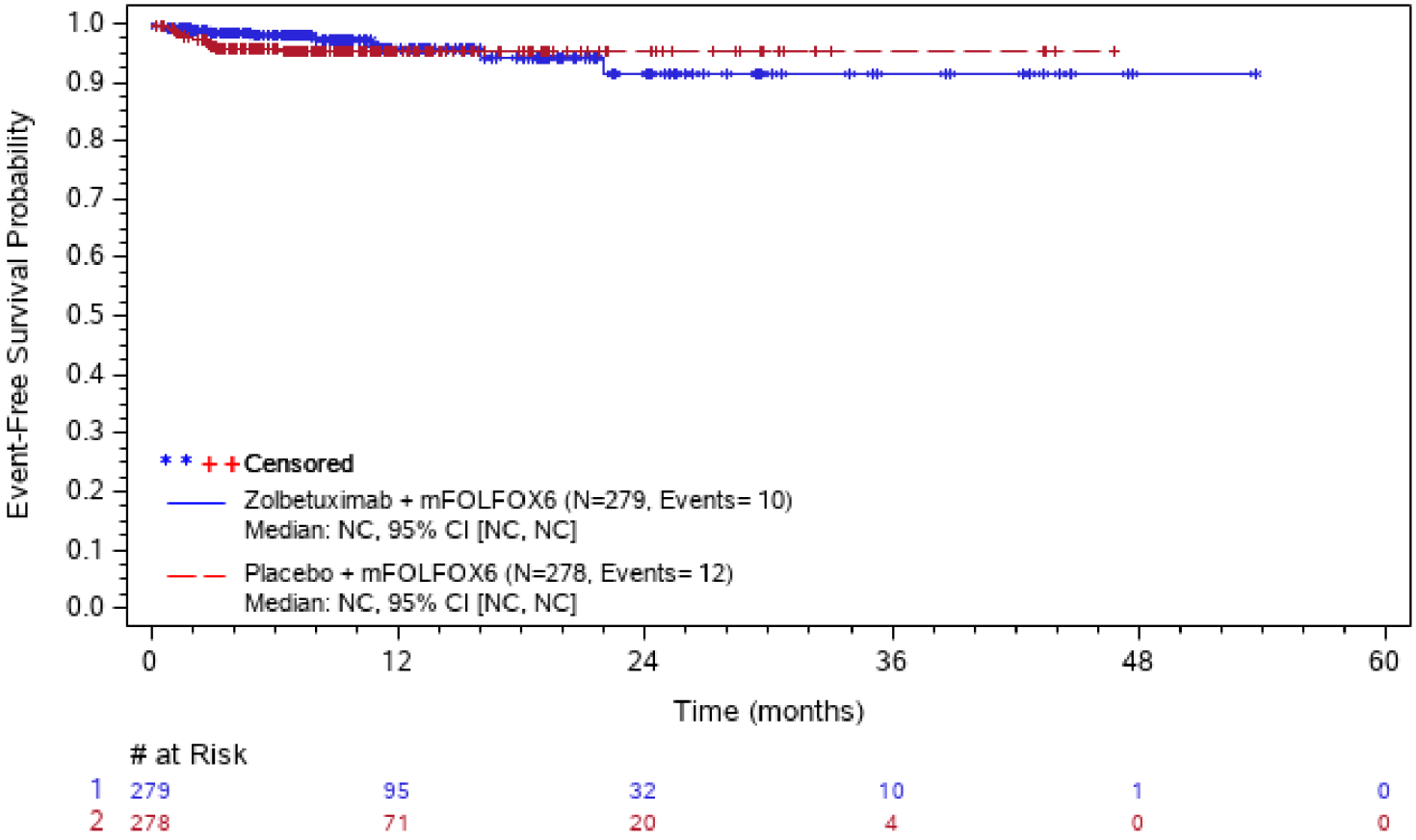


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.15: Kaplan-Meier Plot of Time to first TEAE - Ear and Labyrinth Disorders (SOC) - Safety Analysis Set

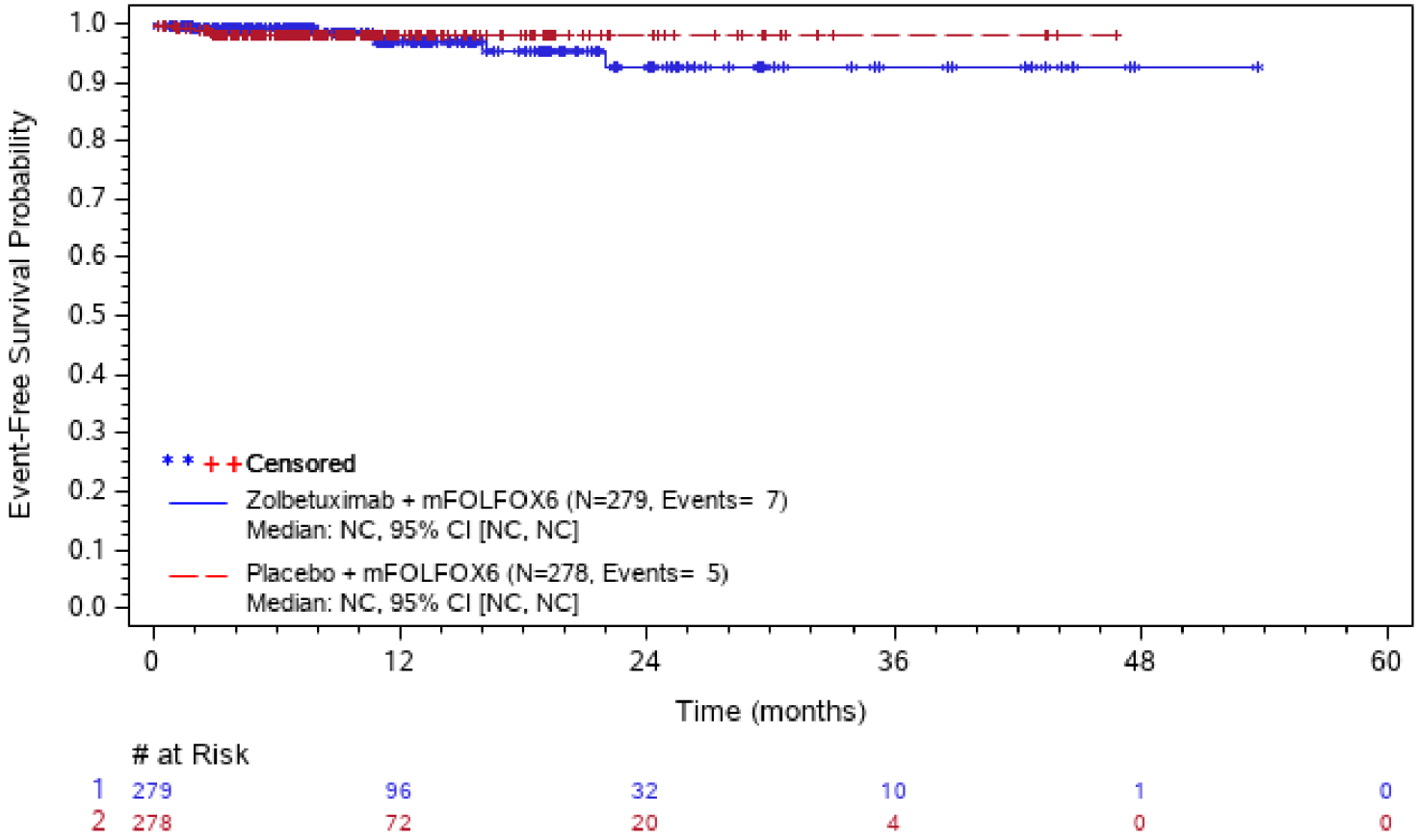


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.16: Kaplan-Meier Plot of Time to first TEAE - Tinnitus (PT) - Safety Analysis Set

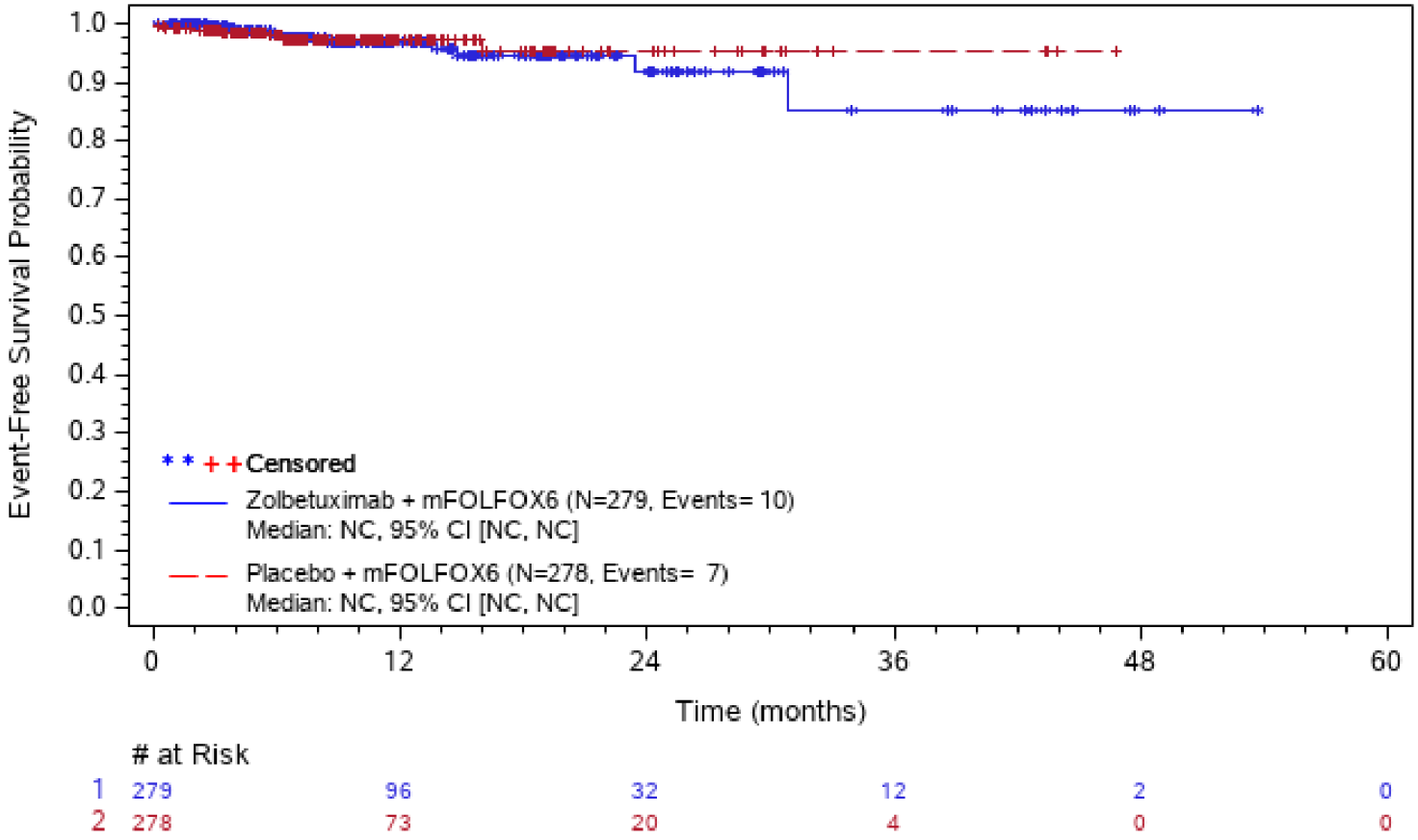


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.17: Kaplan-Meier Plot of Time to first TEAE - Endocrine 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: 08SEP23

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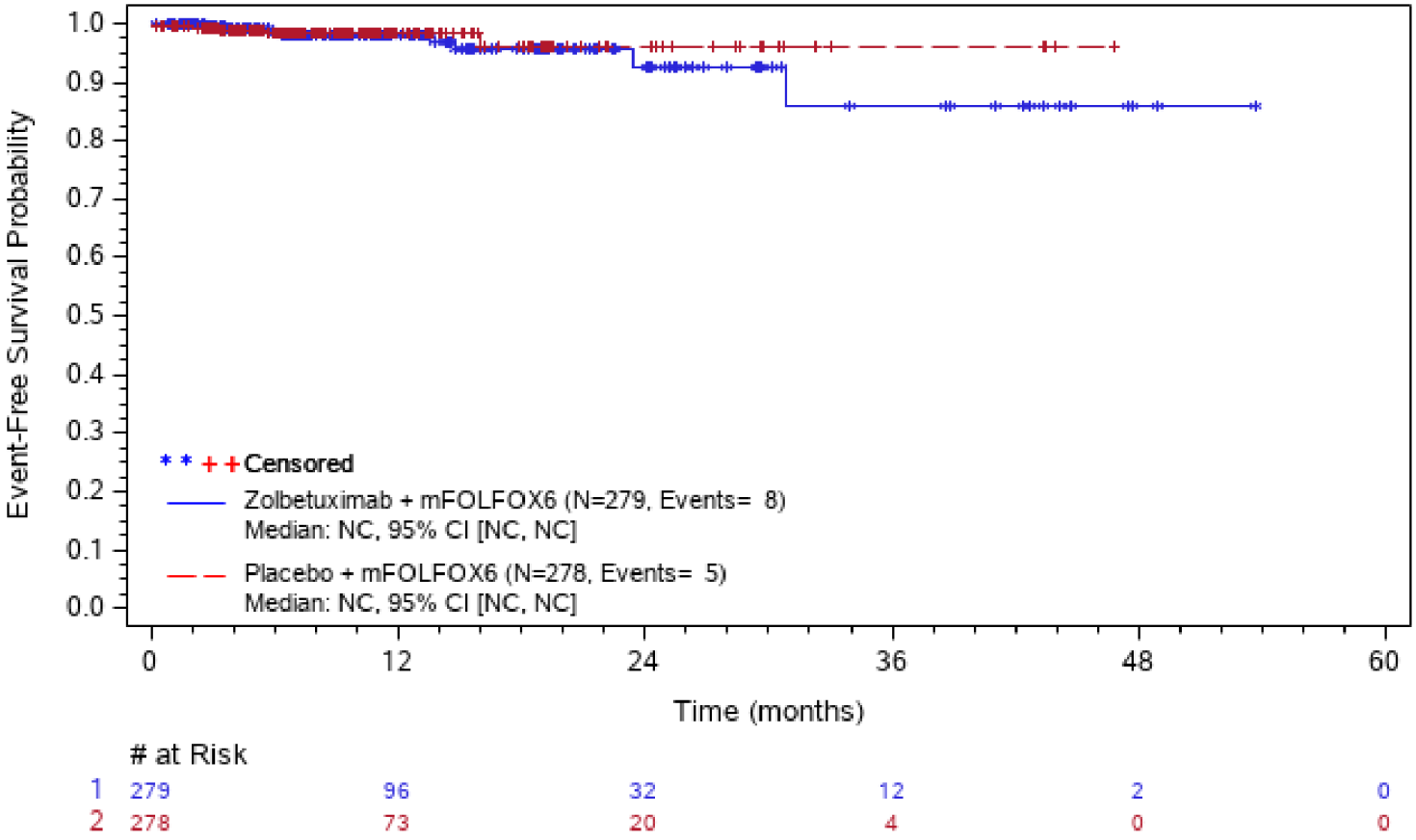
Figure 301.3.2001.18: Kaplan-Meier Plot of Time to first TEAE - Hypothyroidism (PT) - Safety Analysis Set

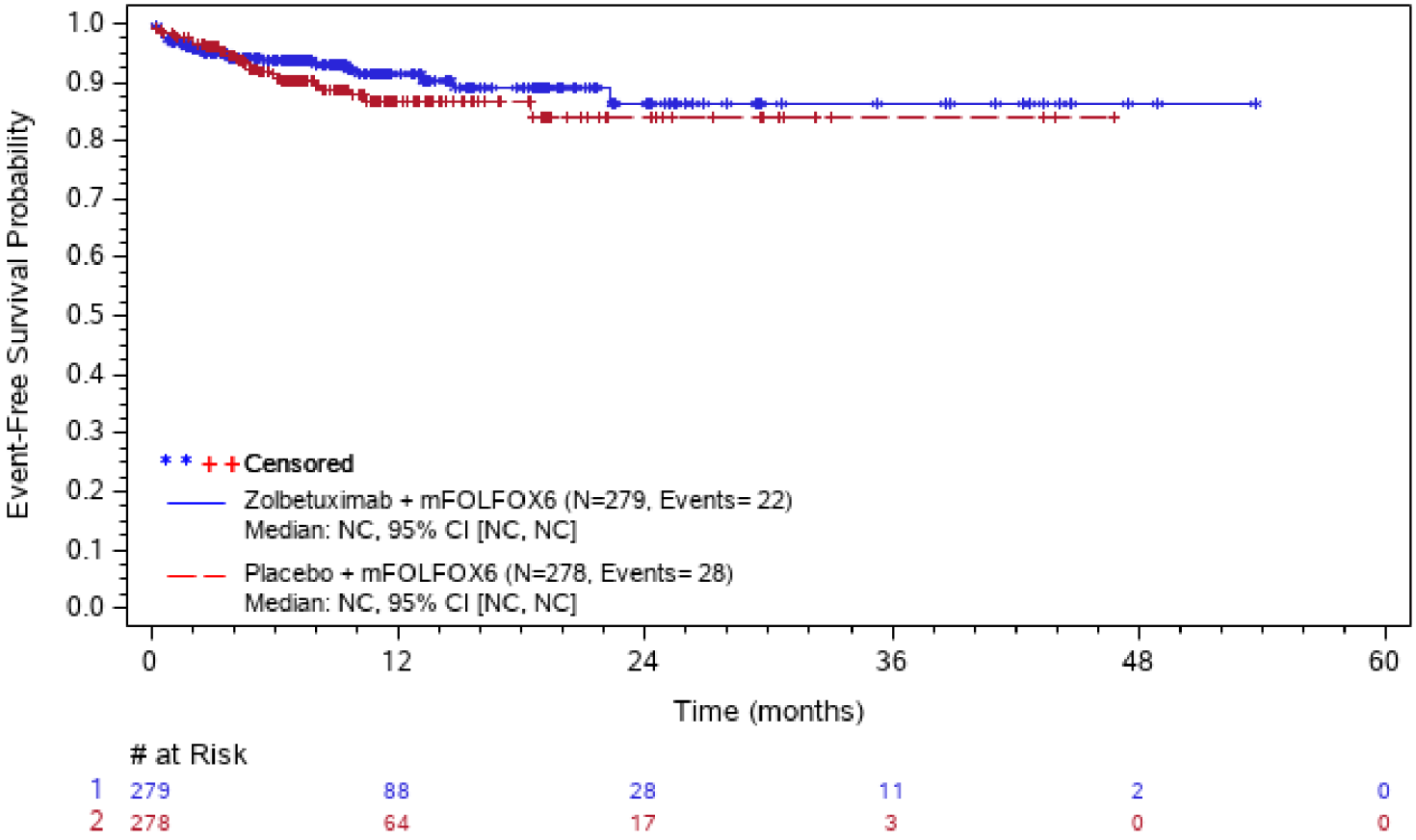


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.19: Kaplan-Meier Plot of Time to first TEAE - Eye 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: 08SEP23

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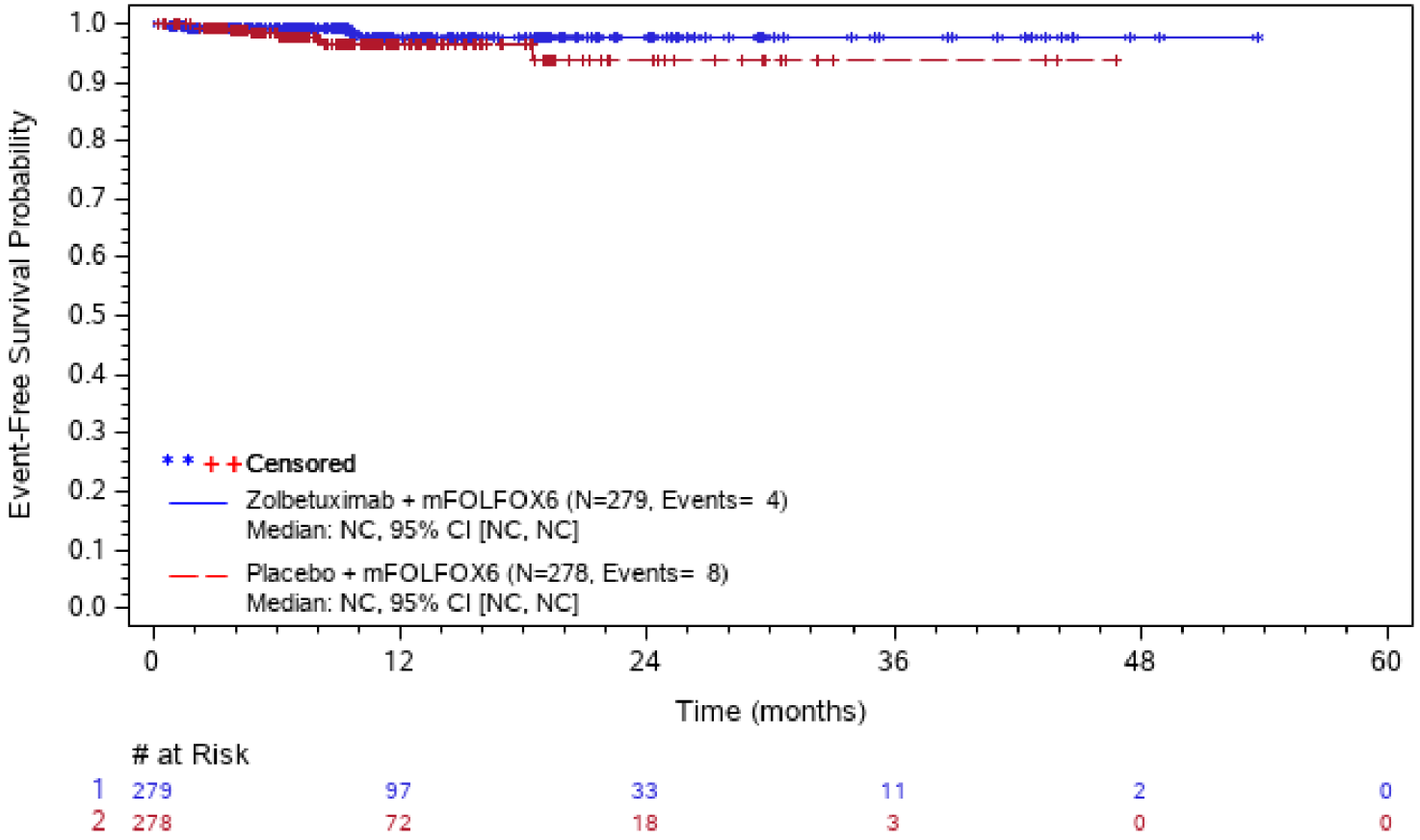
Figure 301.3.2001.20: Kaplan-Meier Plot of Time to first TEAE - Dry Eye (PT) - Safety Analysis Set

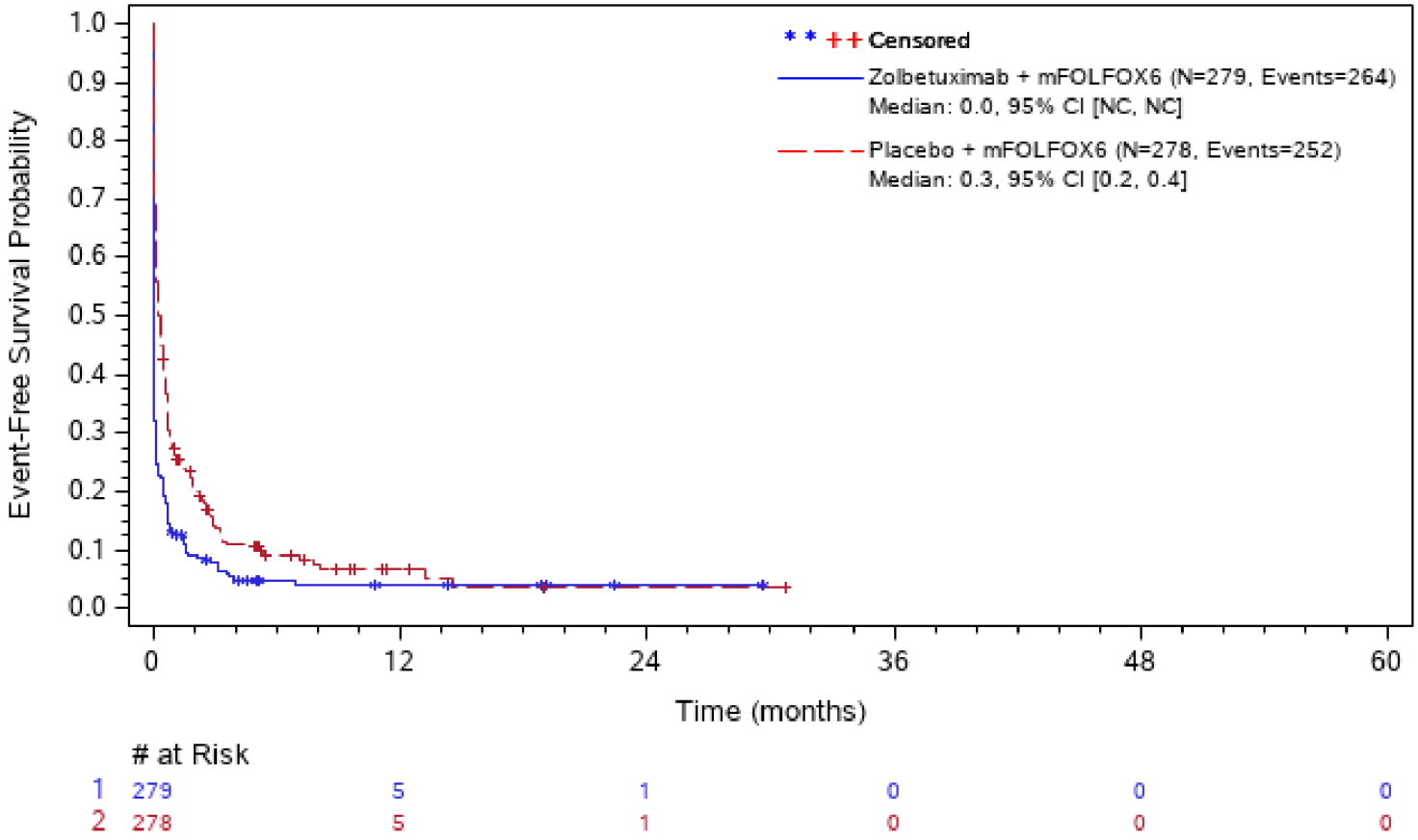


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.21: Kaplan-Meier Plot of Time to first TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set

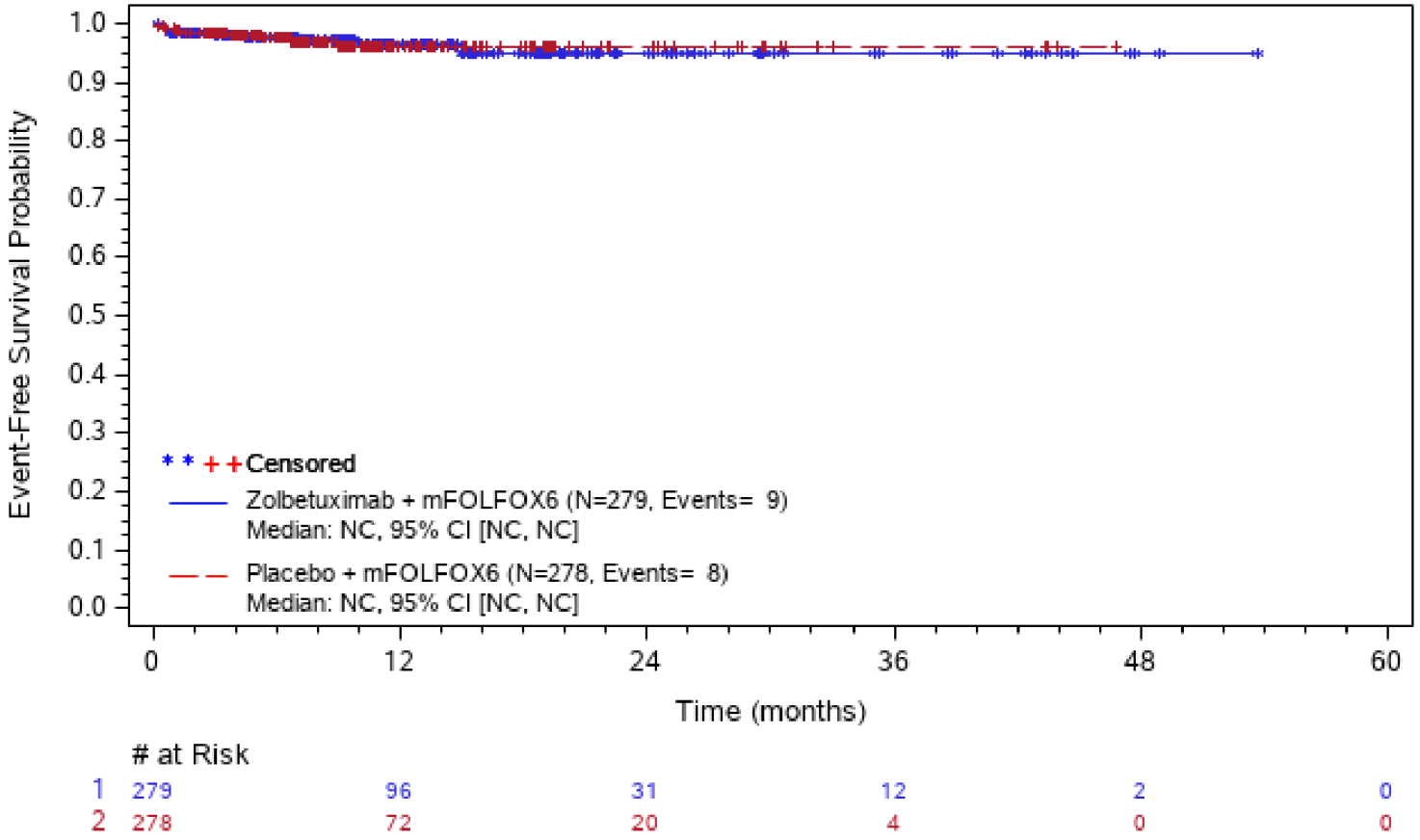


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.22: Kaplan-Meier Plot of Time to first TEAE - Abdominal Discomfort (PT) - Safety Analysis Set

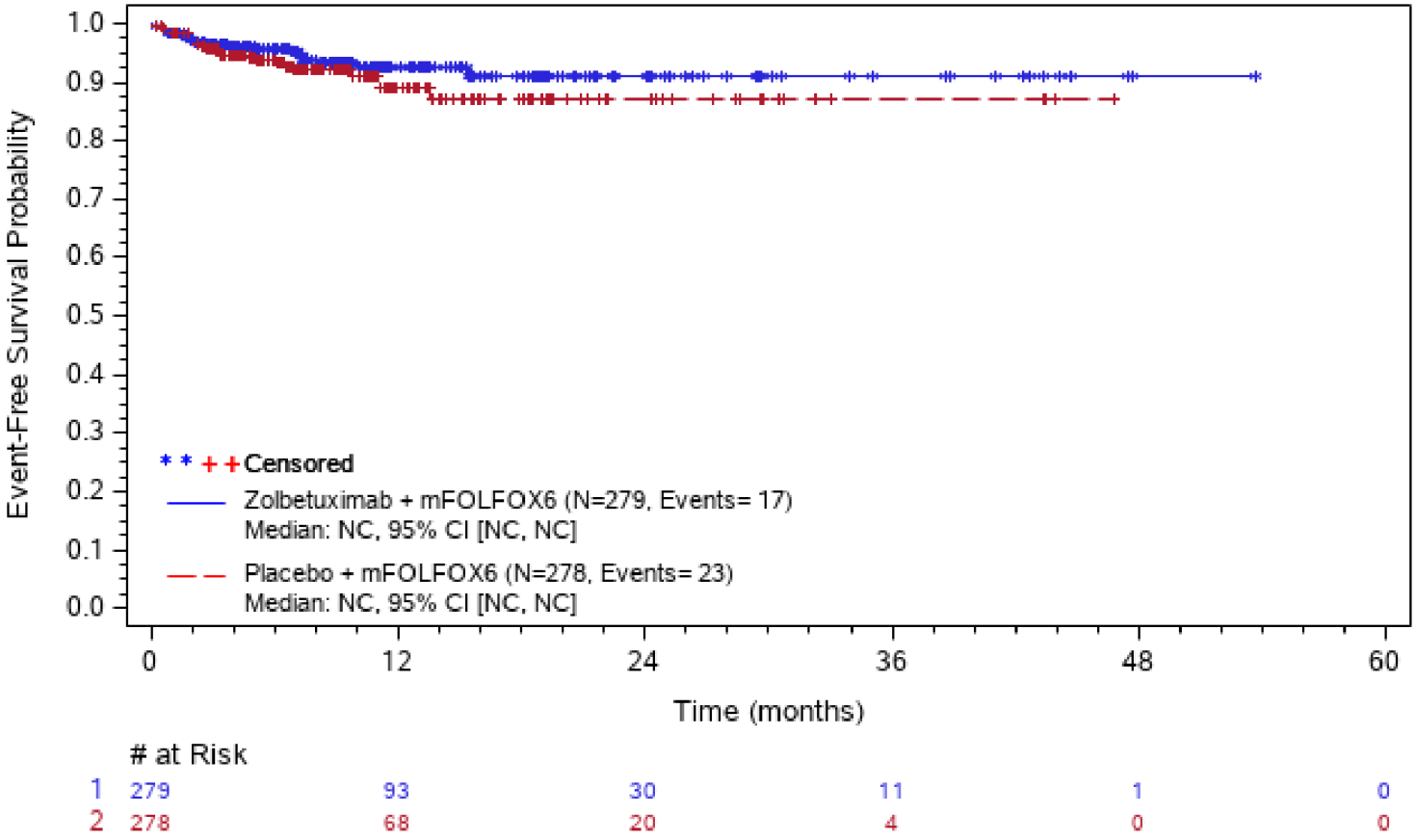


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.23: Kaplan-Meier Plot of Time to first TEAE - Abdominal Distension (PT) - Safety Analysis Set

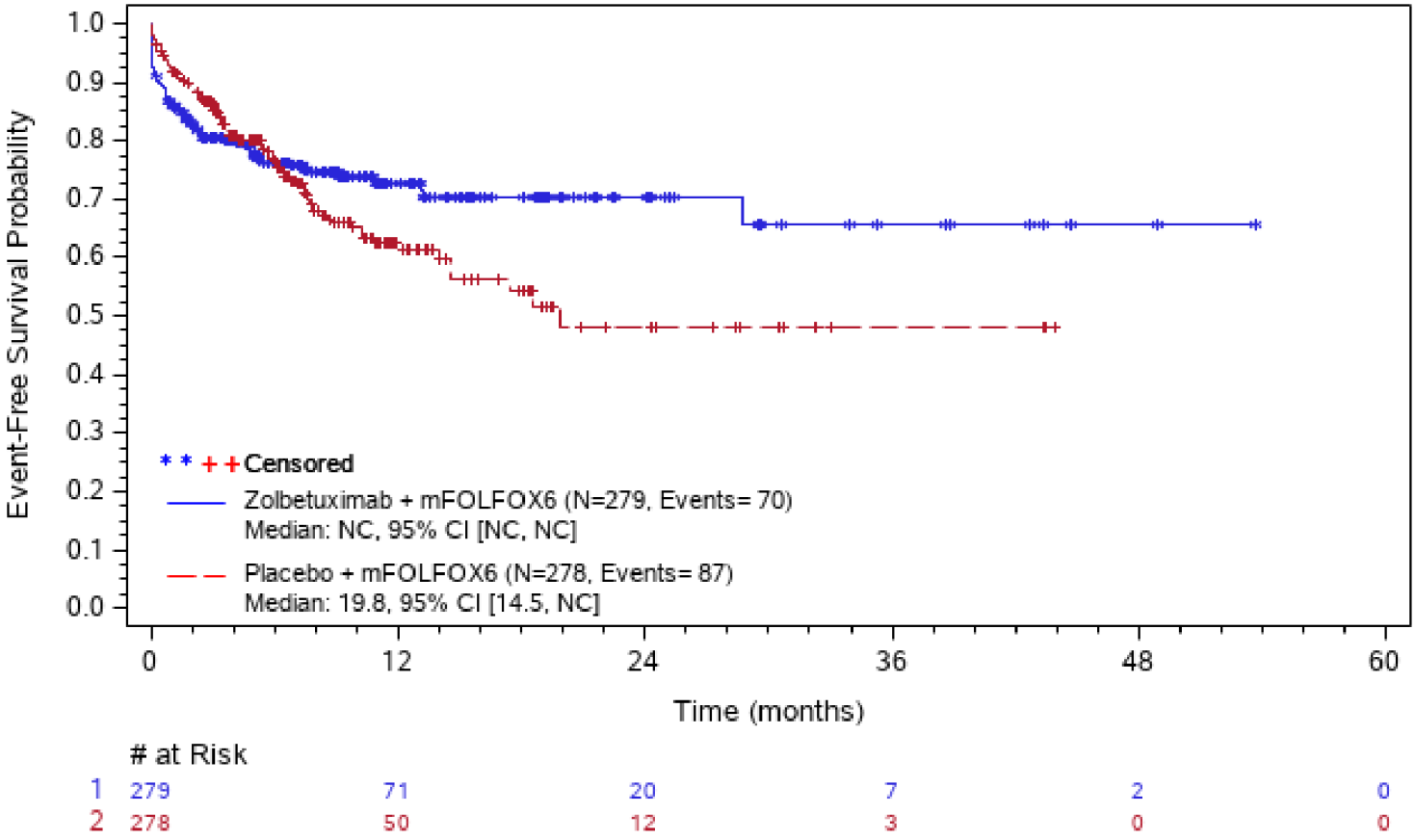


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.24: 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: 08SEP23

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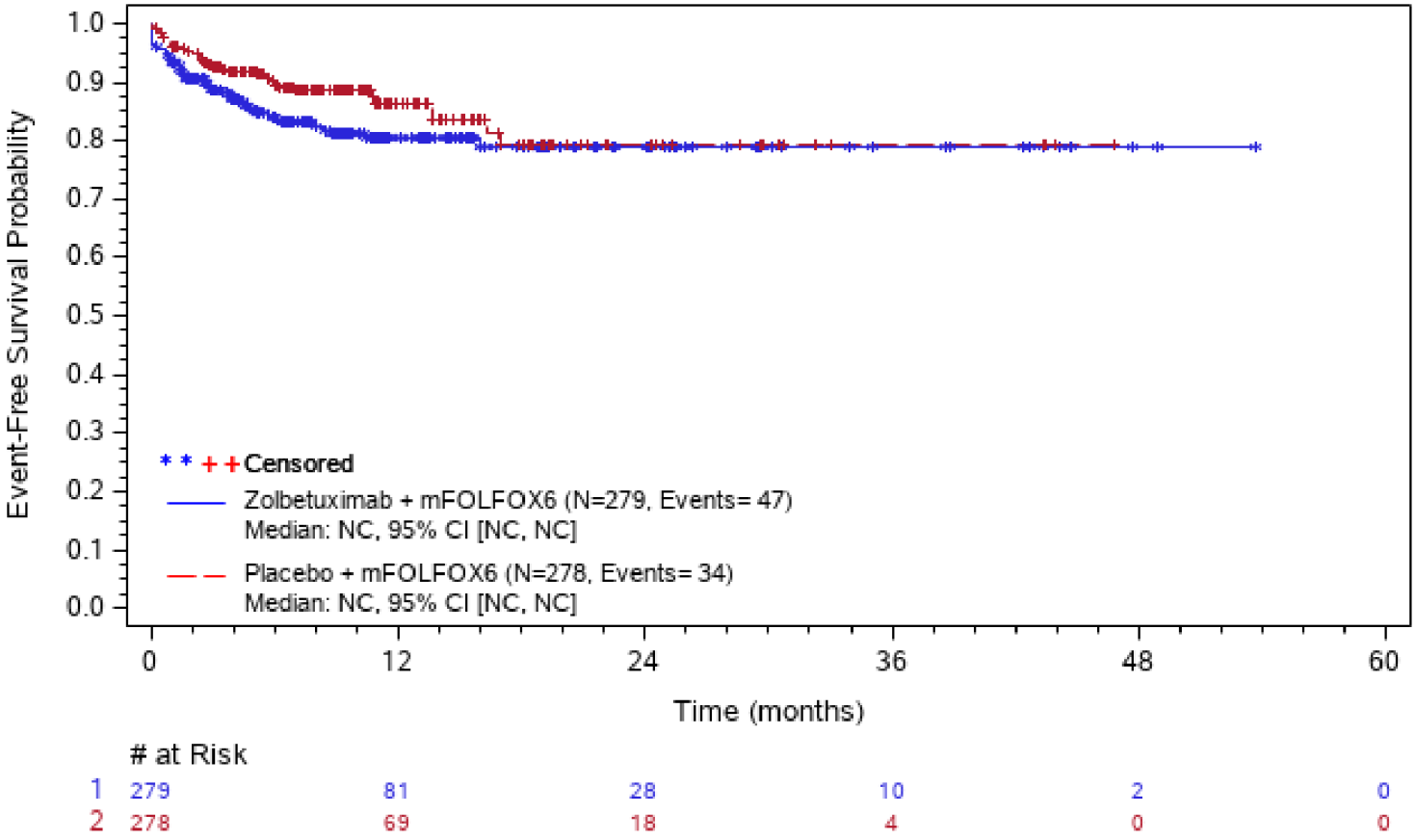
Figure 301.3.2001.25: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain Upper (PT) - Safety Analysis Set



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: 08SEP23

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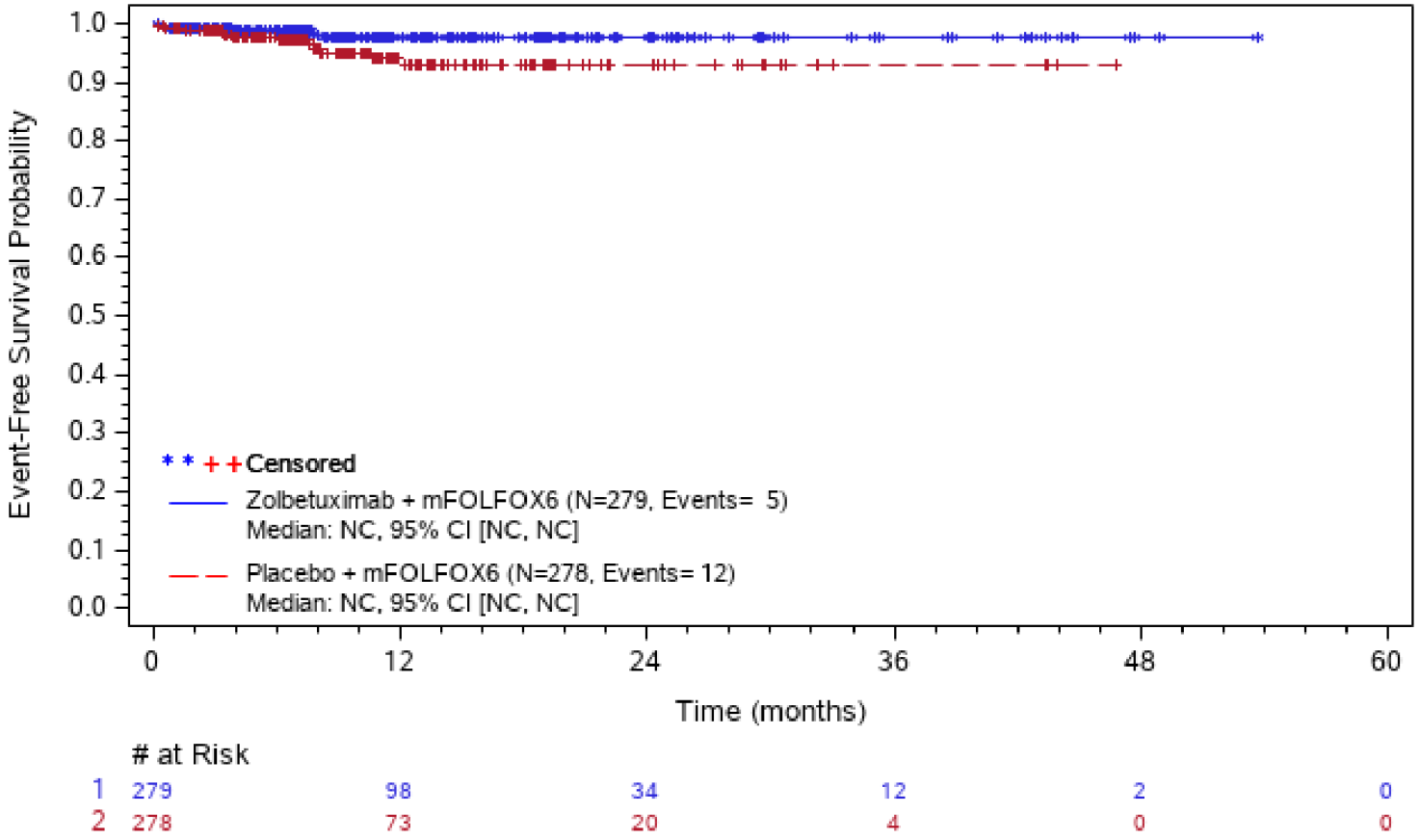
Figure 301.3.2001.26: Kaplan-Meier Plot of Time to first TEAE - Ascites (PT) - Safety Analysis Set



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: 08SEP23

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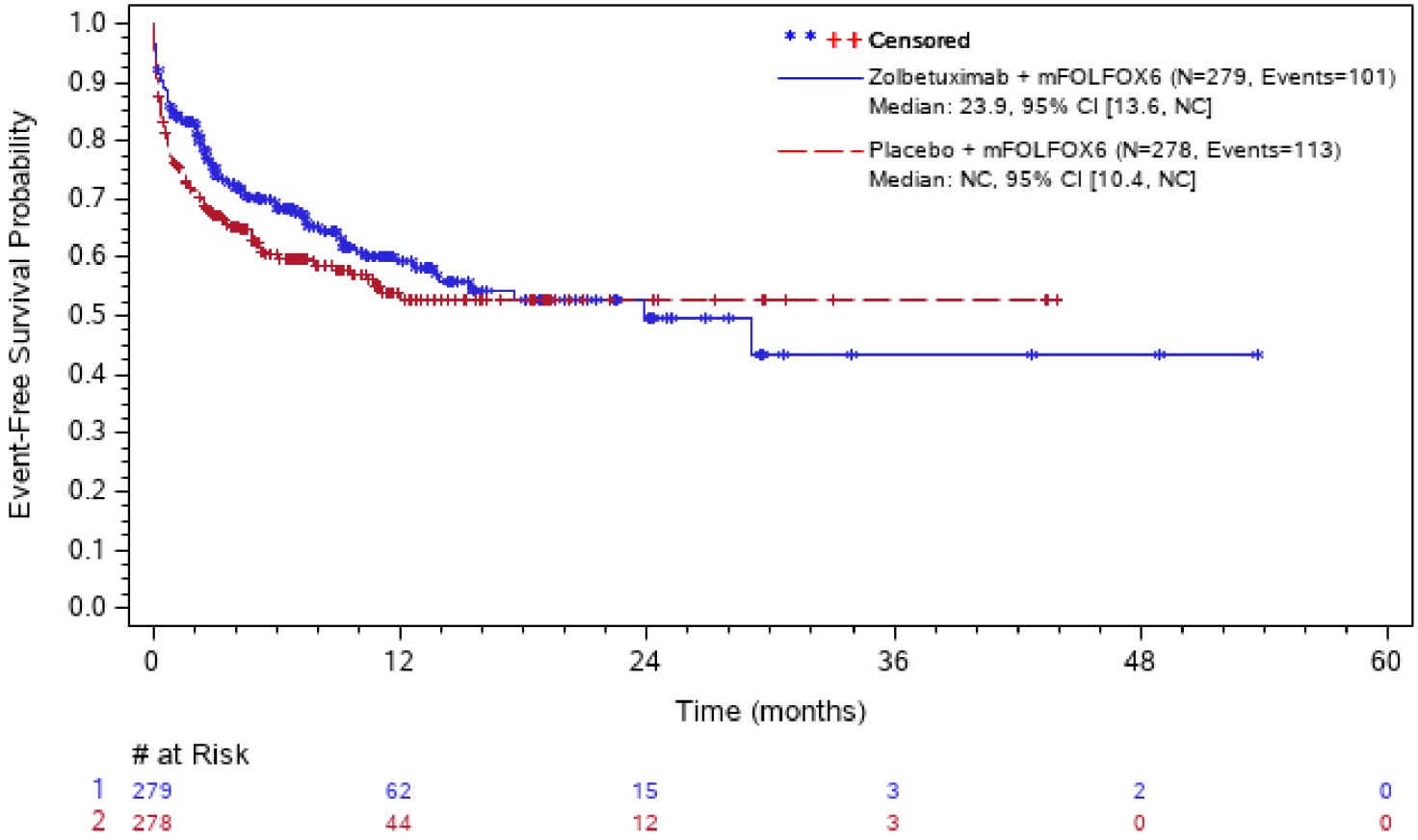
Figure 301.3.2001.27: Kaplan-Meier Plot of Time to first TEAE - Constipation (PT) - Safety Analysis Set



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: 08SEP23

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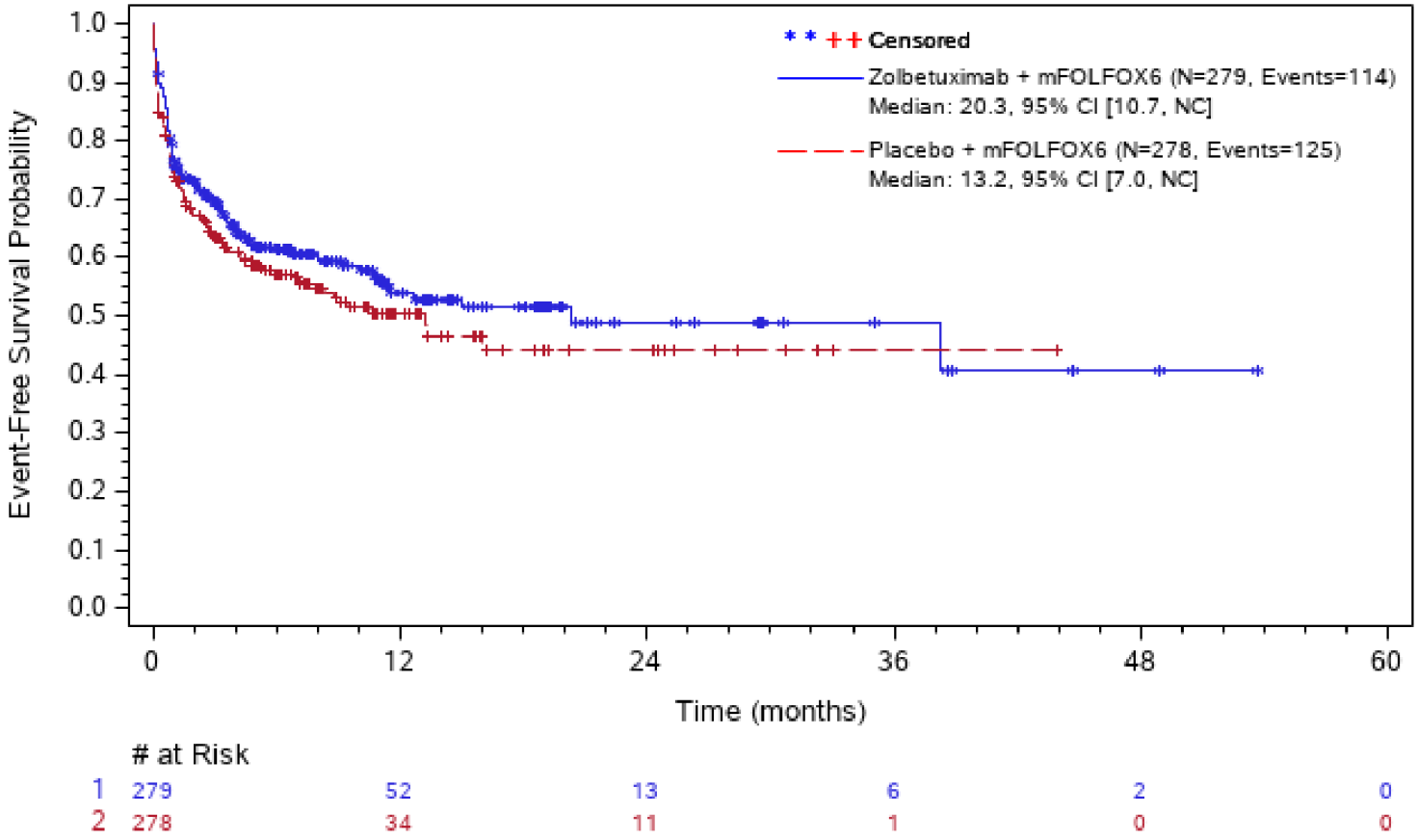
Figure 301.3.2001.28: Kaplan-Meier Plot of Time to first TEAE - Diarrhoea (PT) - Safety Analysis Set



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: 08SEP23

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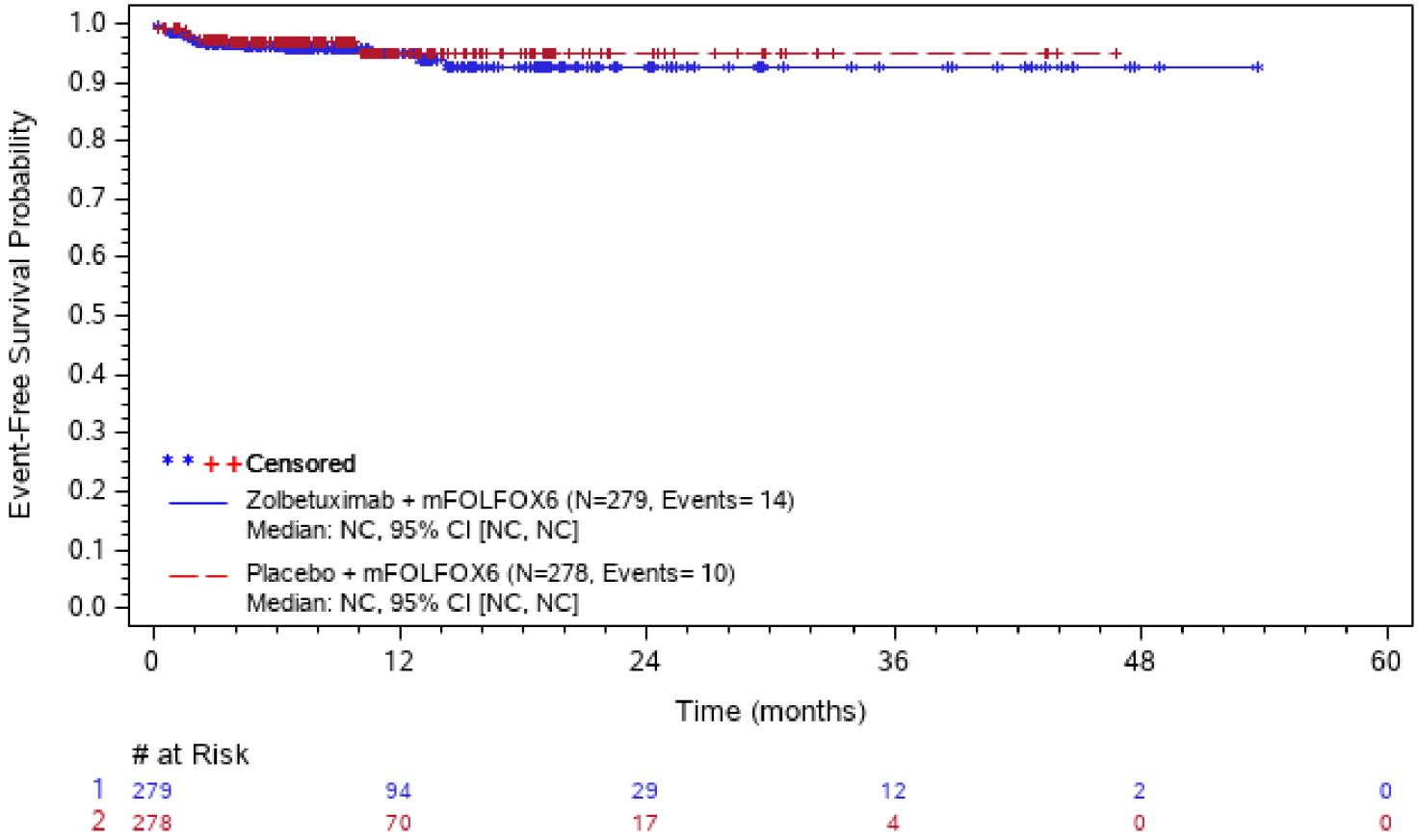
Figure 301.3.2001.29: Kaplan-Meier Plot of Time to first TEAE - Dry Mouth (PT) - Safety Analysis Set



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: 08SEP23

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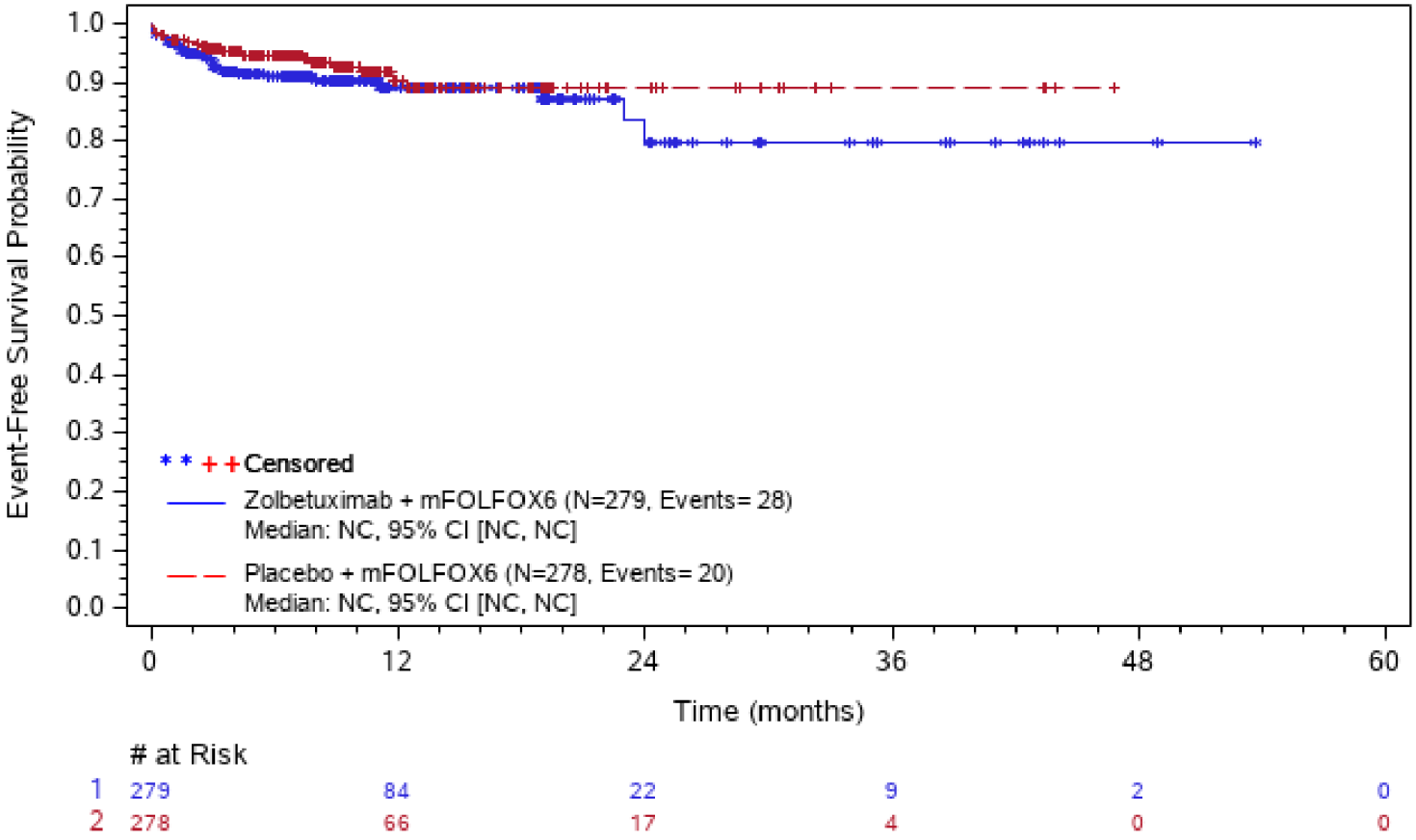
Figure 301.3.2001.30: Kaplan-Meier Plot of Time to first TEAE - Dyspepsia (PT) - Safety Analysis Set



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.

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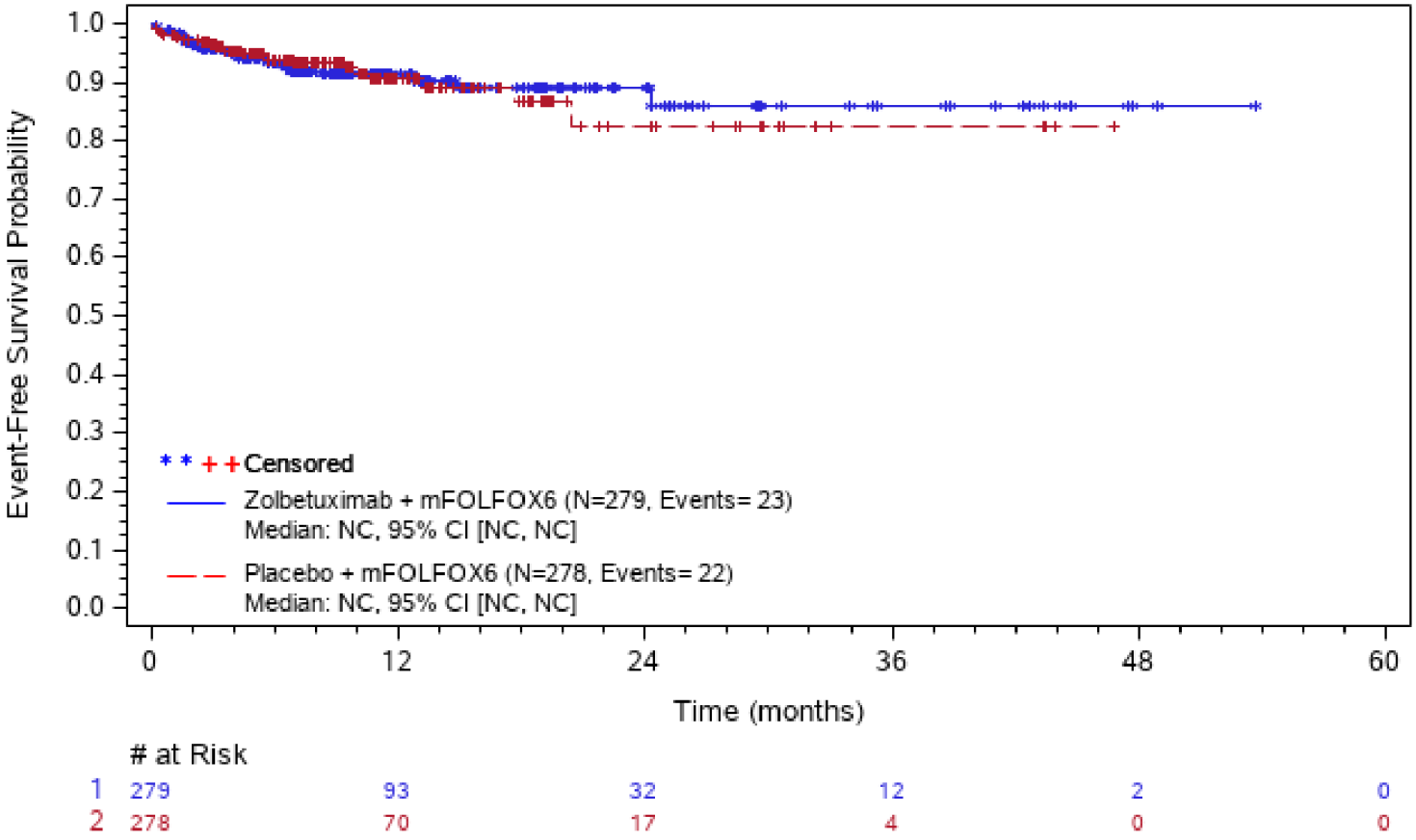
Figure 301.3.2001.31: Kaplan-Meier Plot of Time to first TEAE - Dysphagia (PT) - Safety Analysis Set



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: 08SEP23

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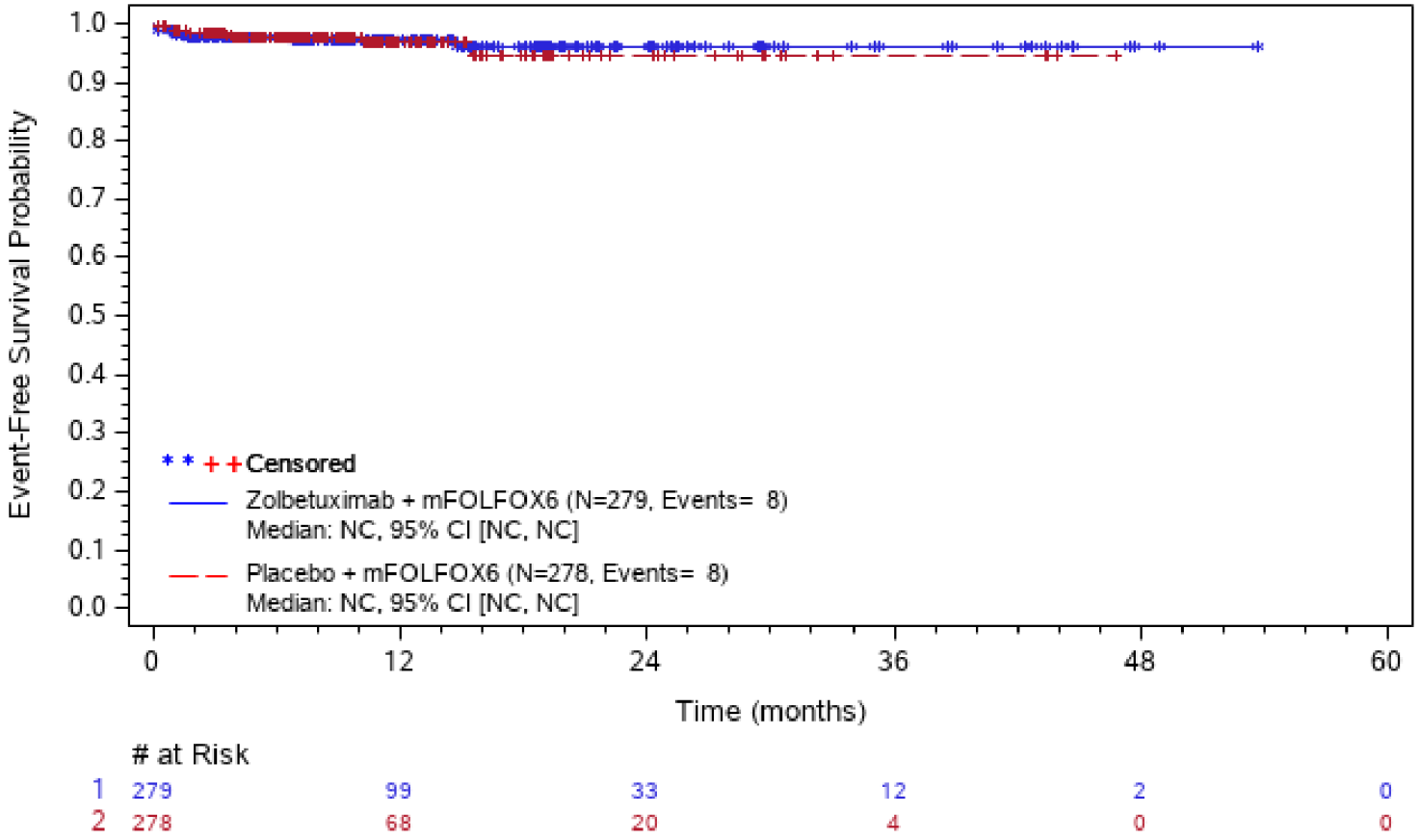
Figure 301.3.2001.32: Kaplan-Meier Plot of Time to first TEAE - Flatulence (PT) - Safety Analysis Set



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: 08SEP23

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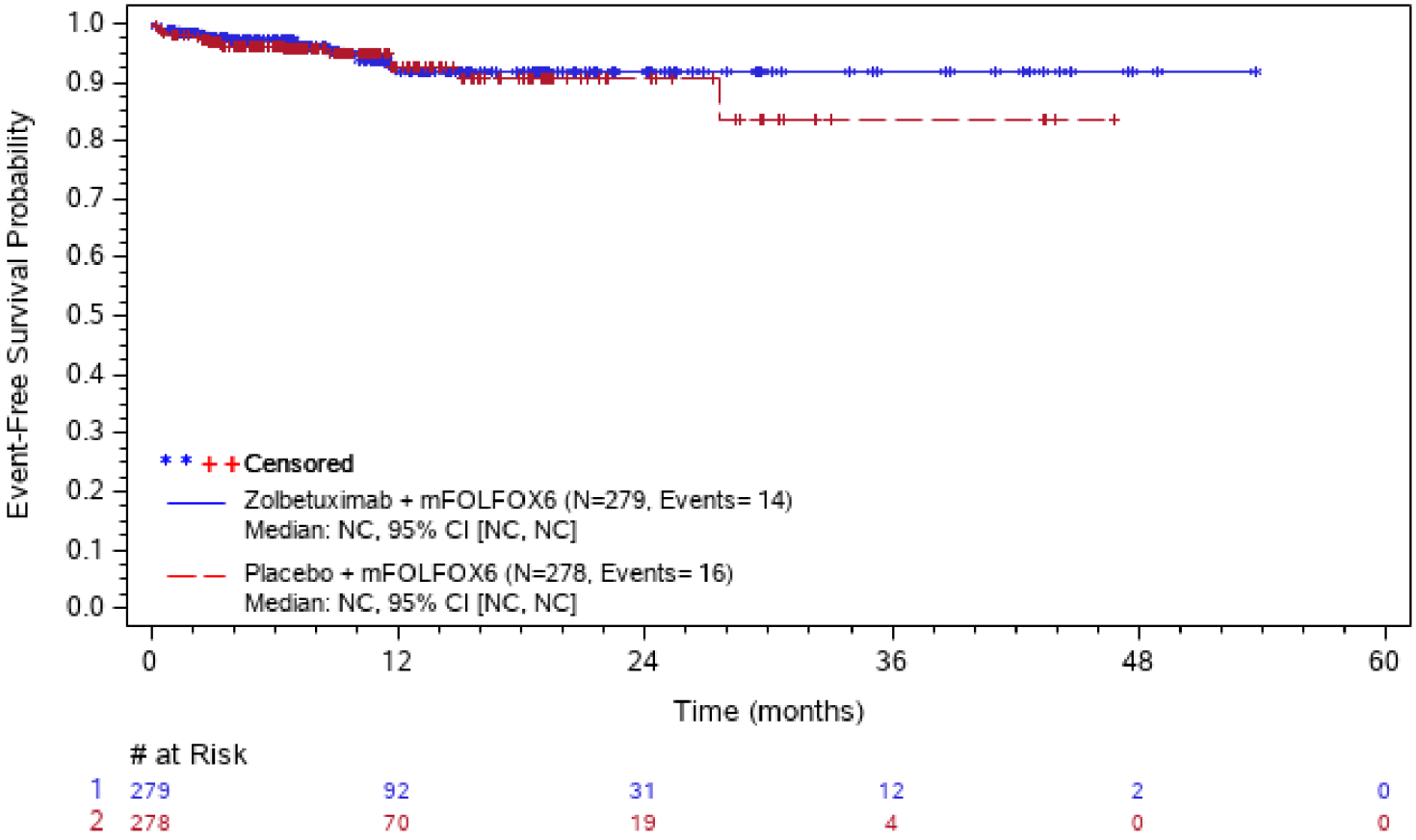
Figure 301.3.2001.33: Kaplan-Meier Plot of Time to first TEAE - Gastrooesophageal Reflux Disease (PT) - Safety Analysis Set



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: 08SEP23

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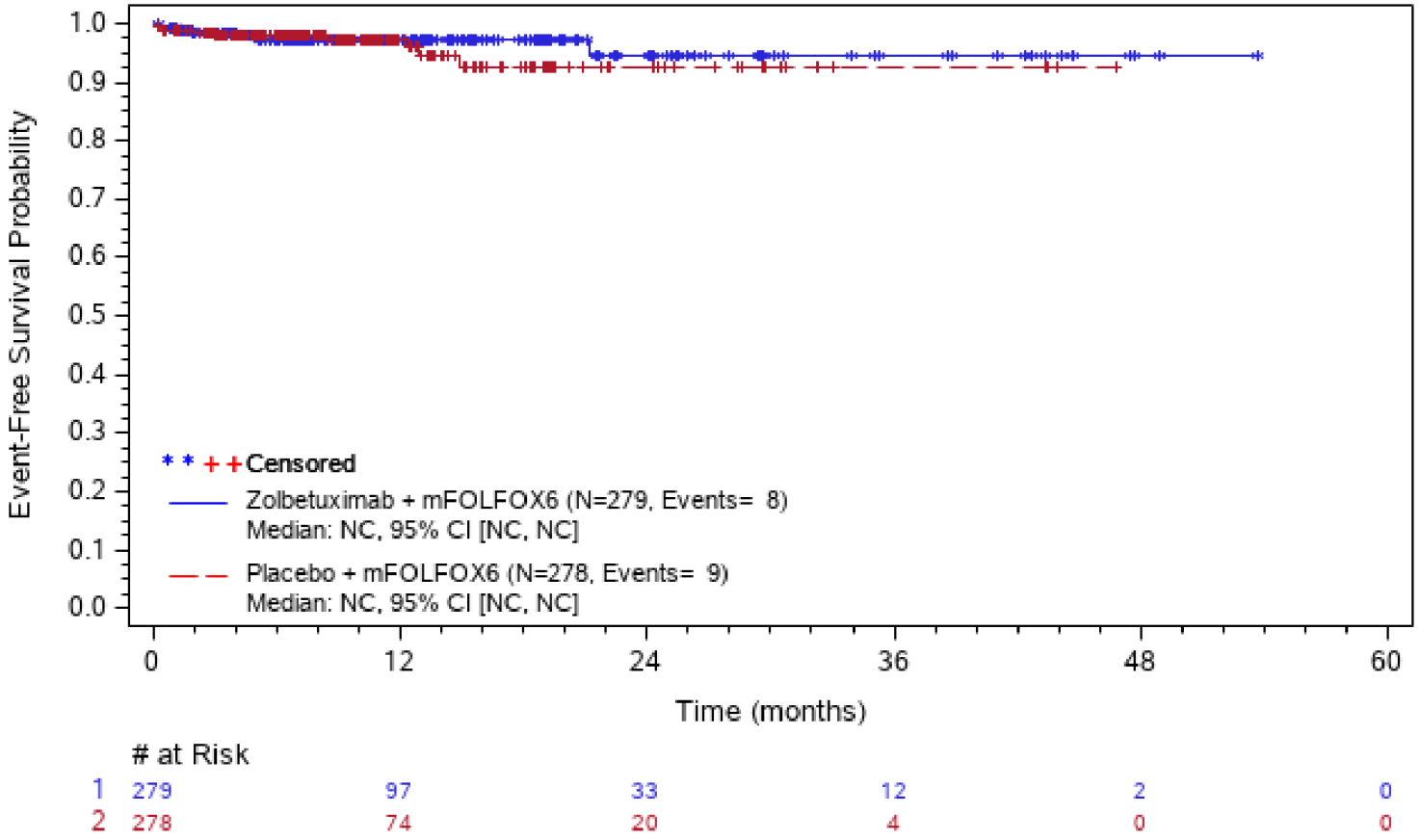
Figure 301.3.2001.34: Kaplan-Meier Plot of Time to first TEAE - Intestinal Obstruction (PT) - Safety Analysis Set



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: 08SEP23

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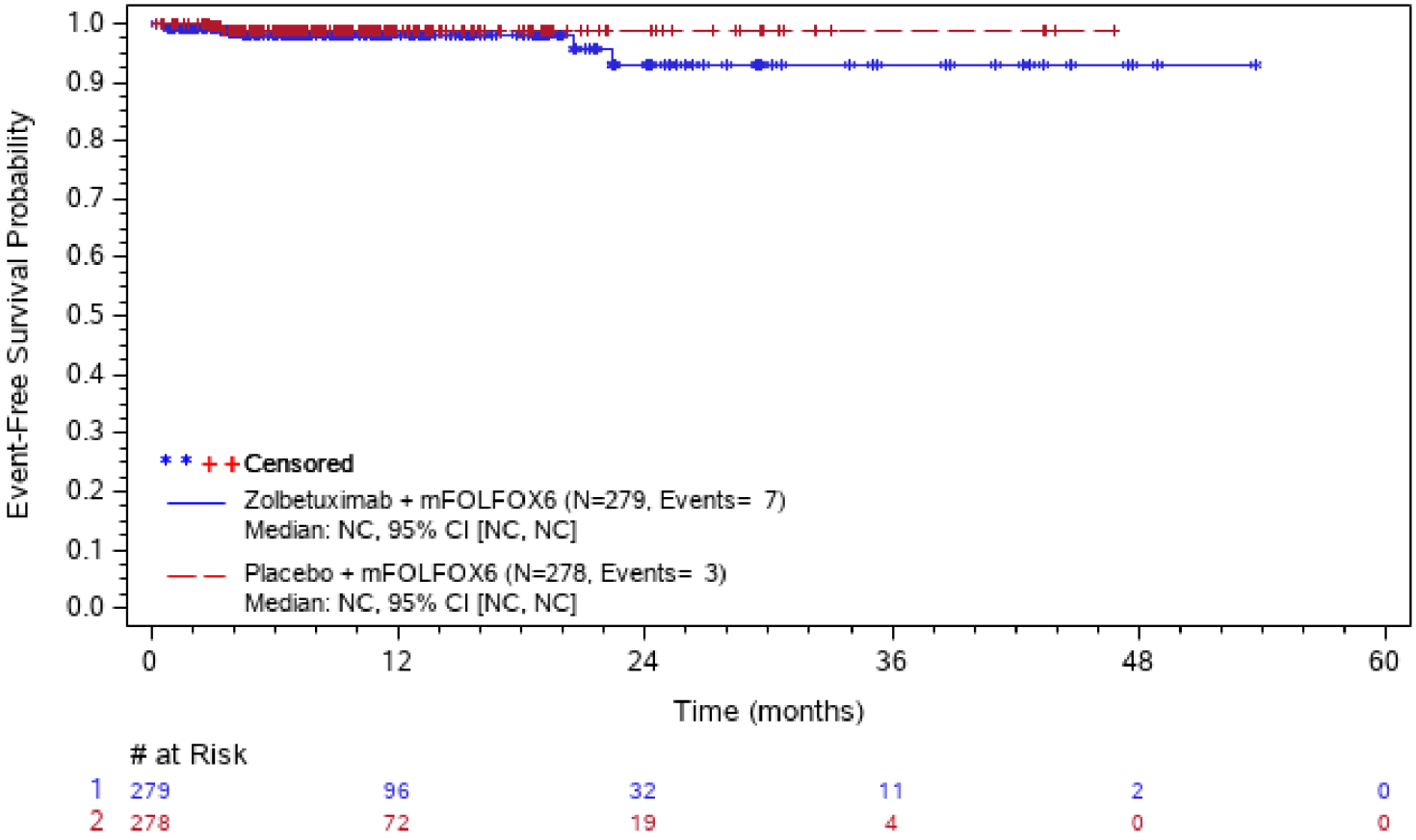
Figure 301.3.2001.35: Kaplan-Meier Plot of Time to first TEAE - Mouth Ulceration (PT) - Safety Analysis Set



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: 08SEP23

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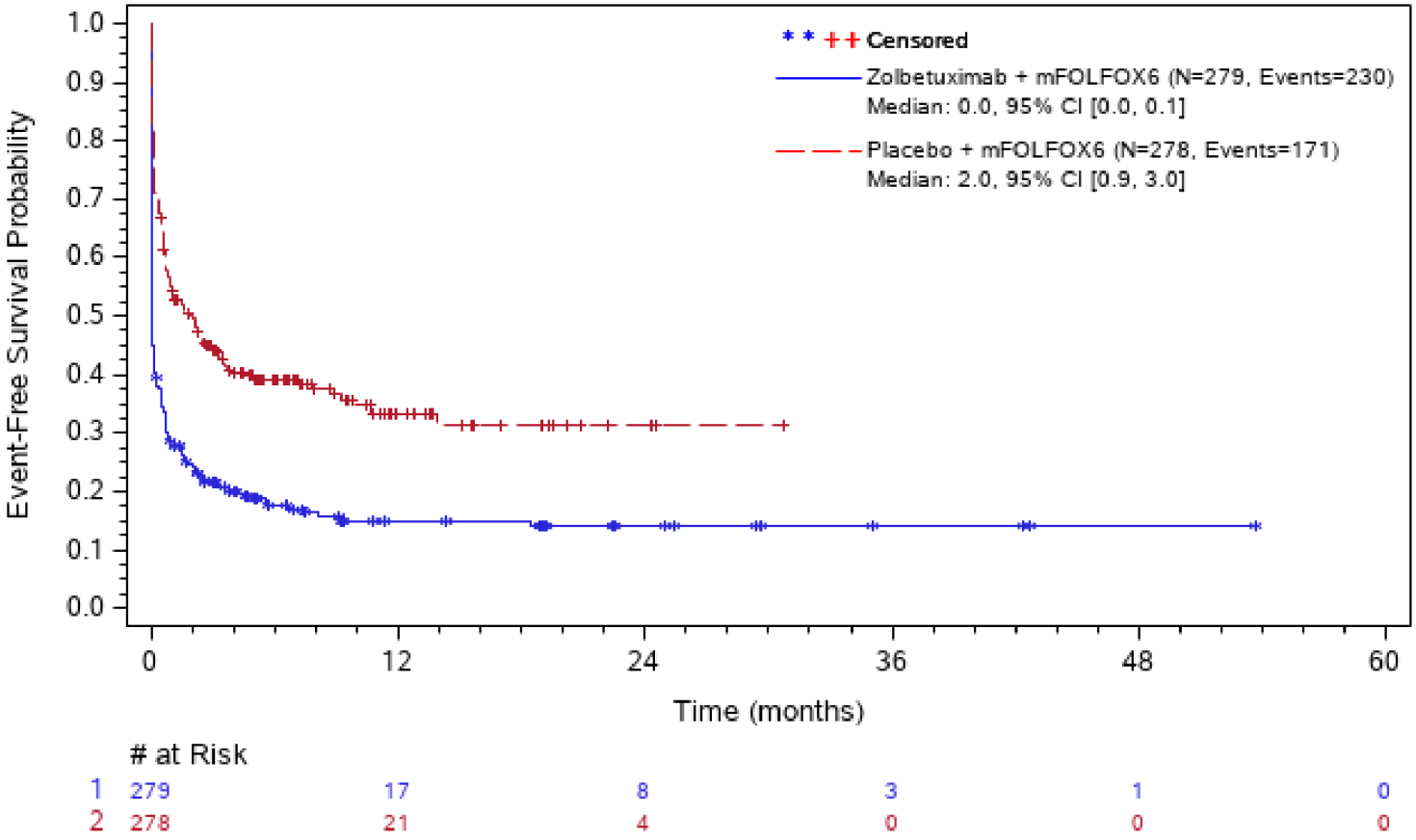
Figure 301.3.2001.36: Kaplan-Meier Plot of Time to first TEAE - Nausea (PT) - Safety Analysis Set



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: 08SEP23

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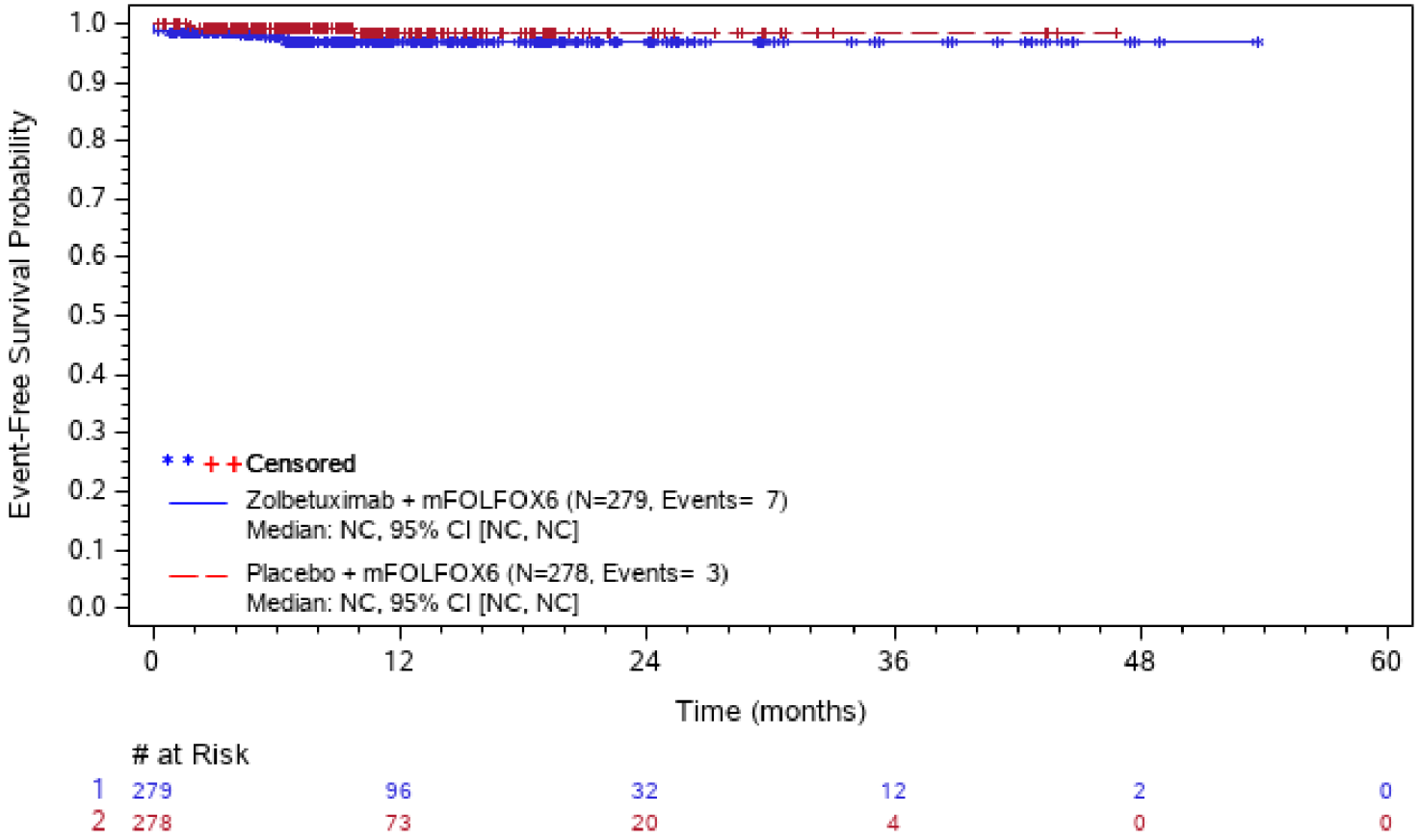
Figure 301.3.2001.37: Kaplan-Meier Plot of Time to first TEAE - Retching (PT) - Safety Analysis Set

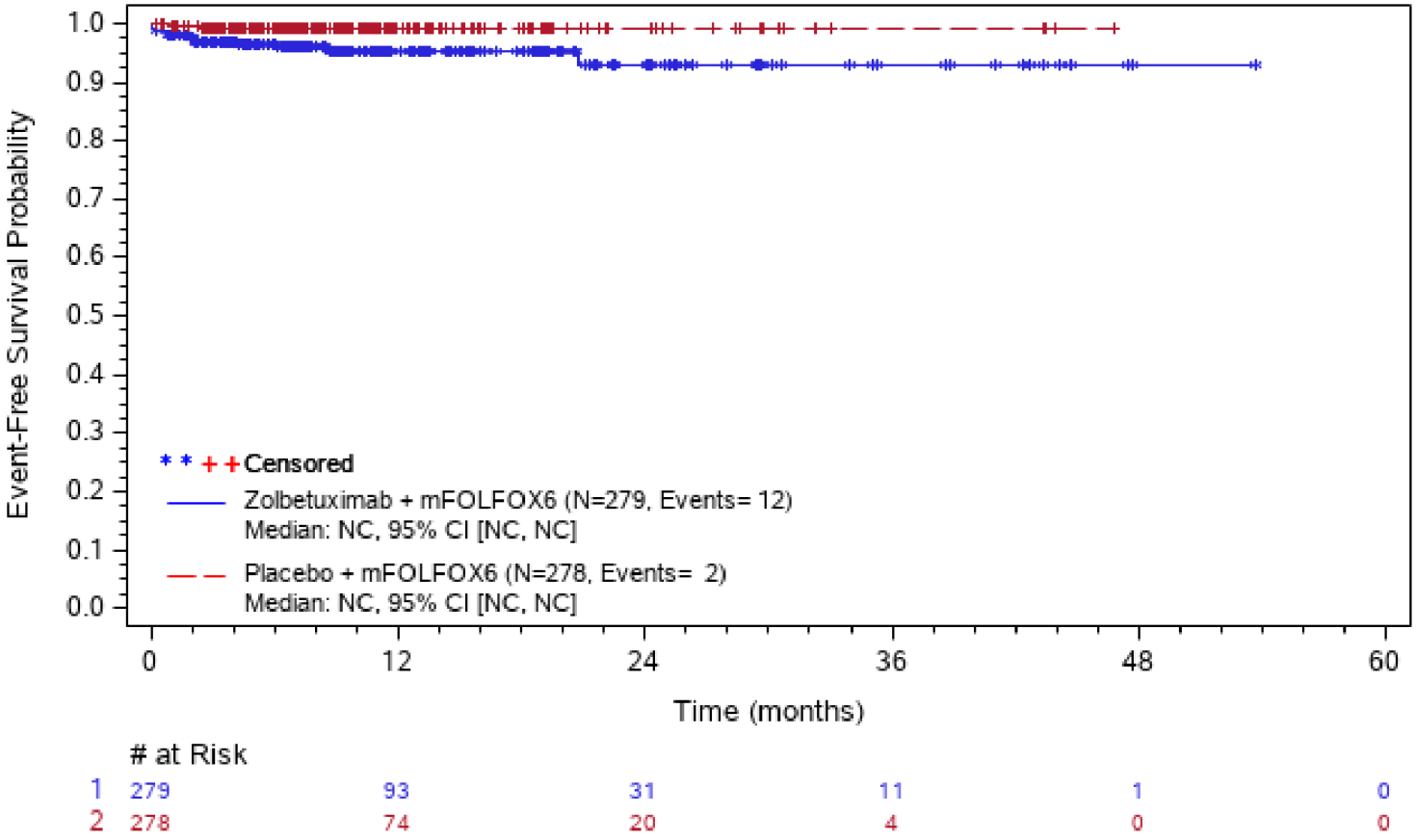


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.38: Kaplan-Meier Plot of Time to first TEAE - Salivary Hypersecretion (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: 08SEP23

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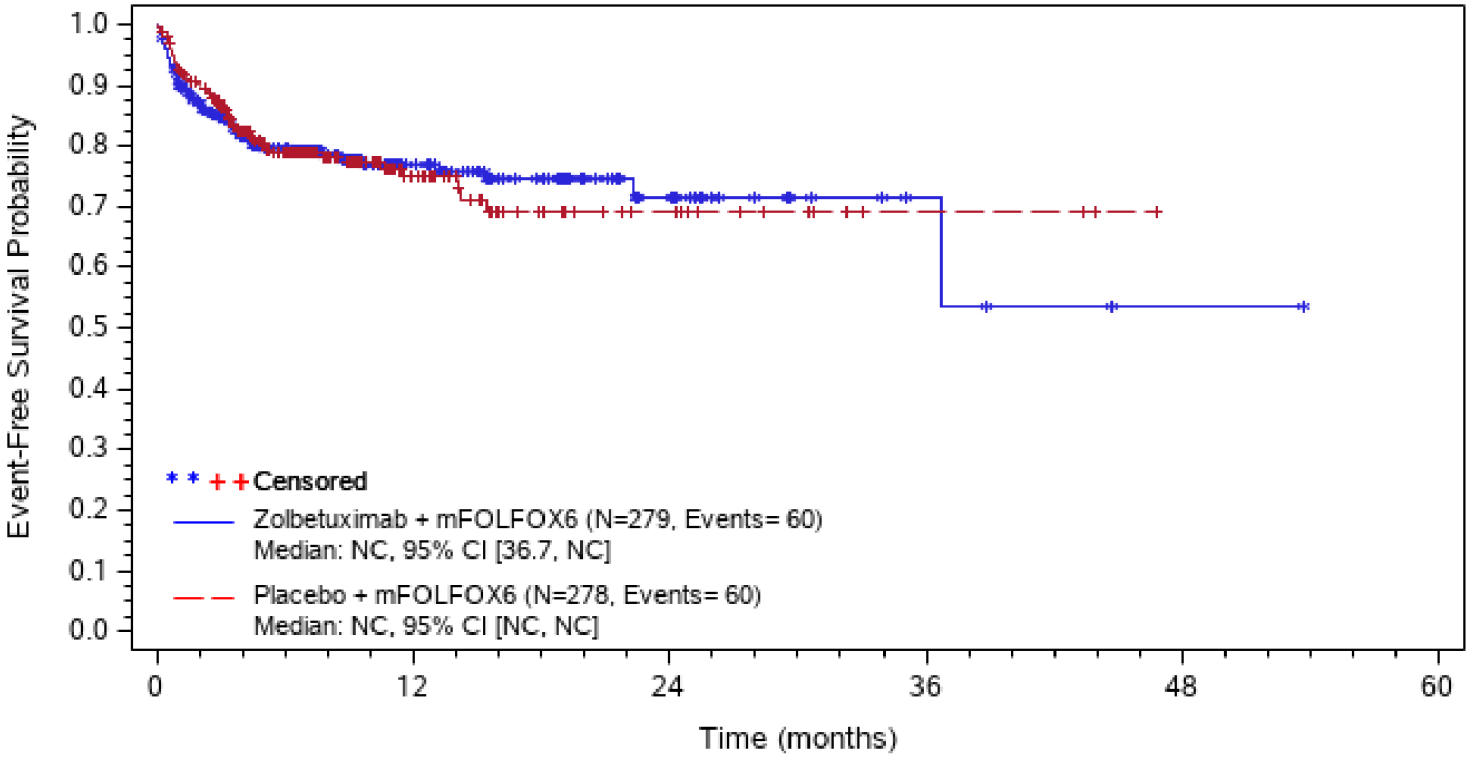
Figure 301.3.2001.39: Kaplan-Meier Plot of Time to first TEAE - Stomatitis (PT) - Safety Analysis Set



# at Risk						
1	279	71	20	4	1	0
2	278	51	14	3	0	0

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.

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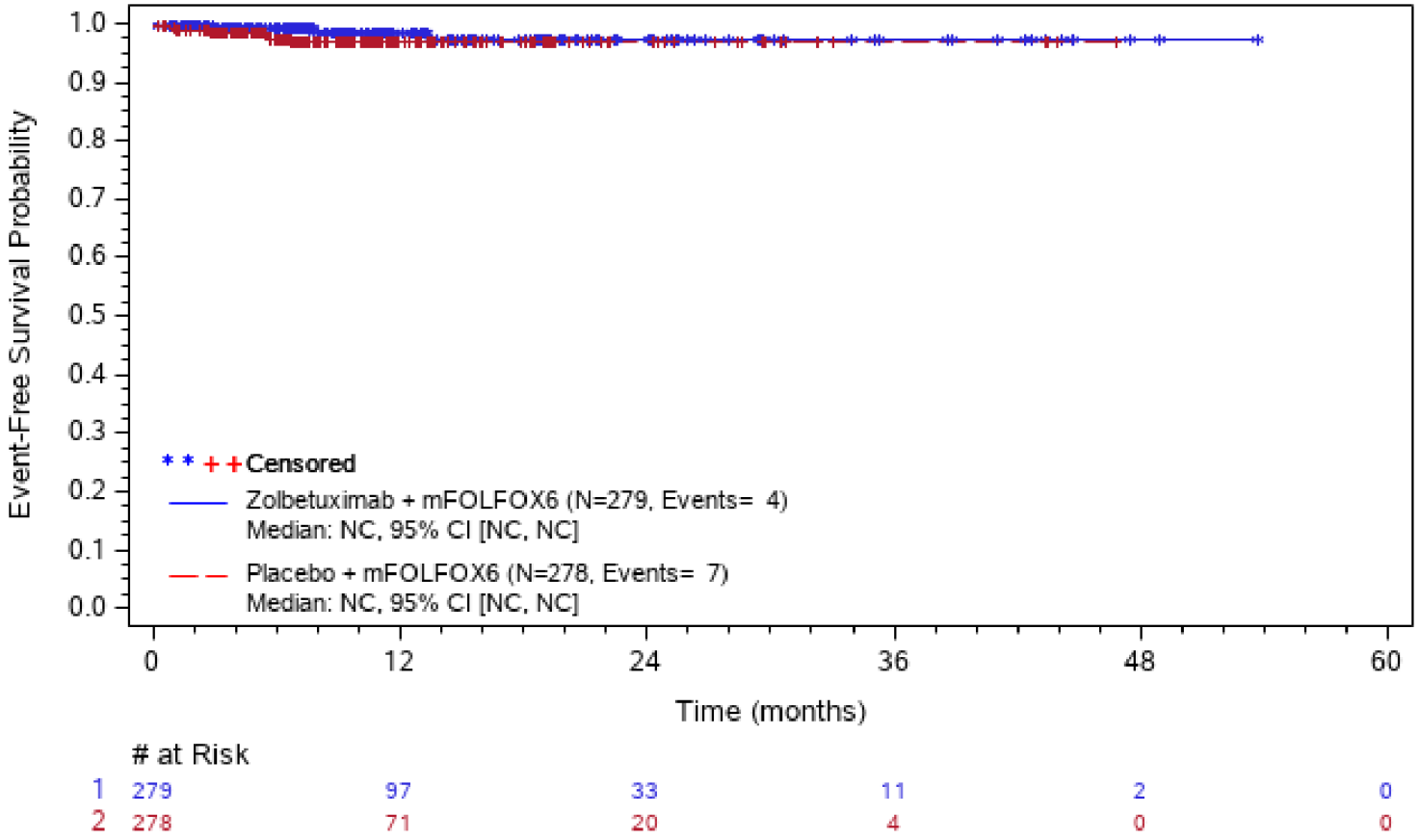
Figure 301.3.2001.40: Kaplan-Meier Plot of Time to first TEAE - Toothache (PT) - Safety Analysis Set



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: 08SEP23

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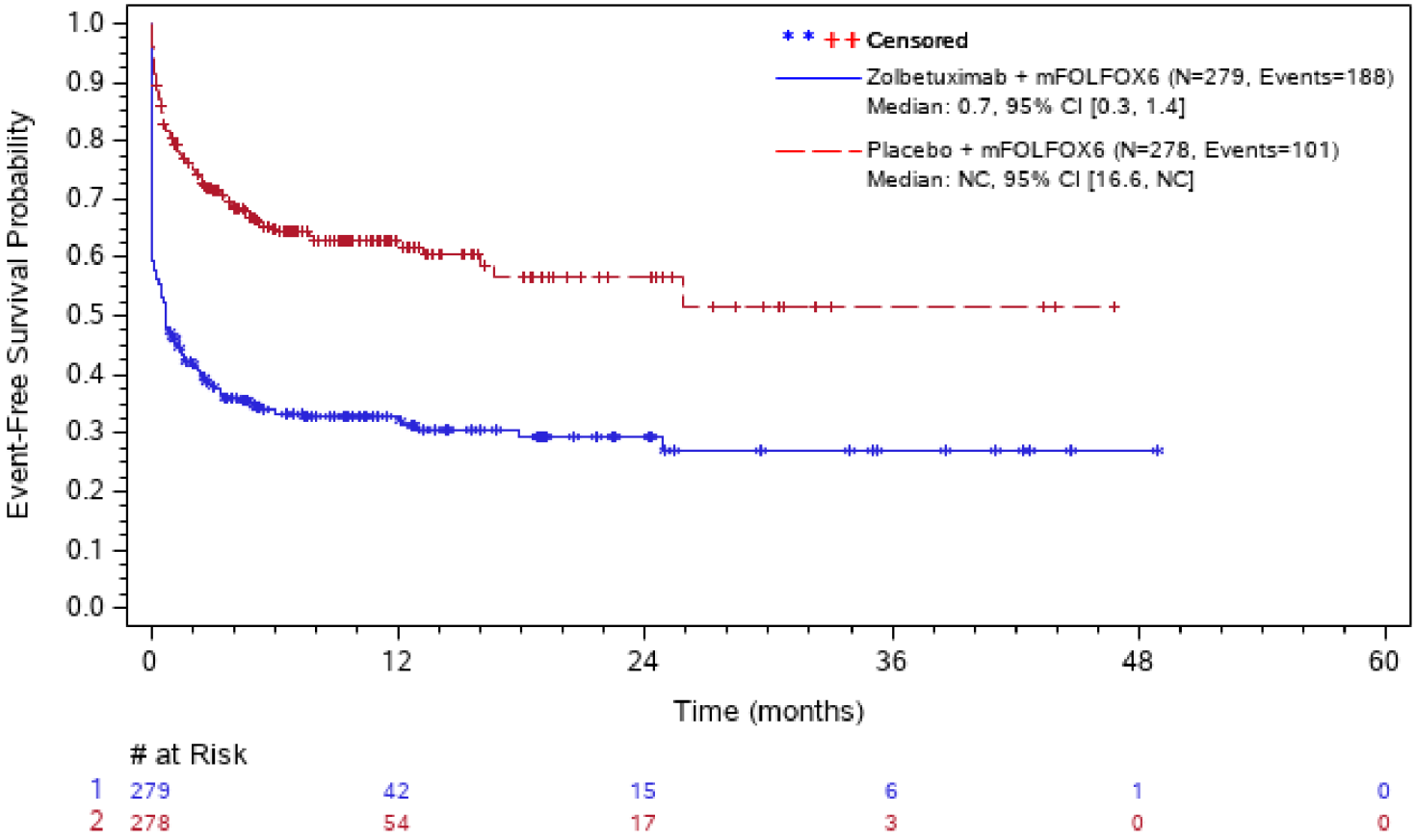
Figure 301.3.2001.41: Kaplan-Meier Plot of Time to first TEAE - Vomiting (PT) - Safety Analysis Set



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: 08SEP23

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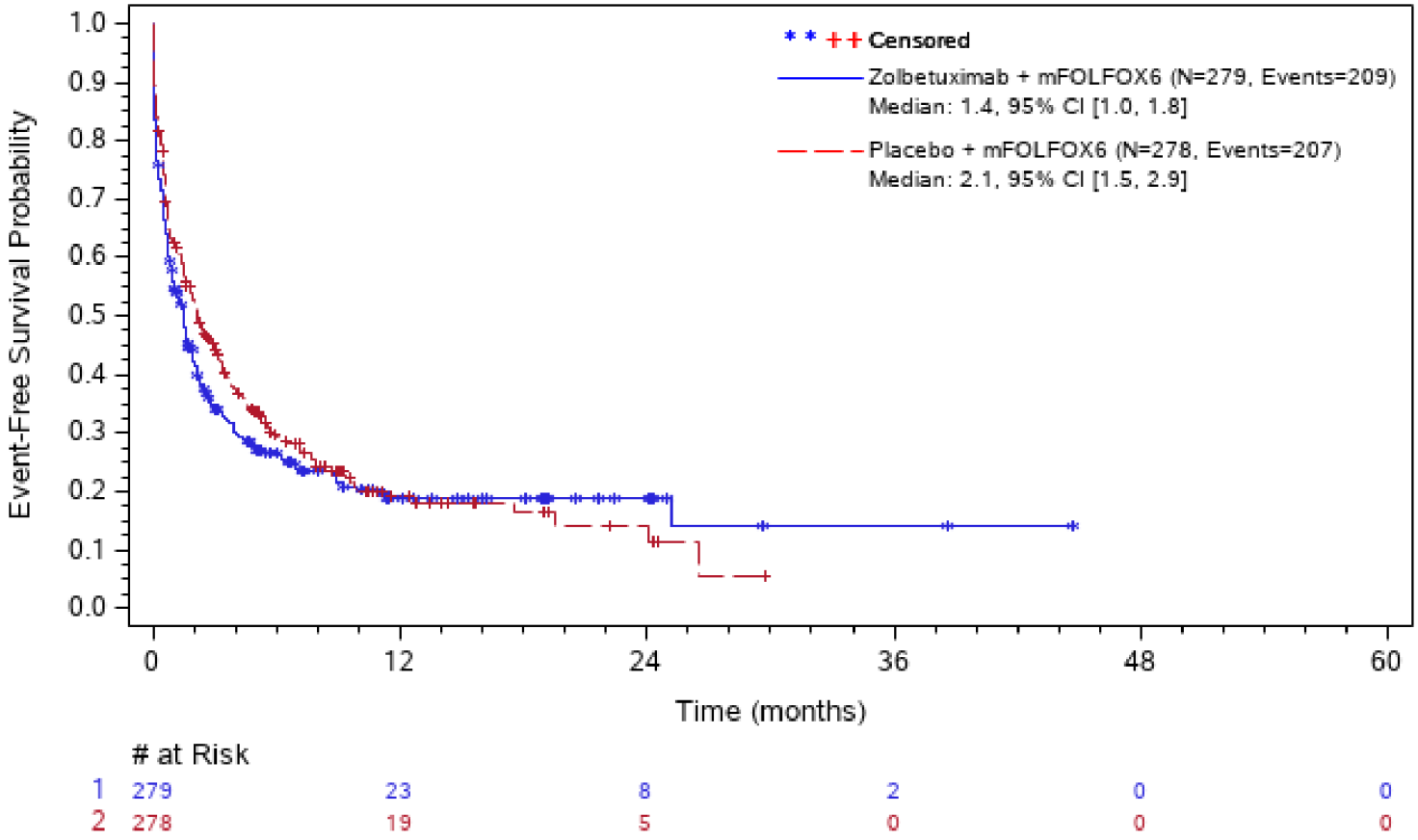
Figure 301.3.2001.42: Kaplan-Meier Plot of Time to first TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 08SEP23

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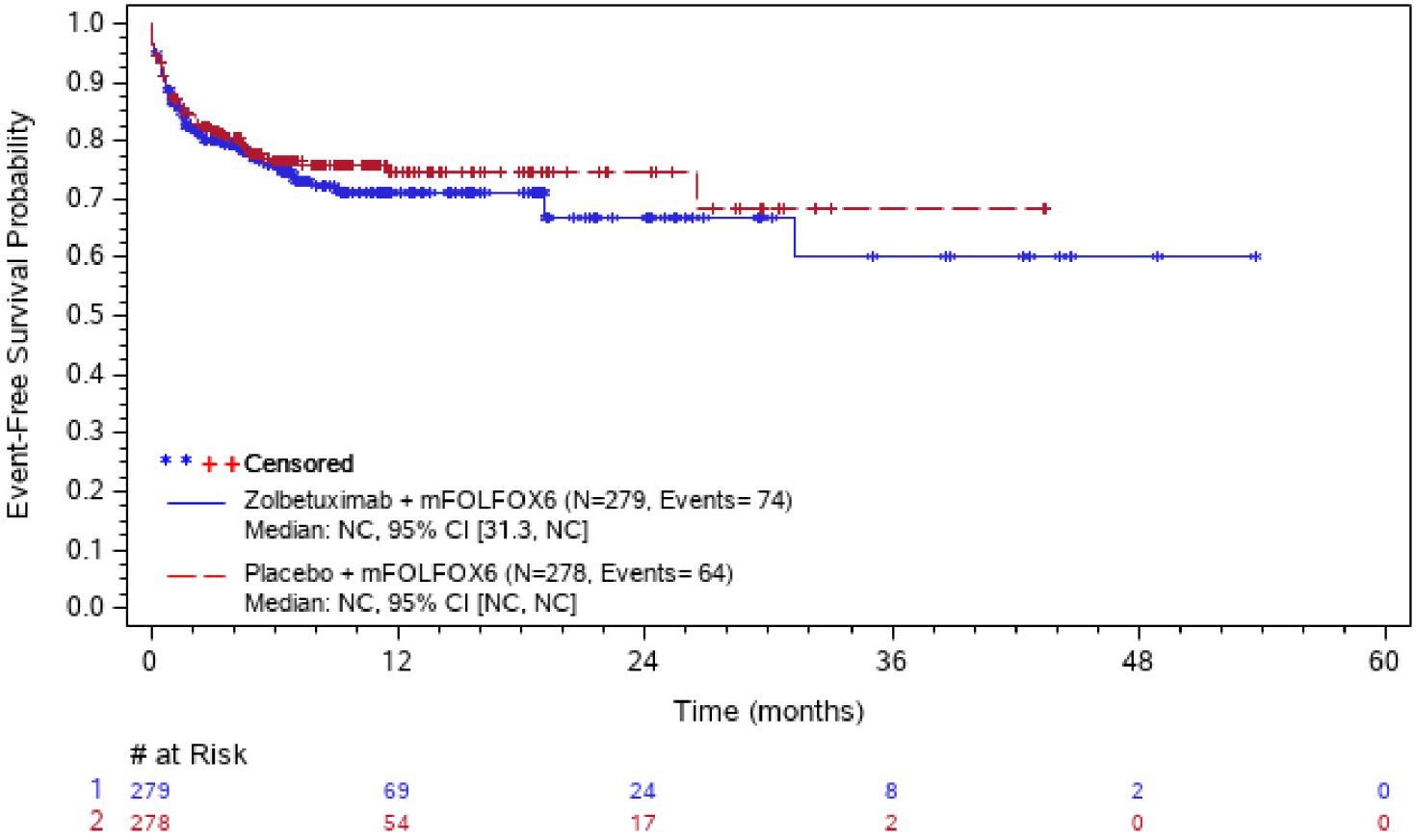
Figure 301.3.2001.43: Kaplan-Meier Plot of Time to first TEAE - Asthenia (PT) - Safety Analysis Set



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.

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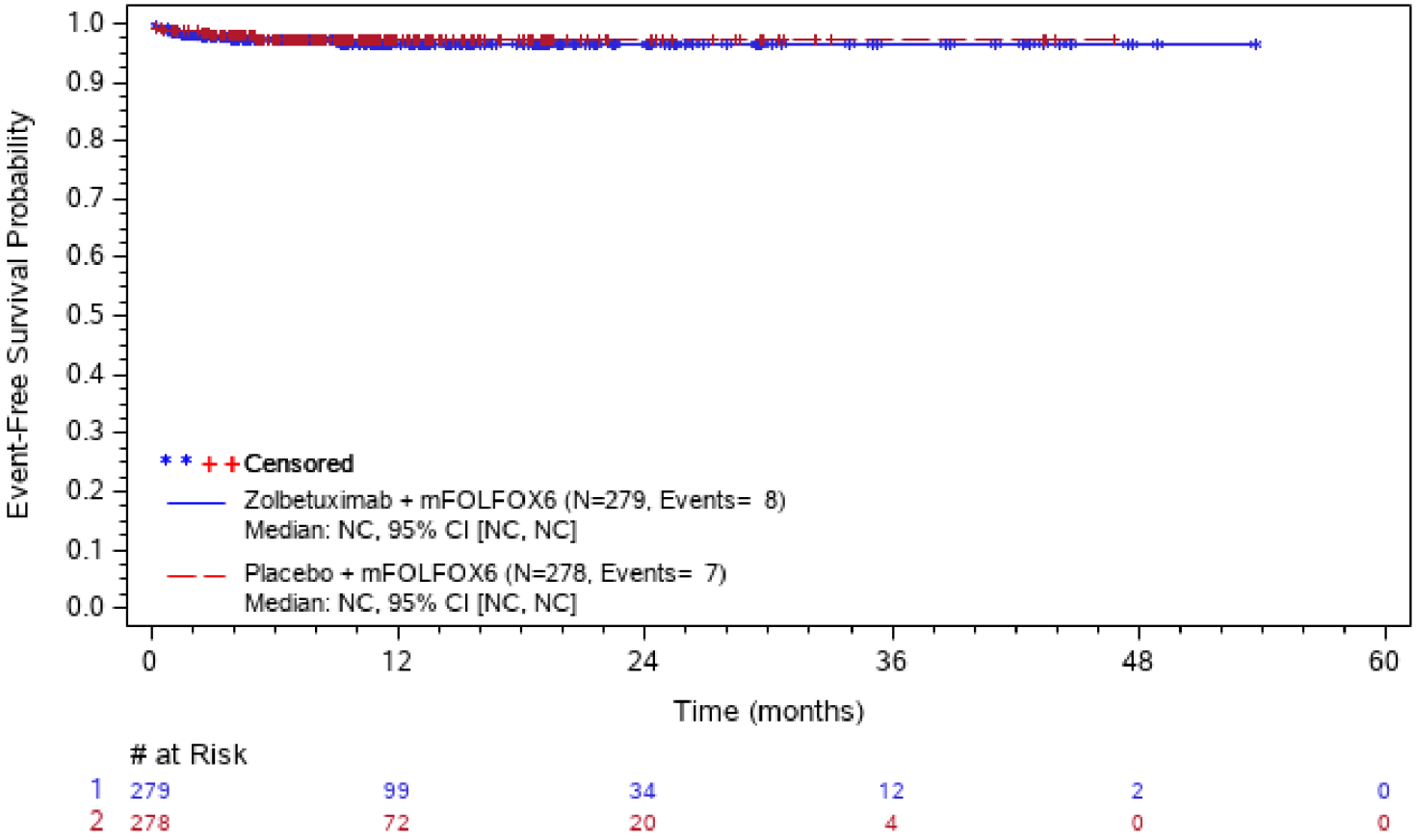
Figure 301.3.2001.44: Kaplan-Meier Plot of Time to first TEAE - Chest Discomfort (PT) - Safety Analysis Set



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.

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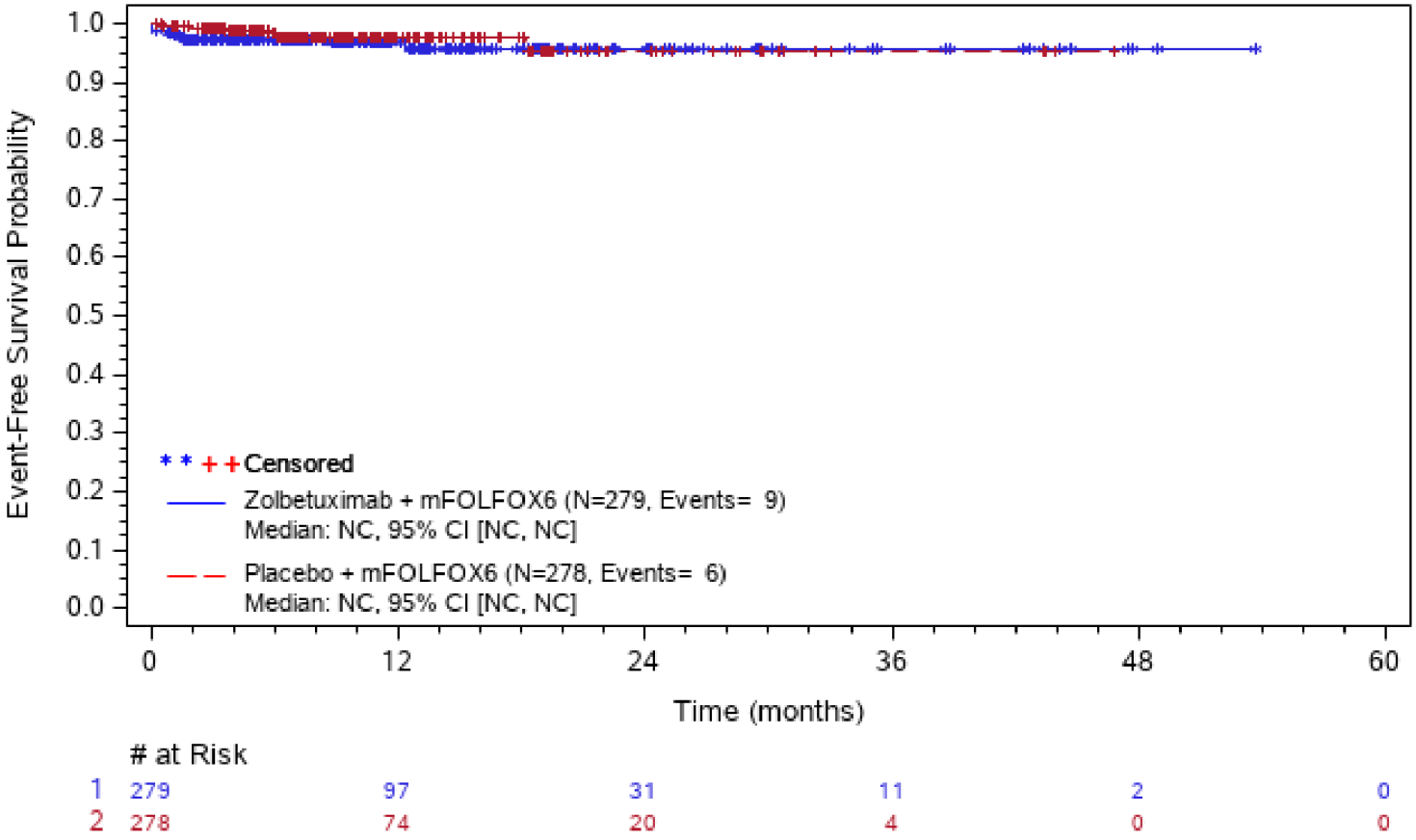
Figure 301.3.2001.45: Kaplan-Meier Plot of Time to first TEAE - Chest Pain (PT) - Safety Analysis Set



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.

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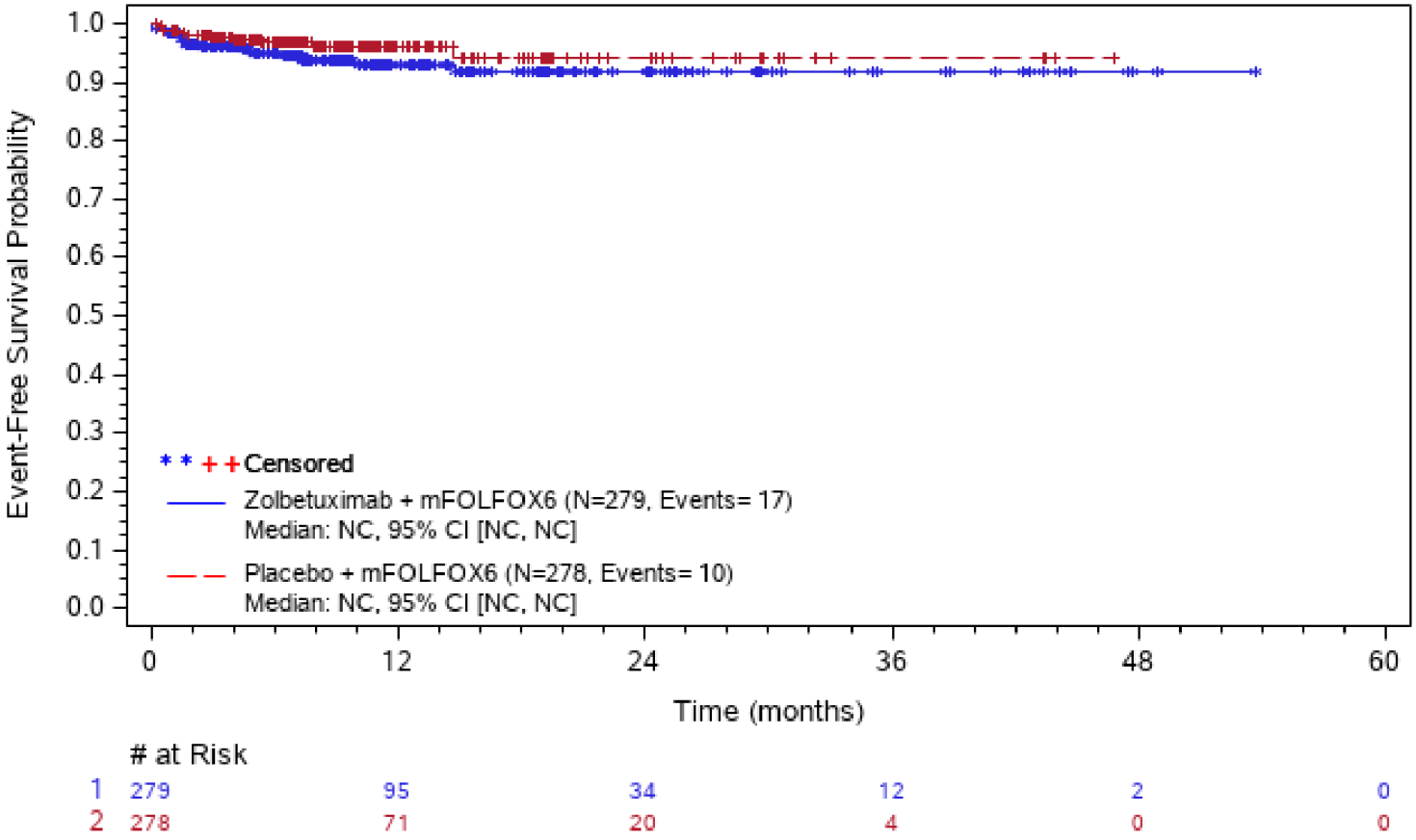
Figure 301.3.2001.46: Kaplan-Meier Plot of Time to first TEAE - Chills (PT) - Safety Analysis Set



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: 08SEP23

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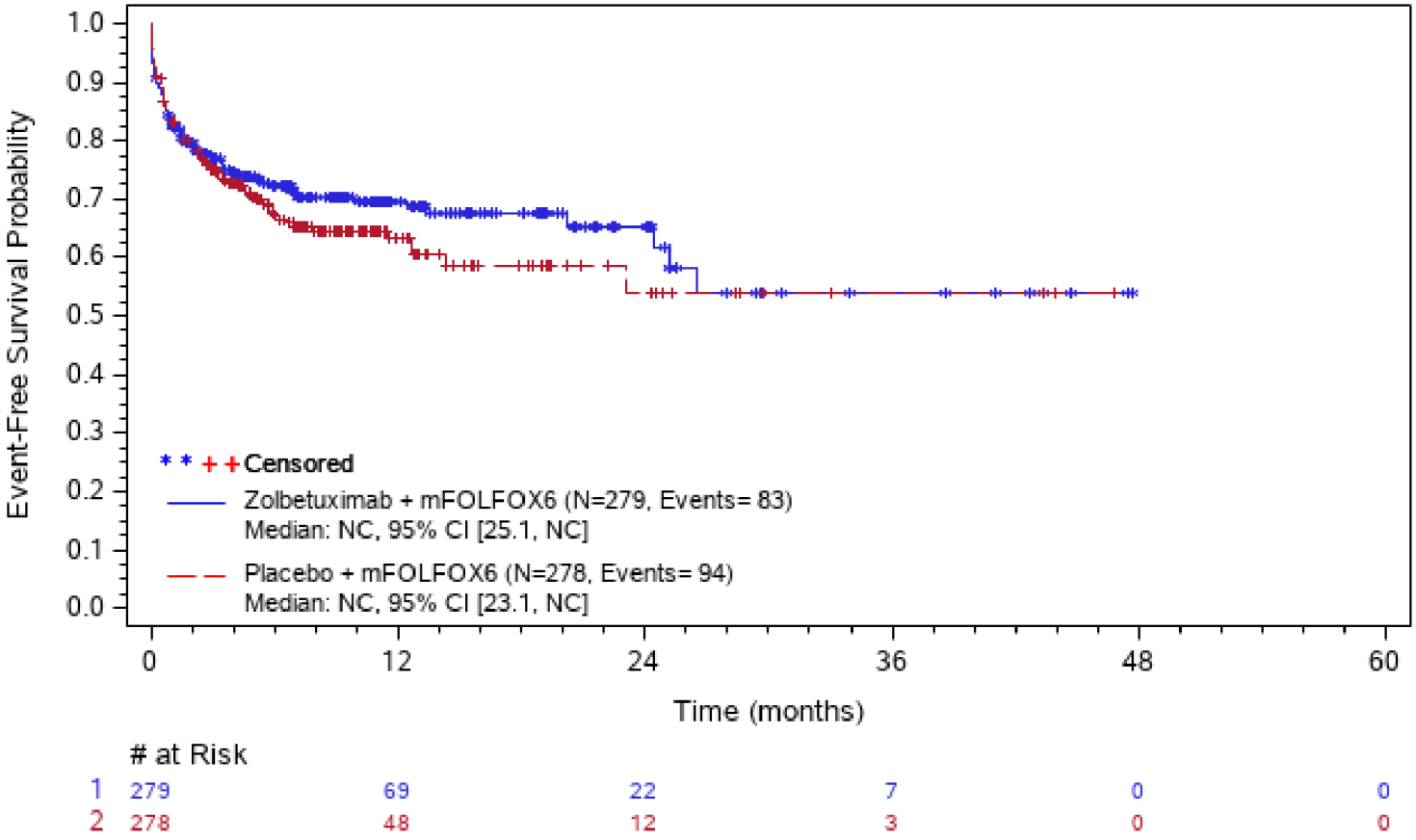
Figure 301.3.2001.47: Kaplan-Meier Plot of Time to first TEAE - Fatigue (PT) - Safety Analysis Set



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: 08SEP23

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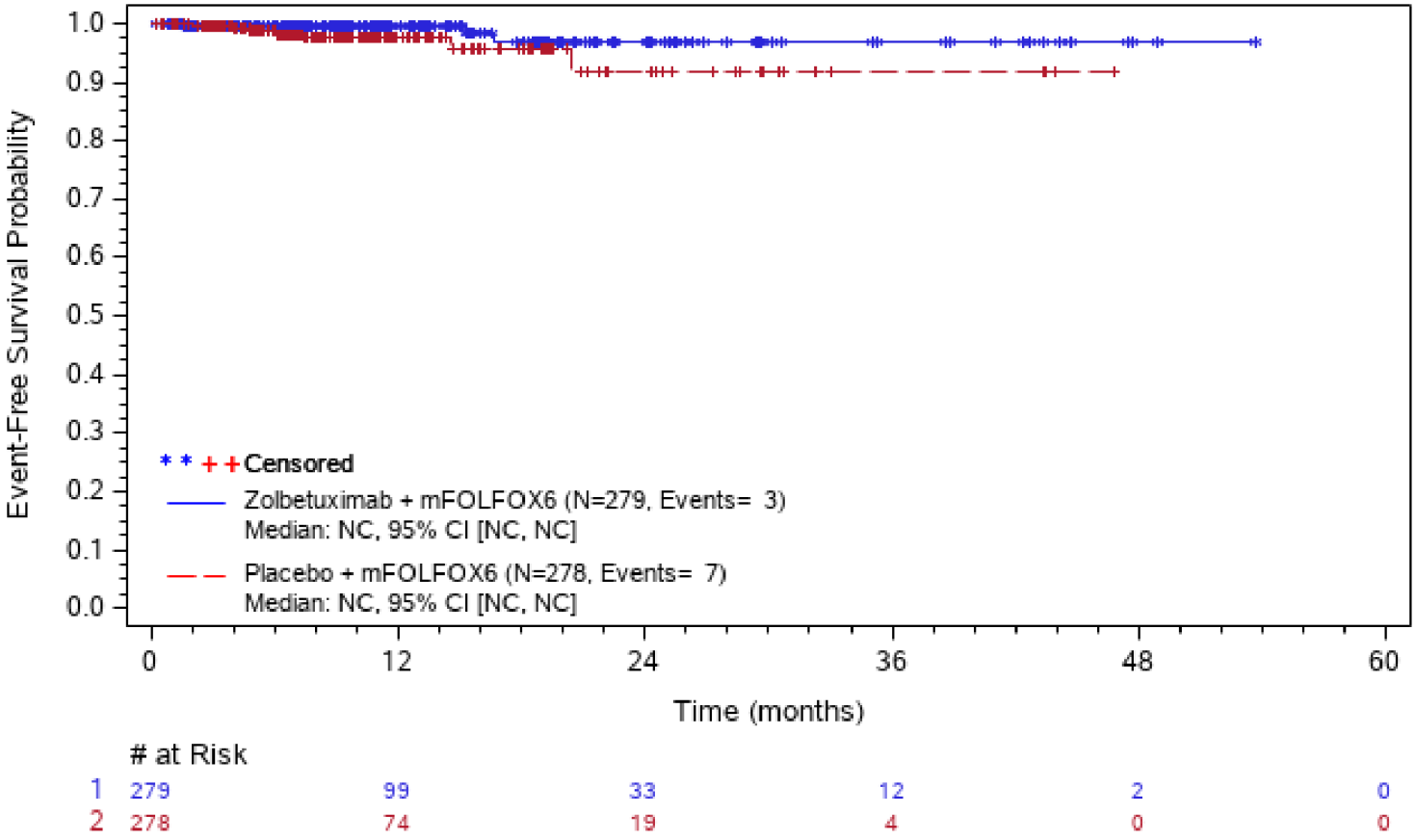
Figure 301.3.2001.48: Kaplan-Meier Plot of Time to first TEAE - General Physical Health Deterioration (PT) - Safety Analysis Set



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: 08SEP23

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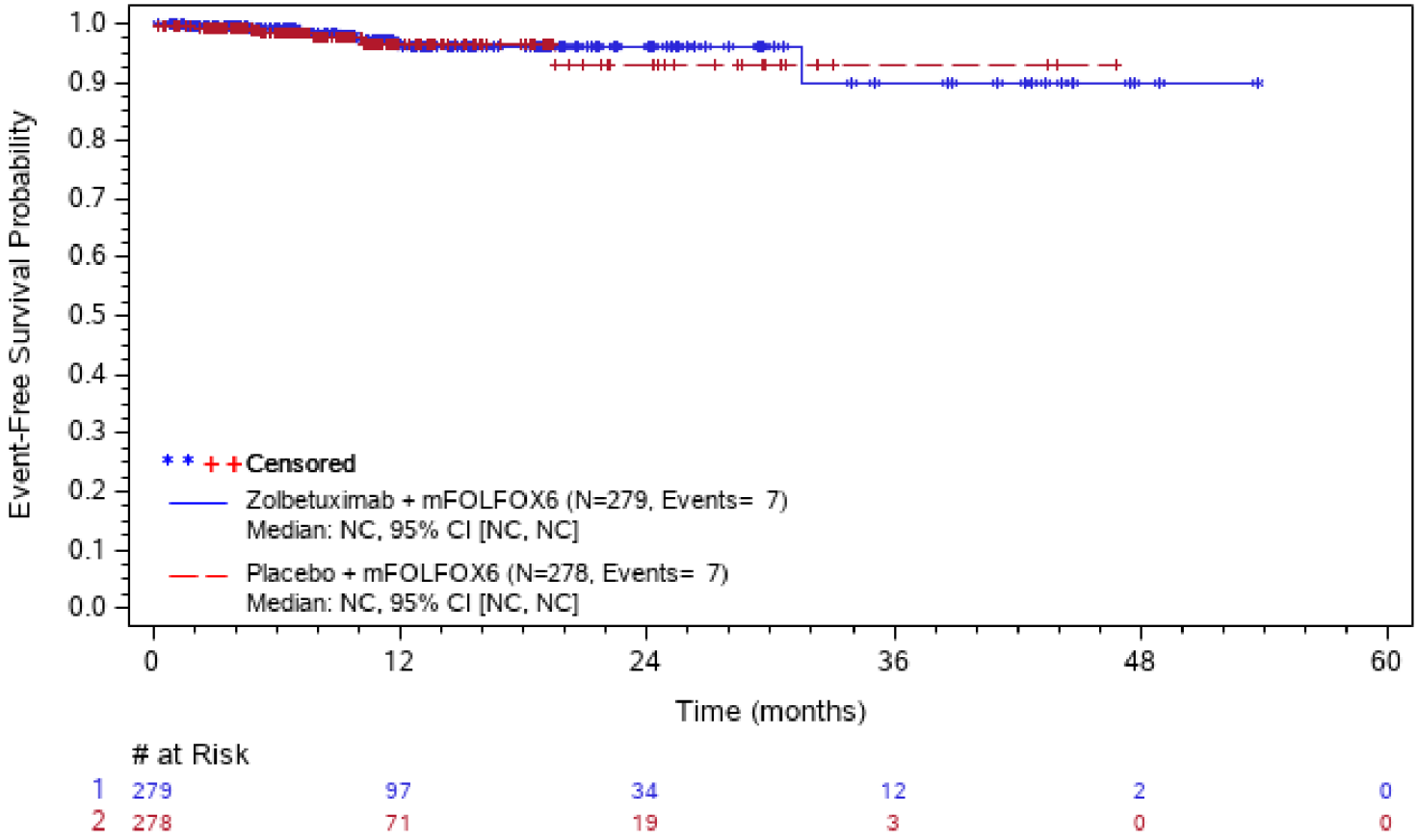
Figure 301.3.2001.49: Kaplan-Meier Plot of Time to first TEAE - Influenza Like Illness (PT) - Safety Analysis Set



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: 08SEP23

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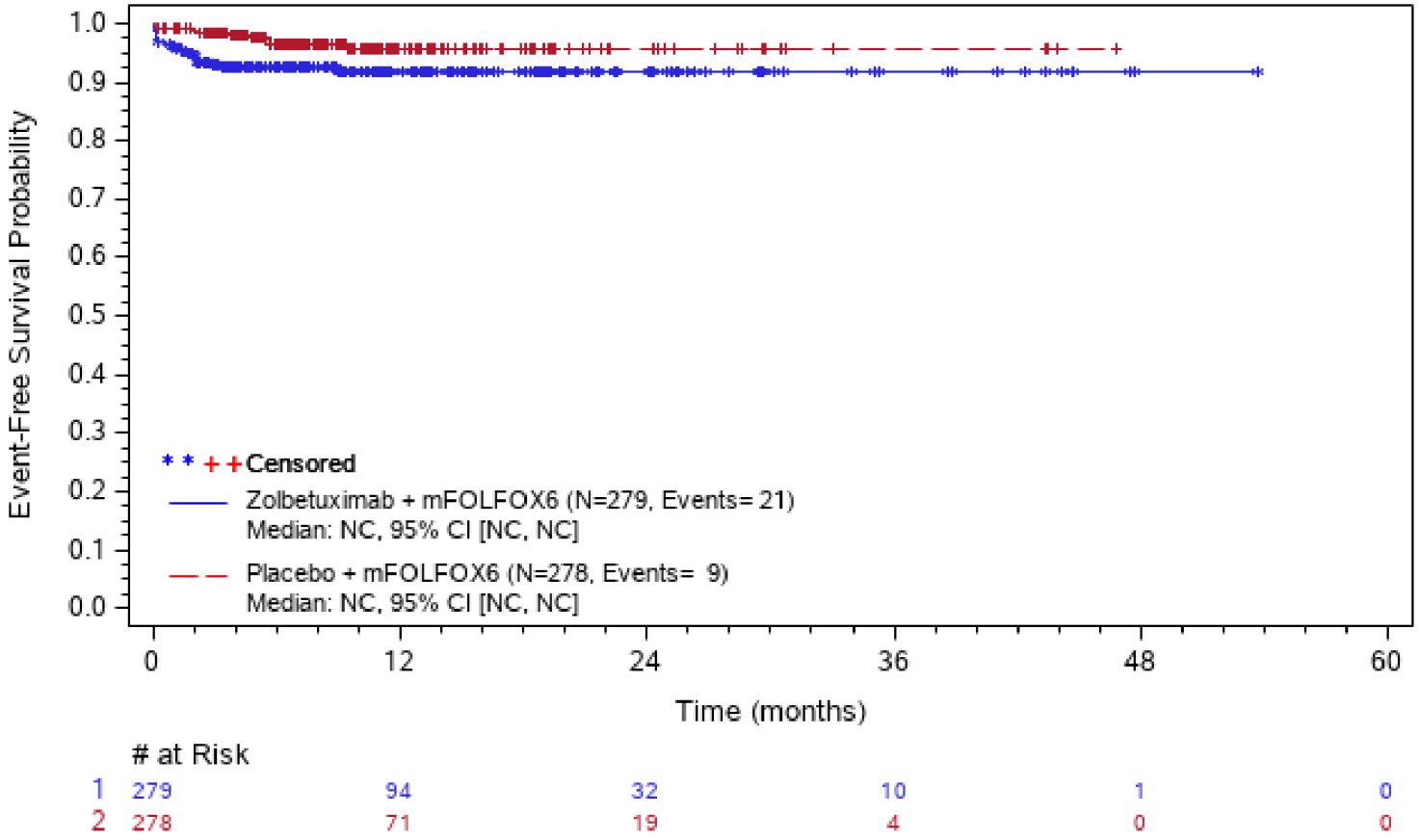
Figure 301.3.2001.50: Kaplan-Meier Plot of Time to first TEAE - Malaise (PT) - Safety Analysis Set



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: 08SEP23

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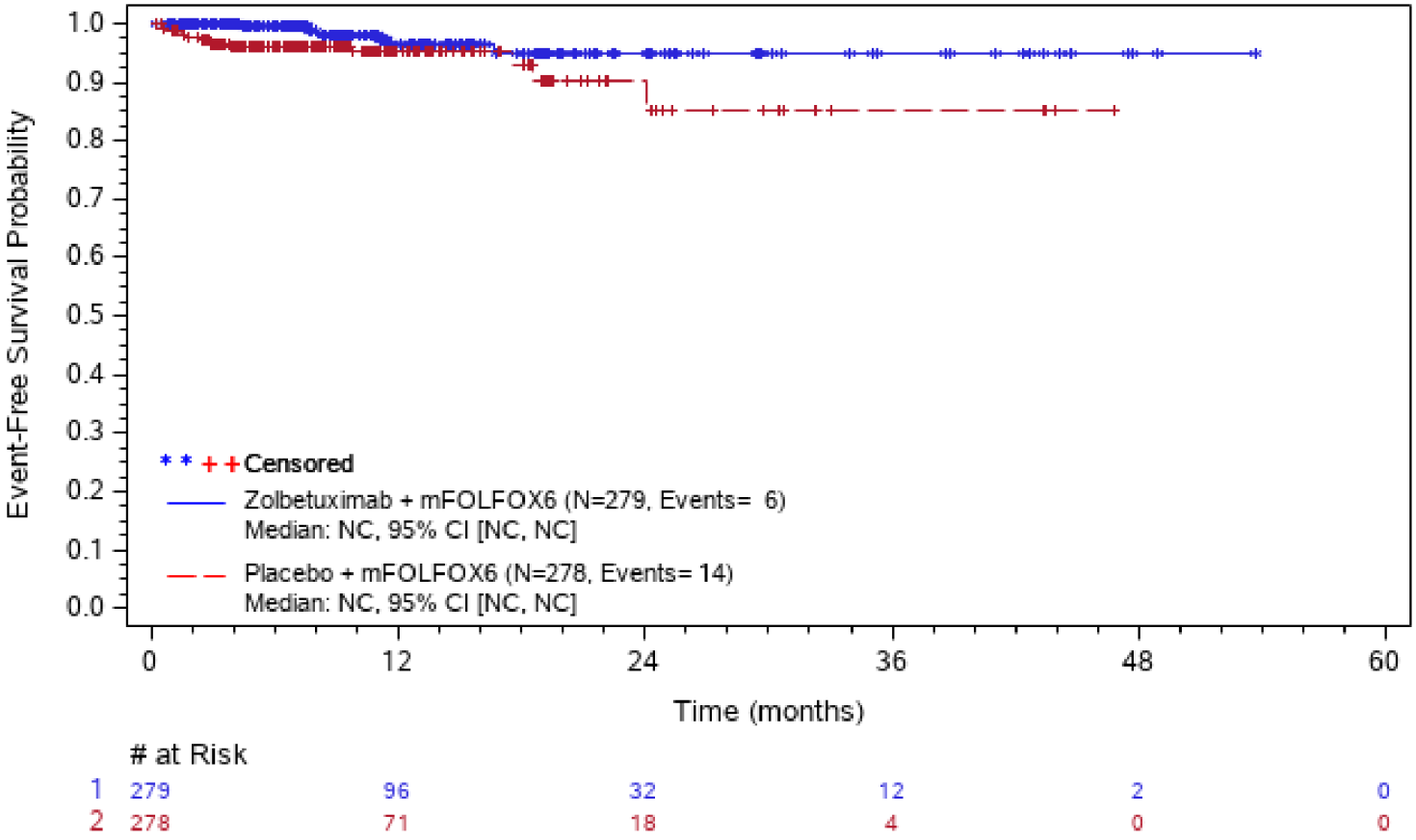
Figure 301.3.2001.51: Kaplan-Meier Plot of Time to first TEAE - Mucosal Inflammation (PT) - Safety Analysis Set



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.

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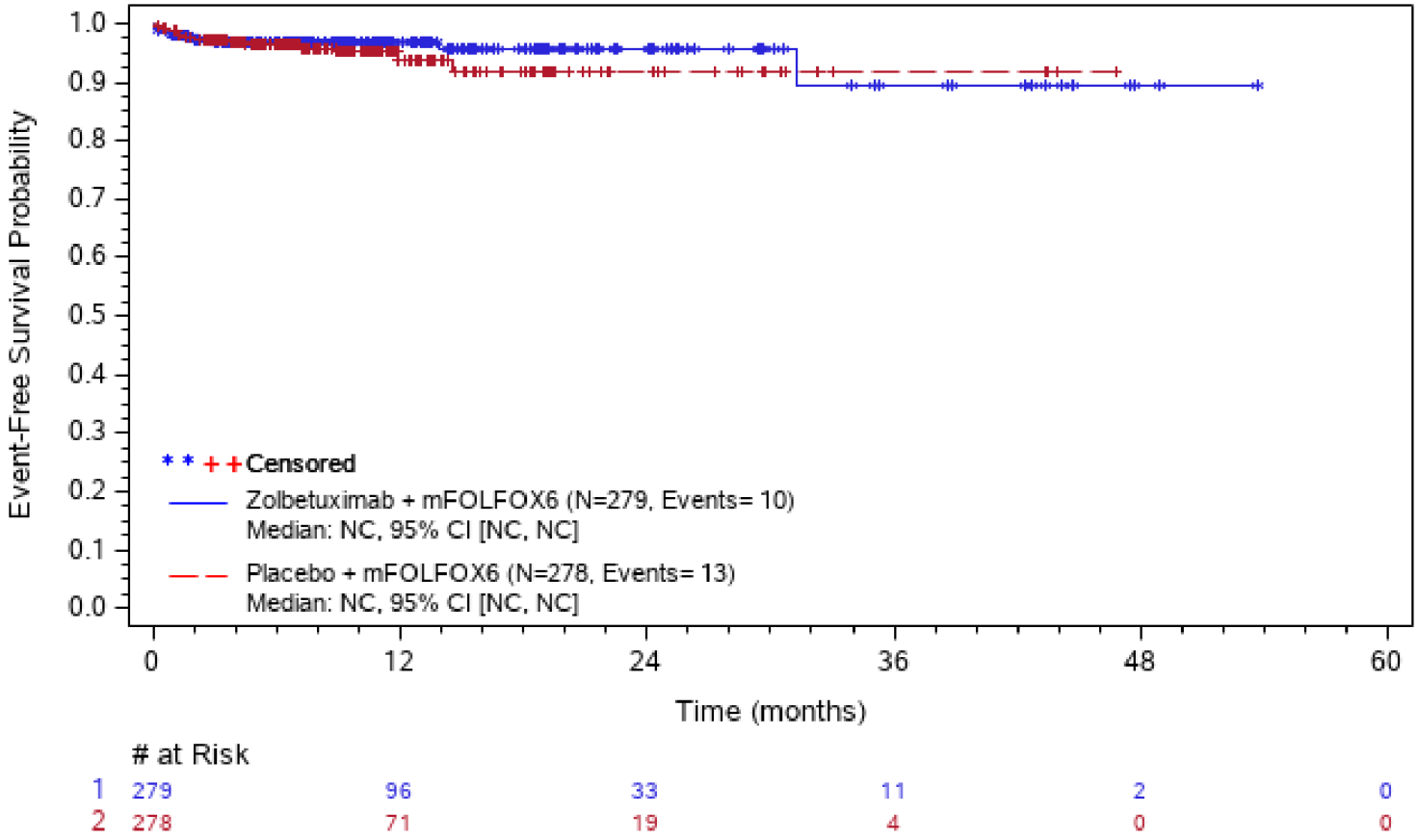
Figure 301.3.2001.52: Kaplan-Meier Plot of Time to first TEAE - Non-Cardiac Chest Pain (PT) - Safety Analysis Set



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: 08SEP23

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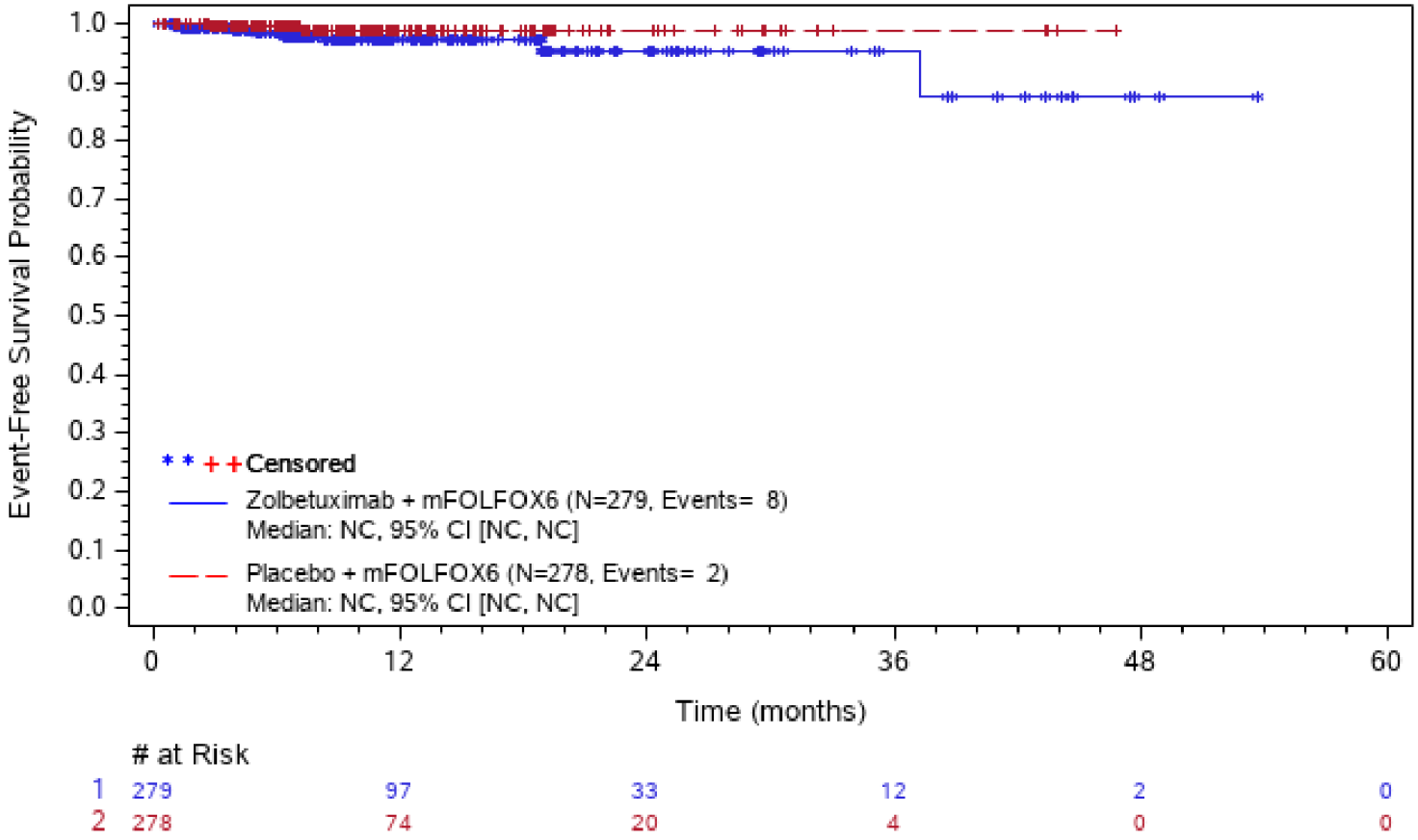
Figure 301.3.2001.53: Kaplan-Meier Plot of Time to first TEAE - Oedema (PT) - Safety Analysis Set

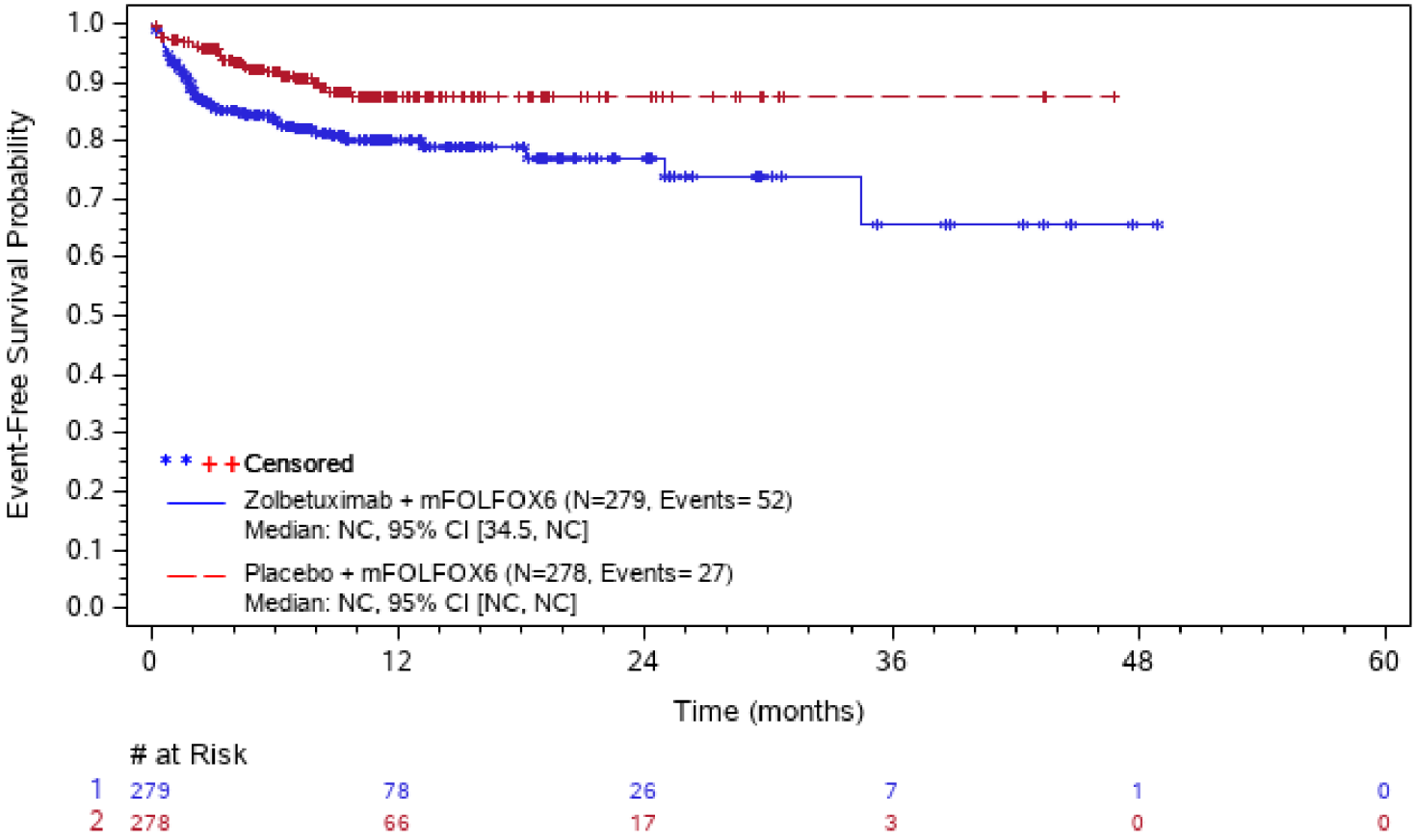


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.54: 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.

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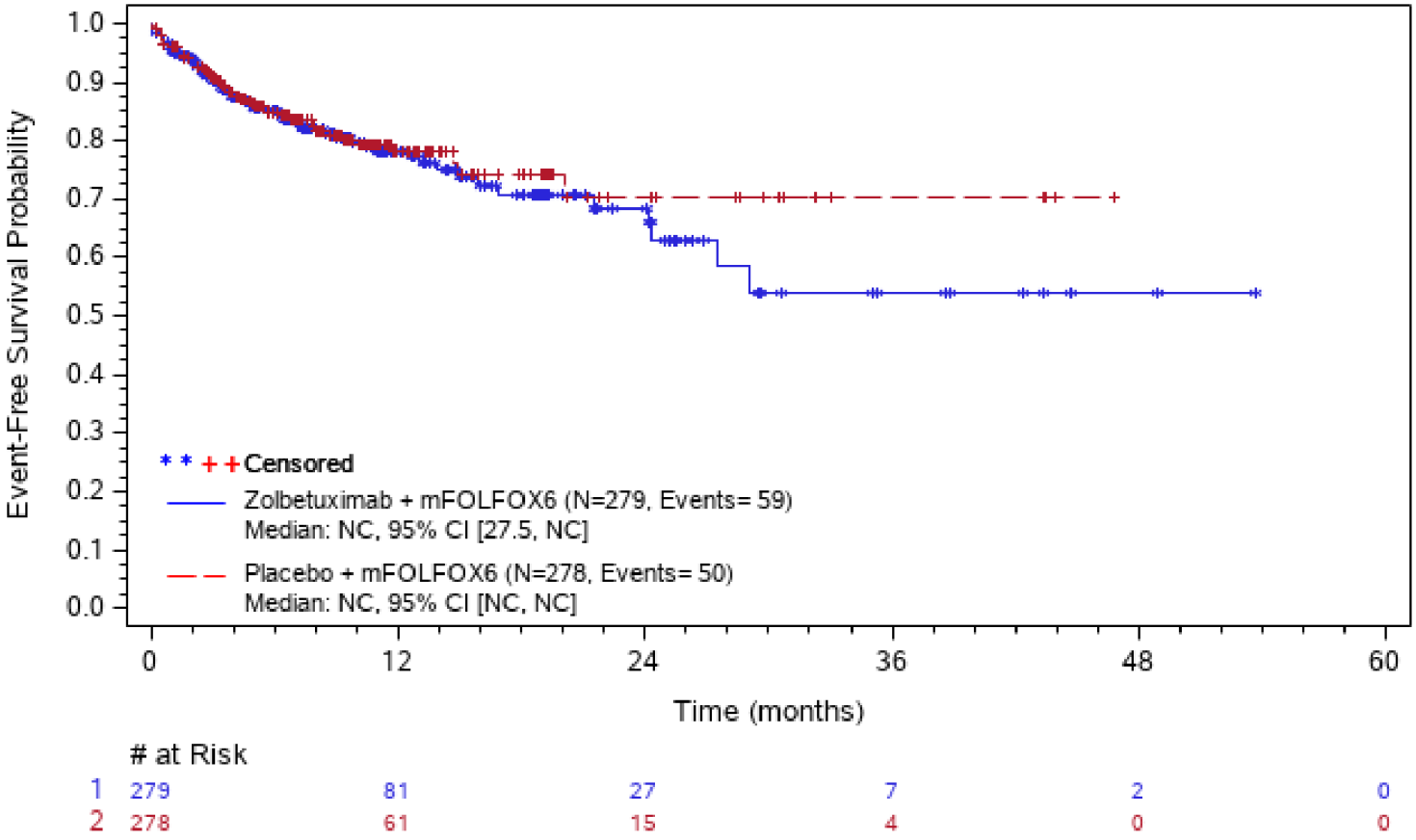
Figure 301.3.2001.55: Kaplan-Meier Plot of Time to first TEAE - Pyrexia (PT) - Safety Analysis Set



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: 08SEP23

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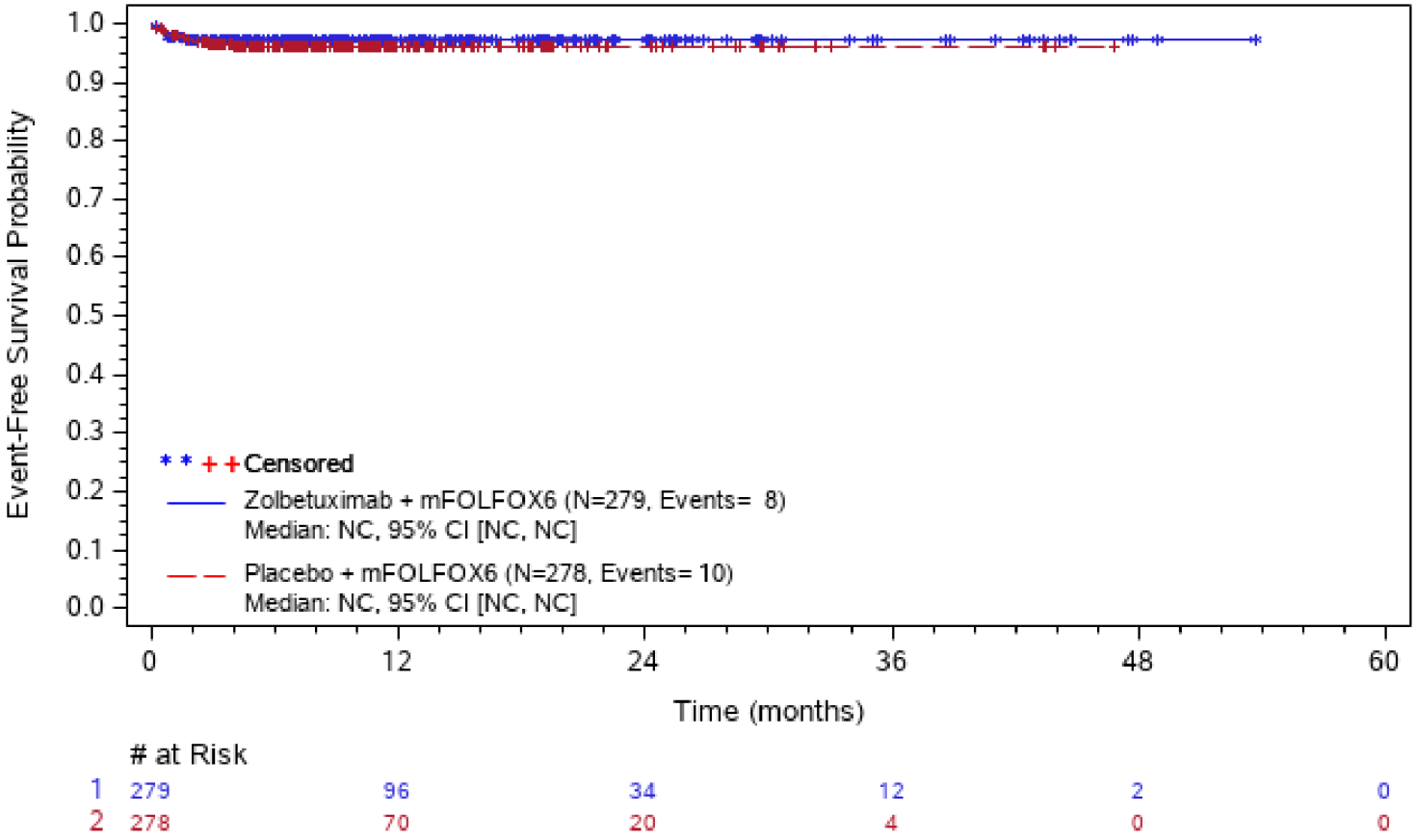
Figure 301.3.2001.56: Kaplan-Meier Plot of Time to first TEAE - Temperature Intolerance (PT) - Safety Analysis Set



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.

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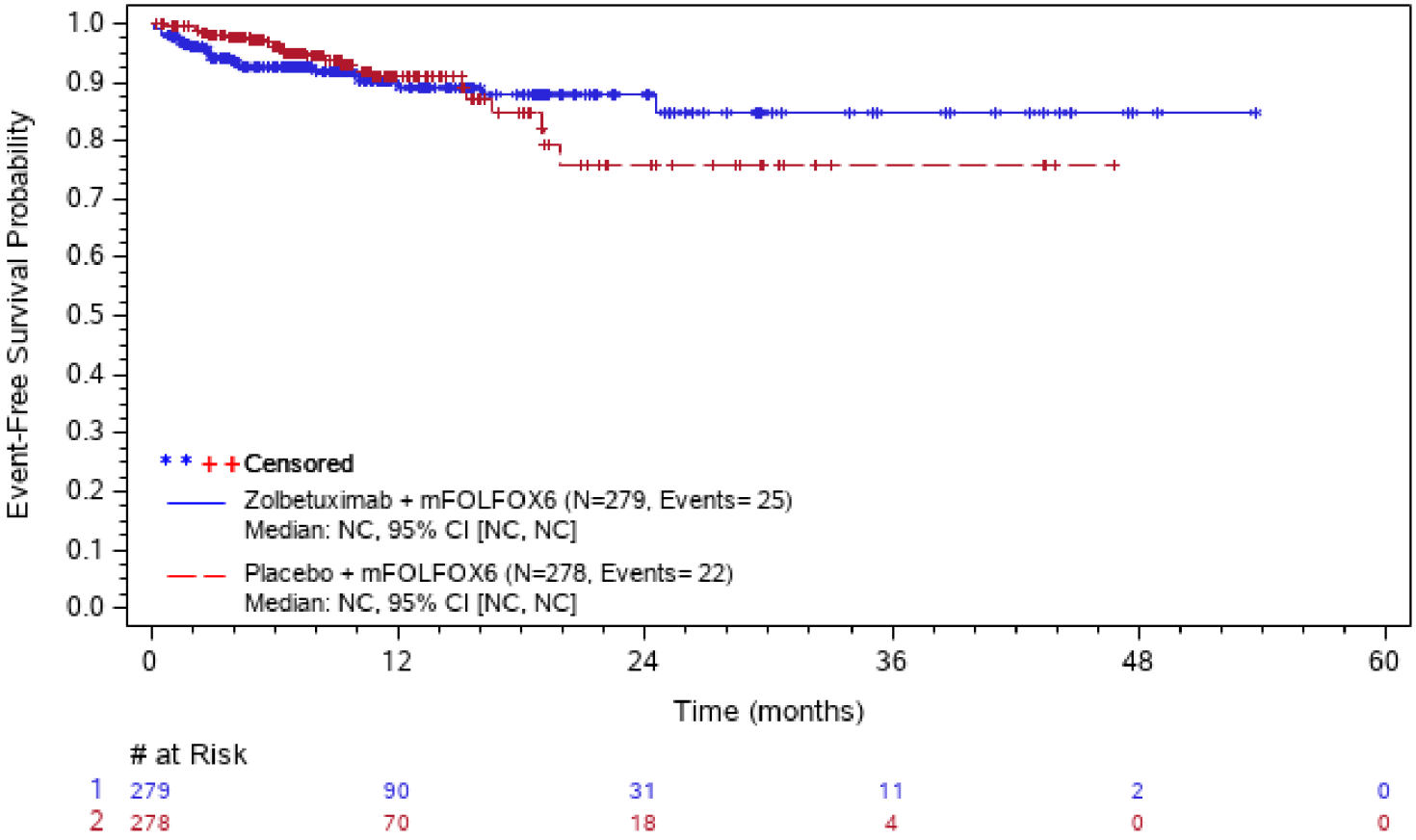
Figure 301.3.2001.57: Kaplan-Meier Plot of Time to first TEAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set



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.

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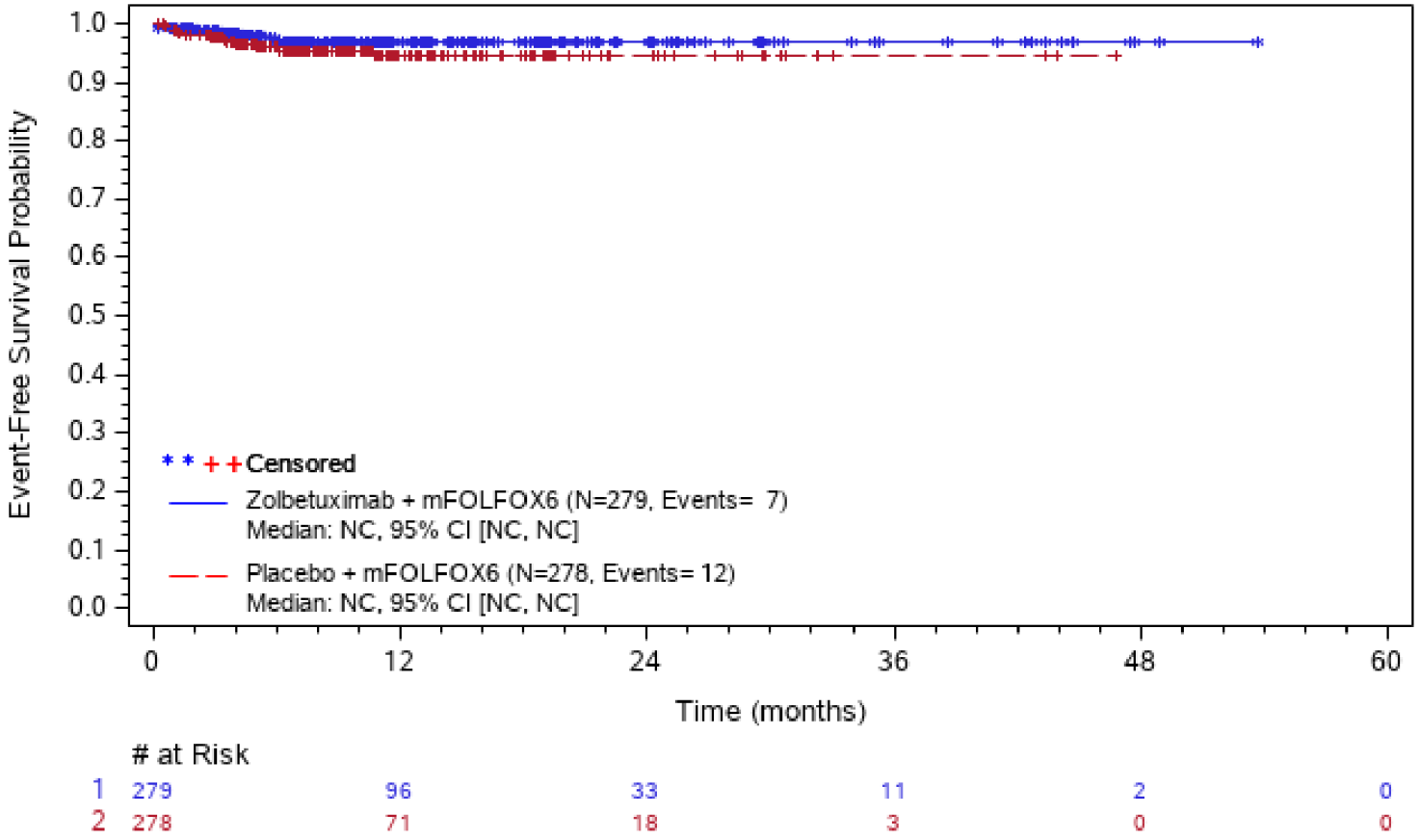
Figure 301.3.2001.58: Kaplan-Meier Plot of Time to first TEAE - Immune System Disorders (SOC) - Safety Analysis Set



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: 08SEP23

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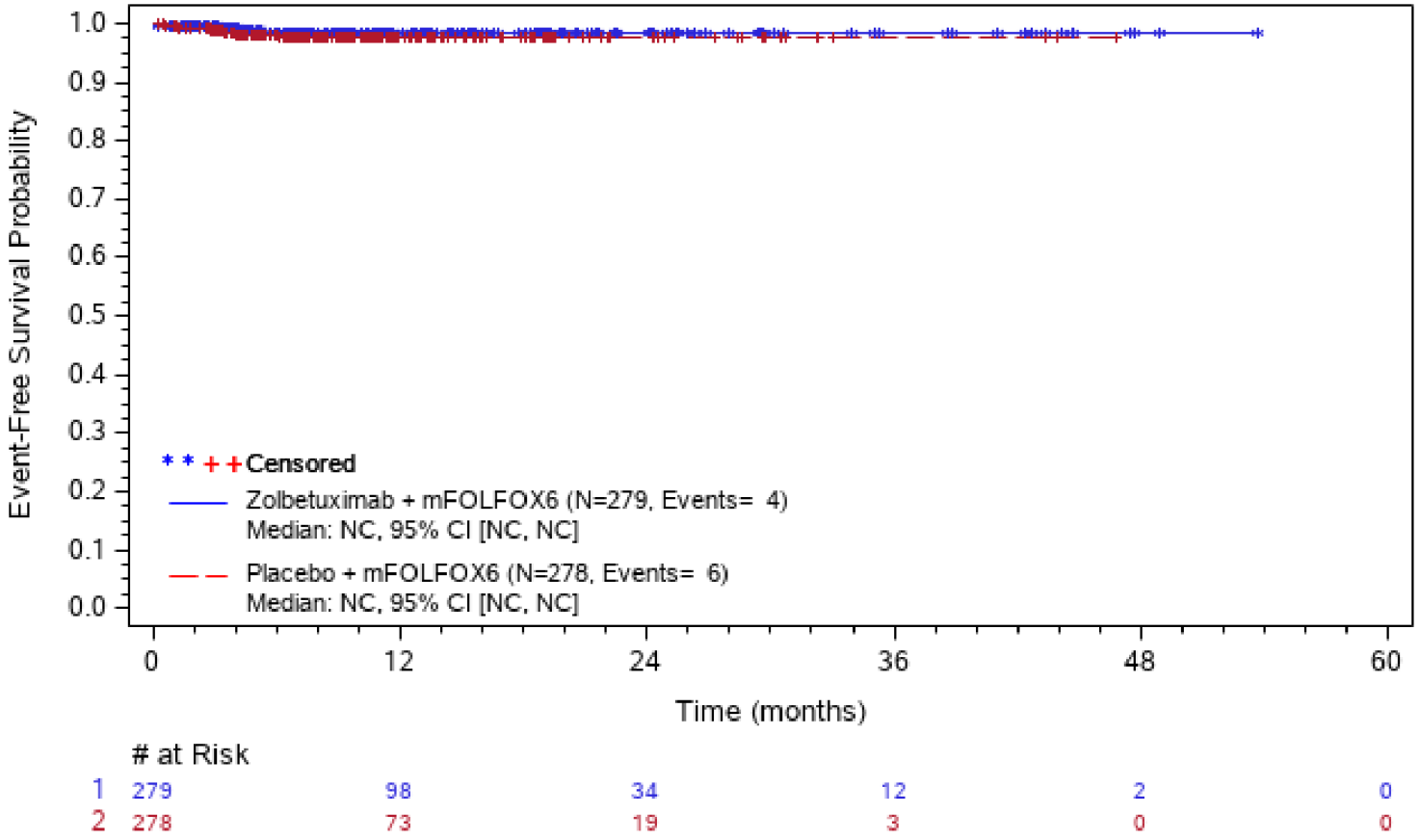
Figure 301.3.2001.59: Kaplan-Meier Plot of Time to first TEAE - Drug Hypersensitivity (PT) - Safety Analysis Set



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: 08SEP23

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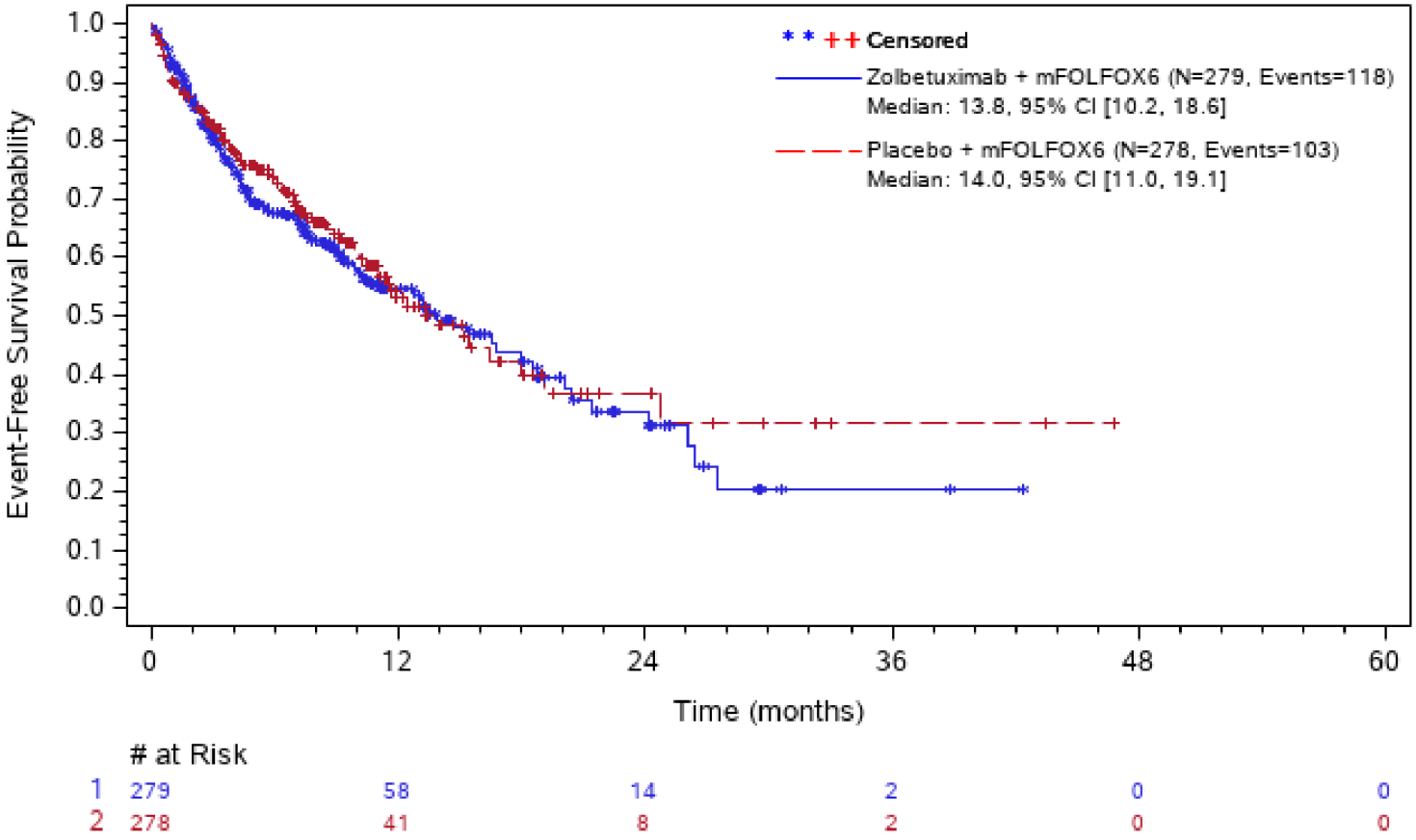
Figure 301.3.2001.60: Kaplan-Meier Plot of Time to first TEAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 08SEP23

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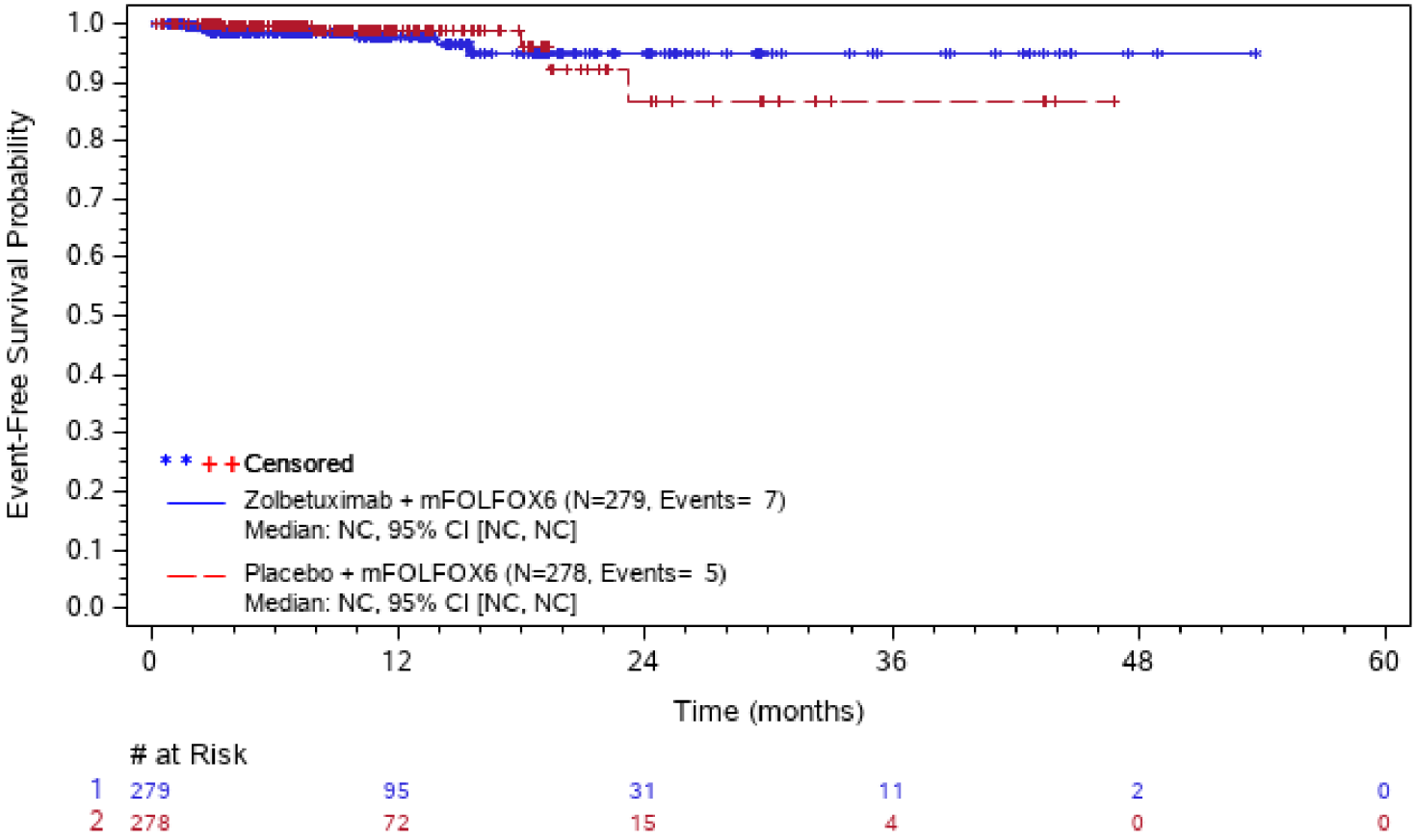
Figure 301.3.2001.61: Kaplan-Meier Plot of Time to first TEAE - Conjunctivitis (PT) - Safety Analysis Set



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: 08SEP23

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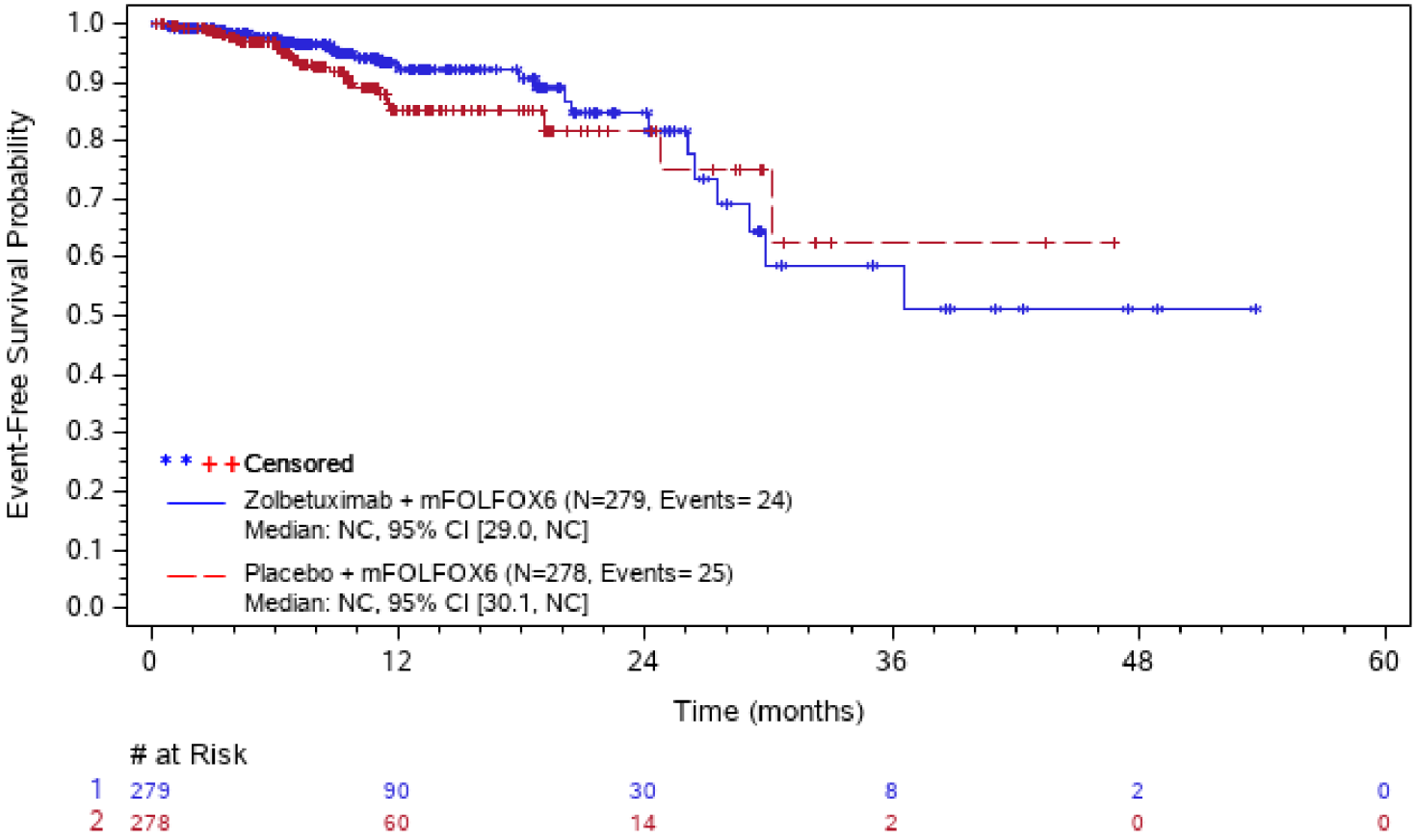
Figure 301.3.2001.62: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set



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.

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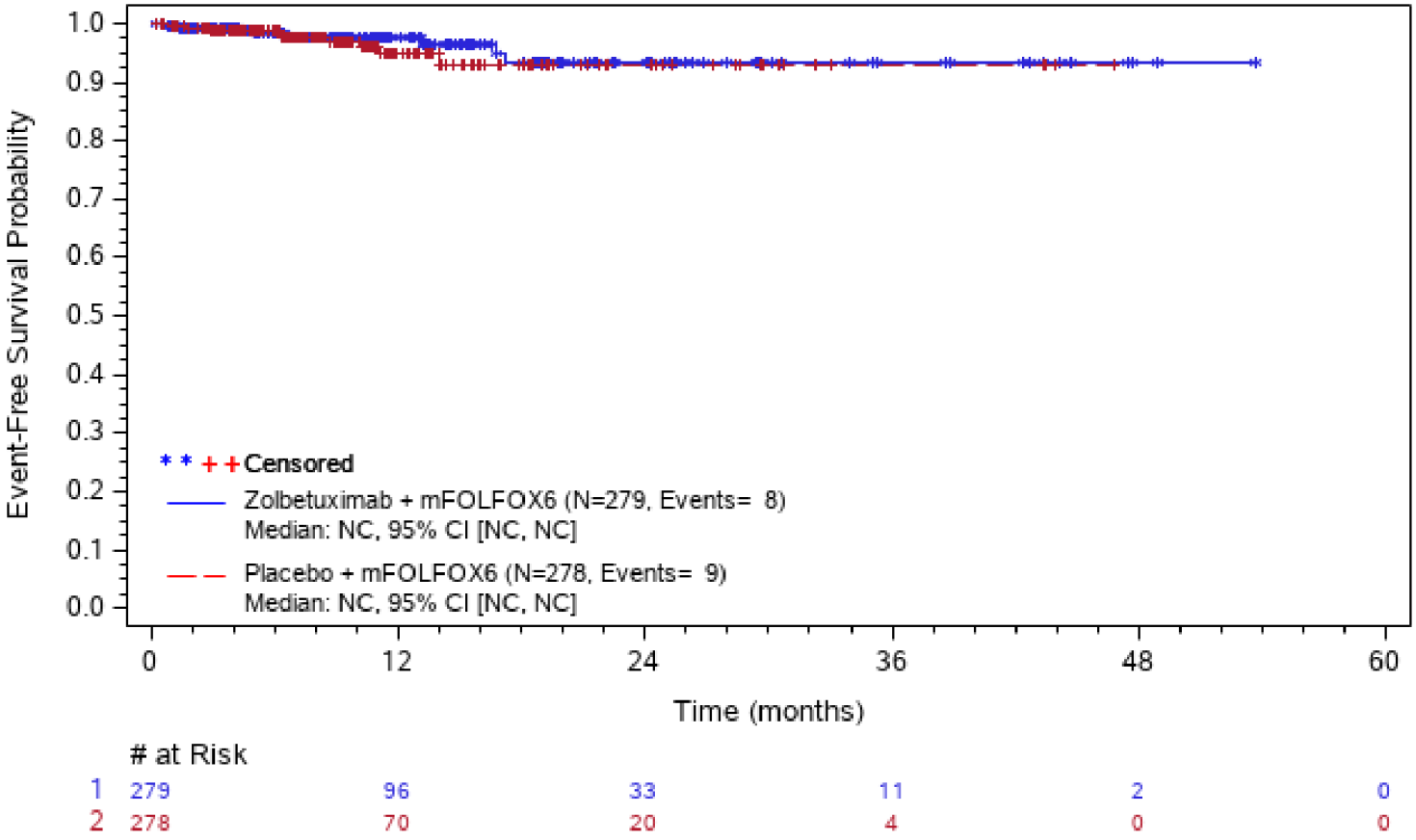
Figure 301.3.2001.63: Kaplan-Meier Plot of Time to first TEAE - Covid-19 (PT) - Safety Analysis Set

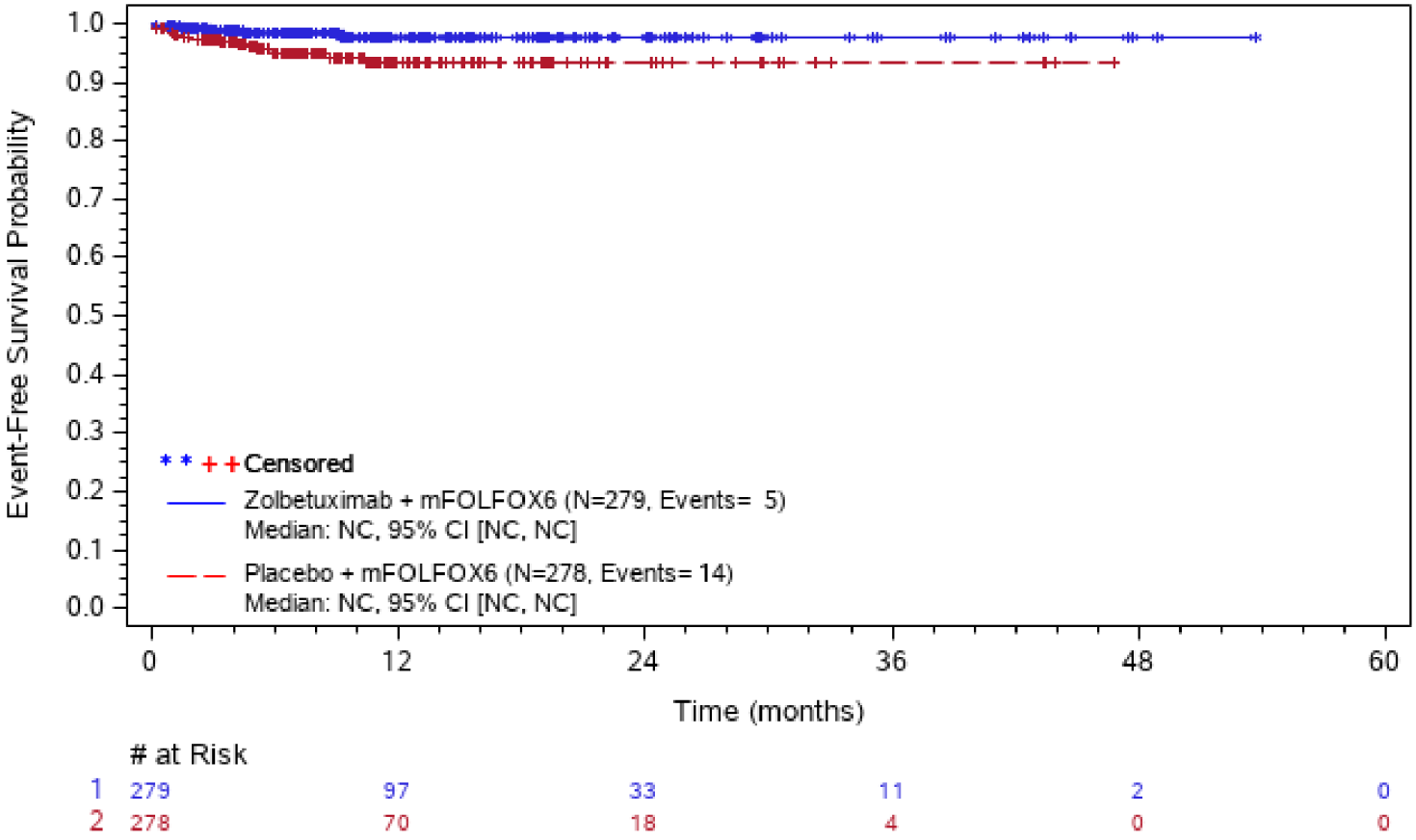


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.64: Kaplan-Meier Plot of Time to first TEAE - Oral Candidiasis (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: 08SEP23

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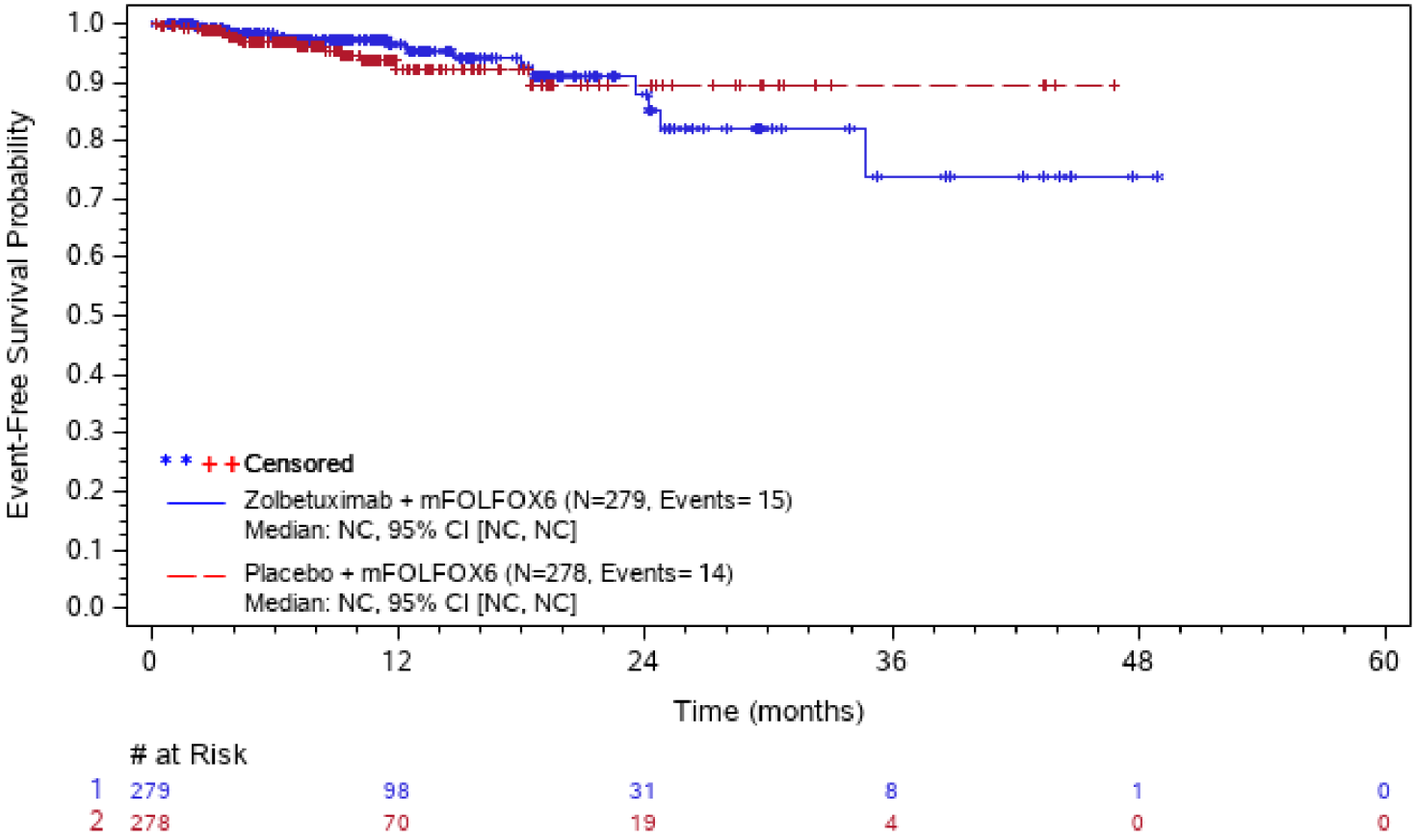
Figure 301.3.2001.65: Kaplan-Meier Plot of Time to first TEAE - Pneumonia (PT) - Safety Analysis Set



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: 08SEP23

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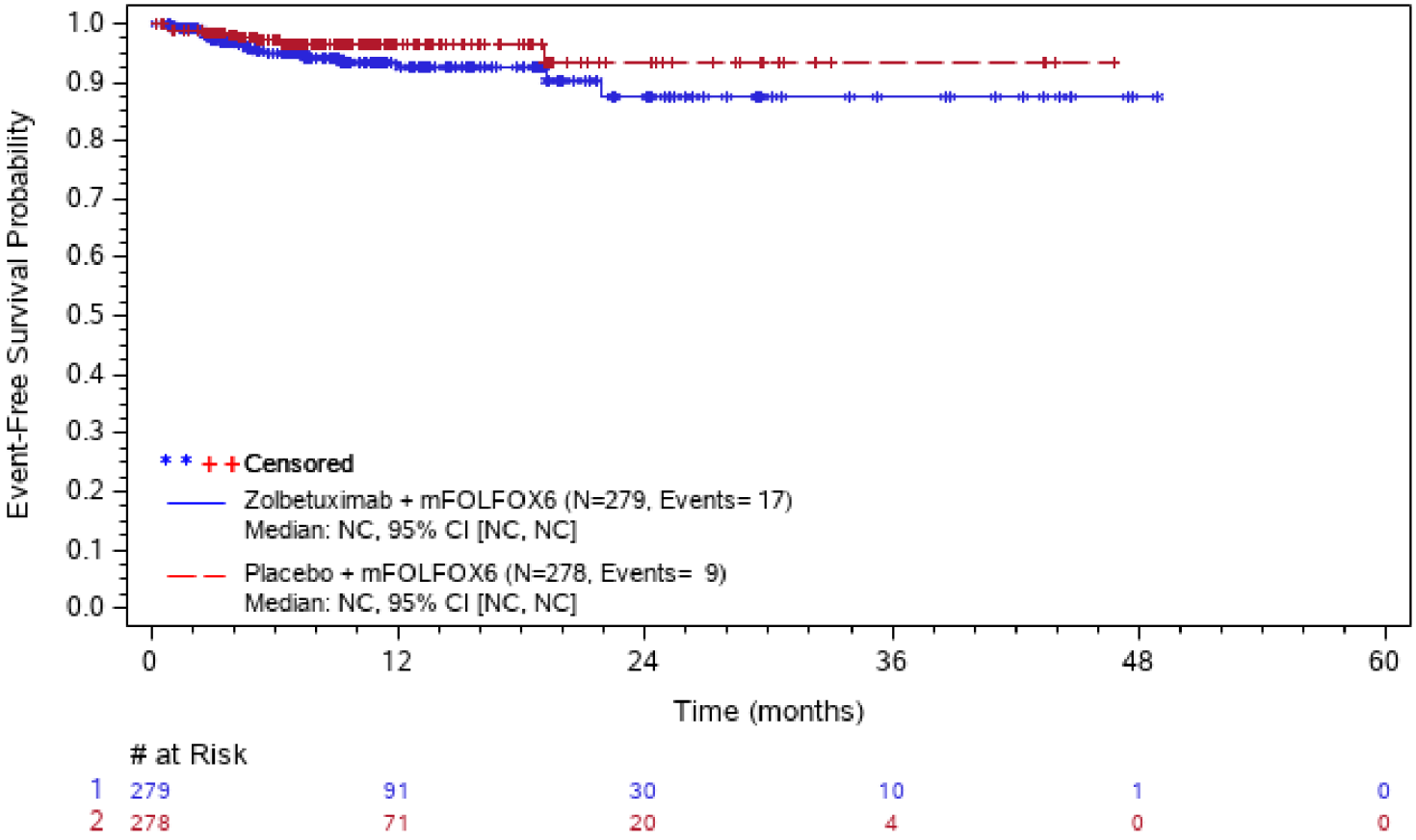
Figure 301.3.2001.66: Kaplan-Meier Plot of Time to first TEAE - Urinary Tract Infection (PT) - Safety Analysis Set



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: 08SEP23

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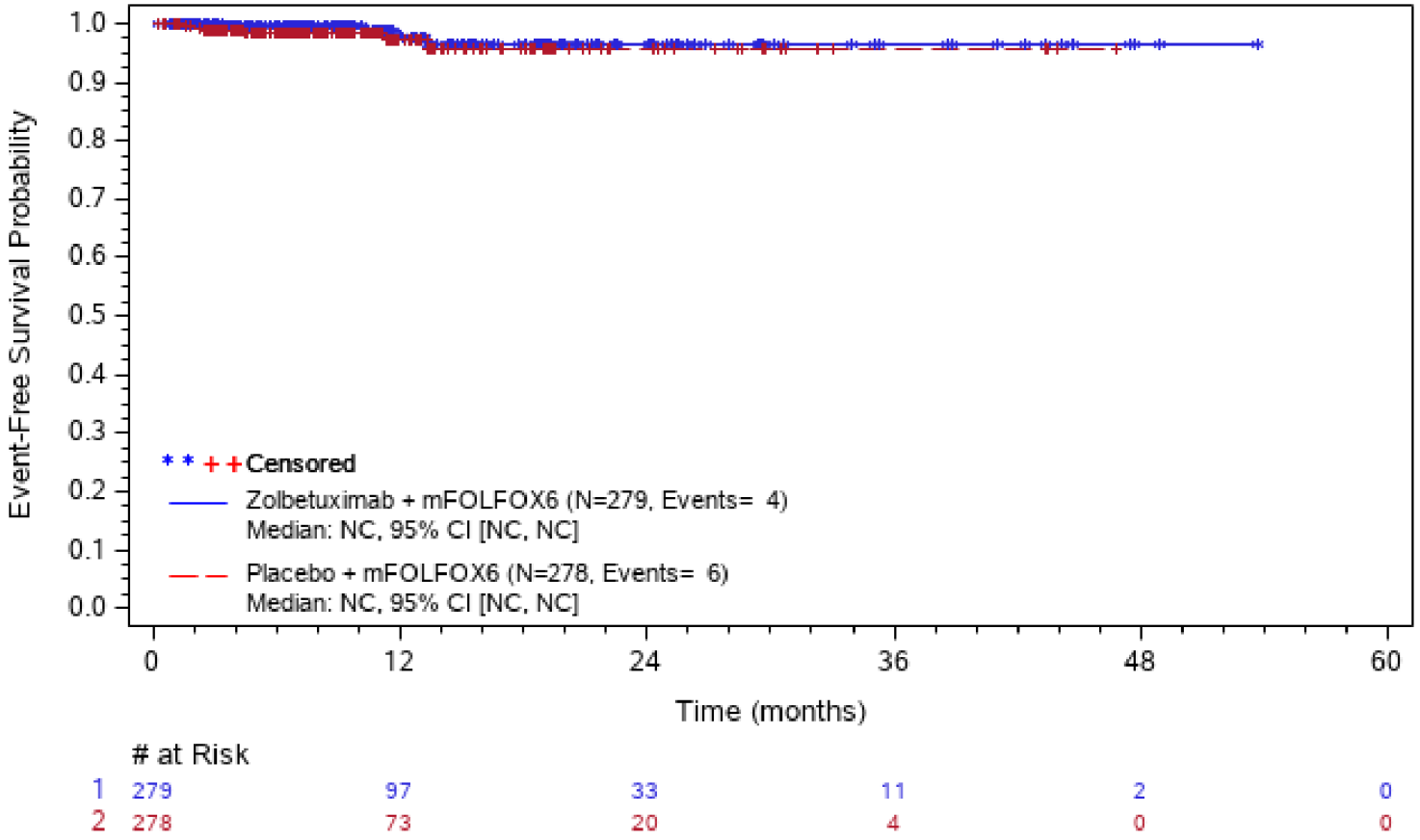
Figure 301.3.2001.67: Kaplan-Meier Plot of Time to first TEAE - Urinary Tract Infection Bacterial (PT) - Safety Analysis Set



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: 08SEP23

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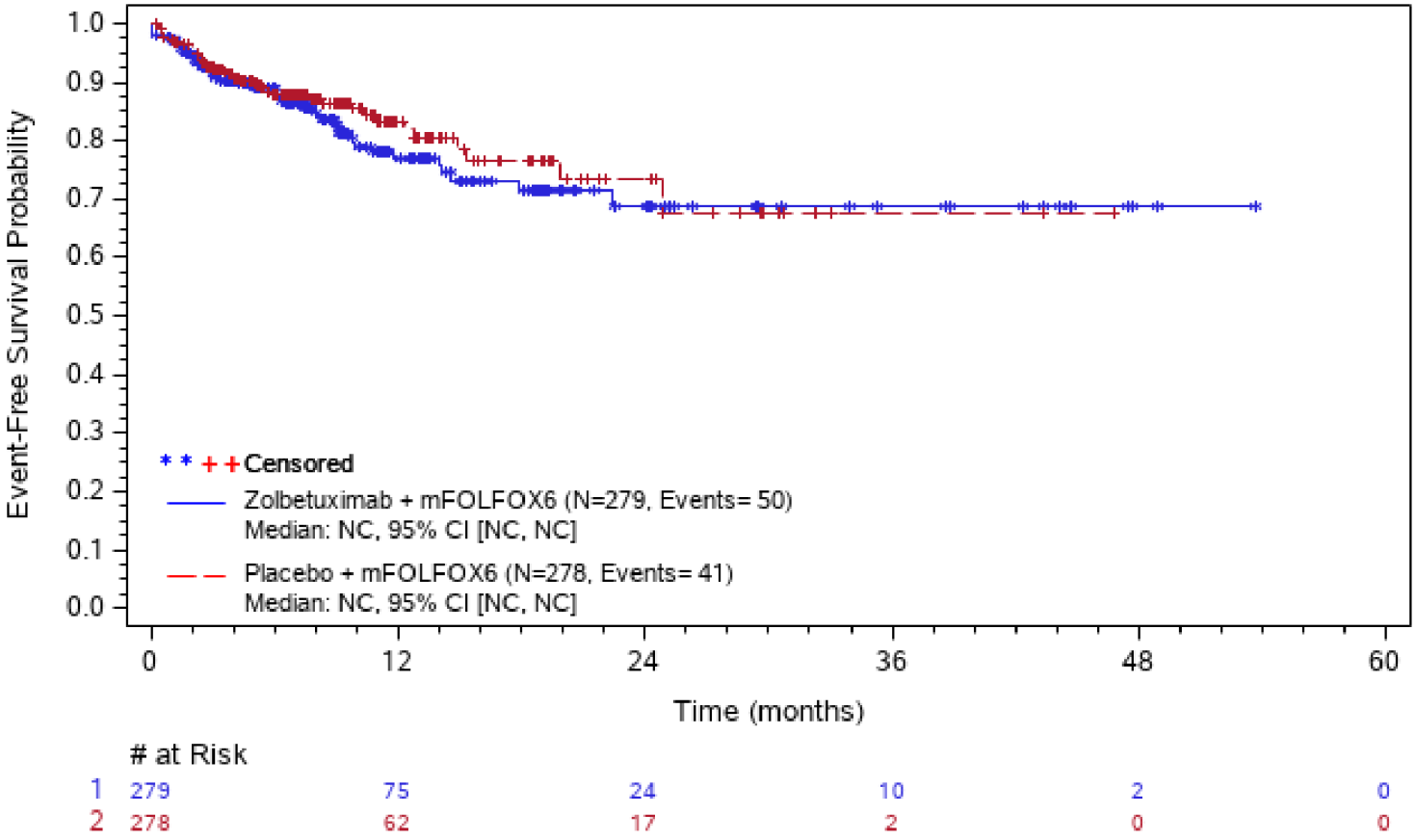
Figure 301.3.2001.68: Kaplan-Meier Plot of Time to first TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

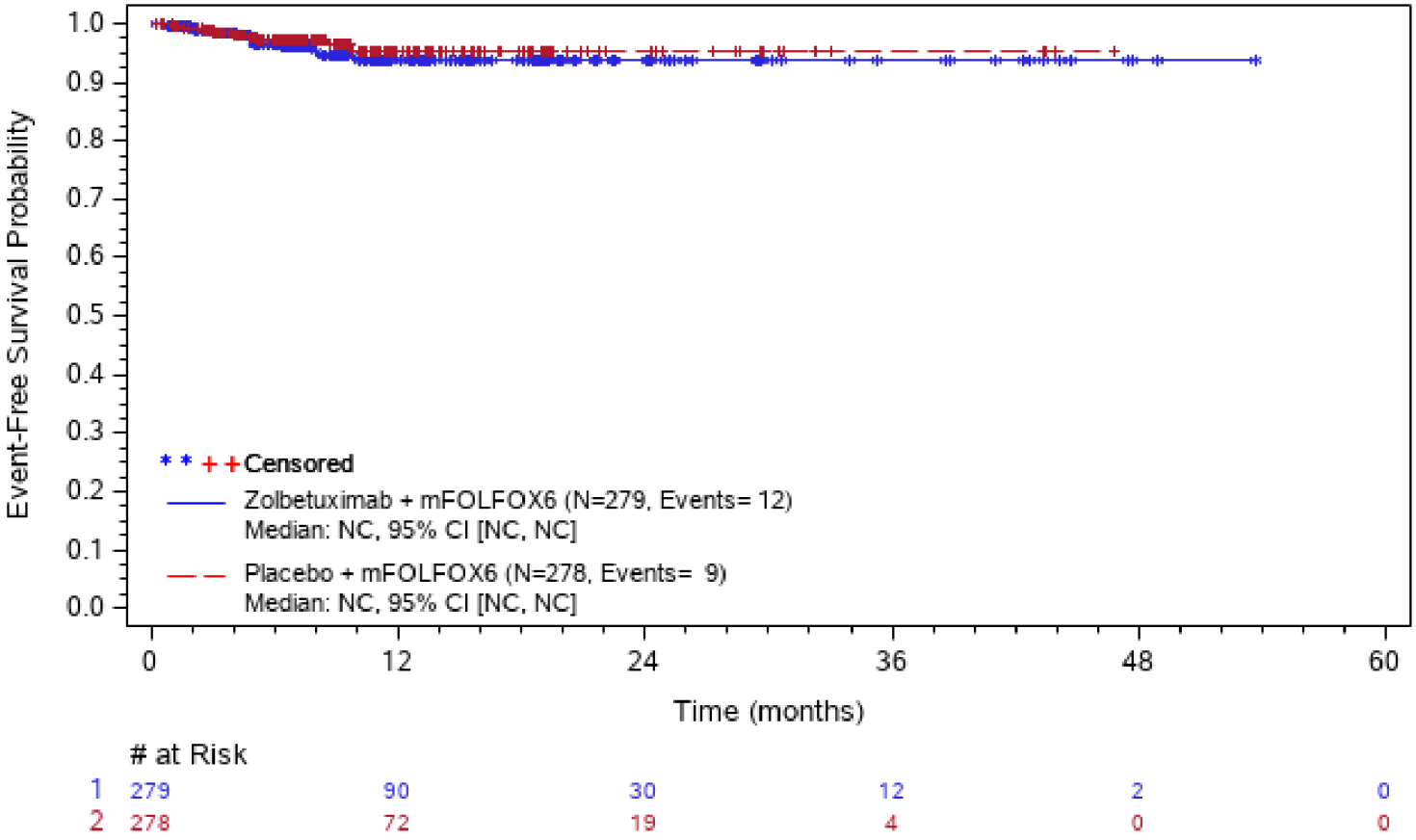


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.69: Kaplan-Meier Plot of Time to first TEAE - Fall (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: 08SEP23

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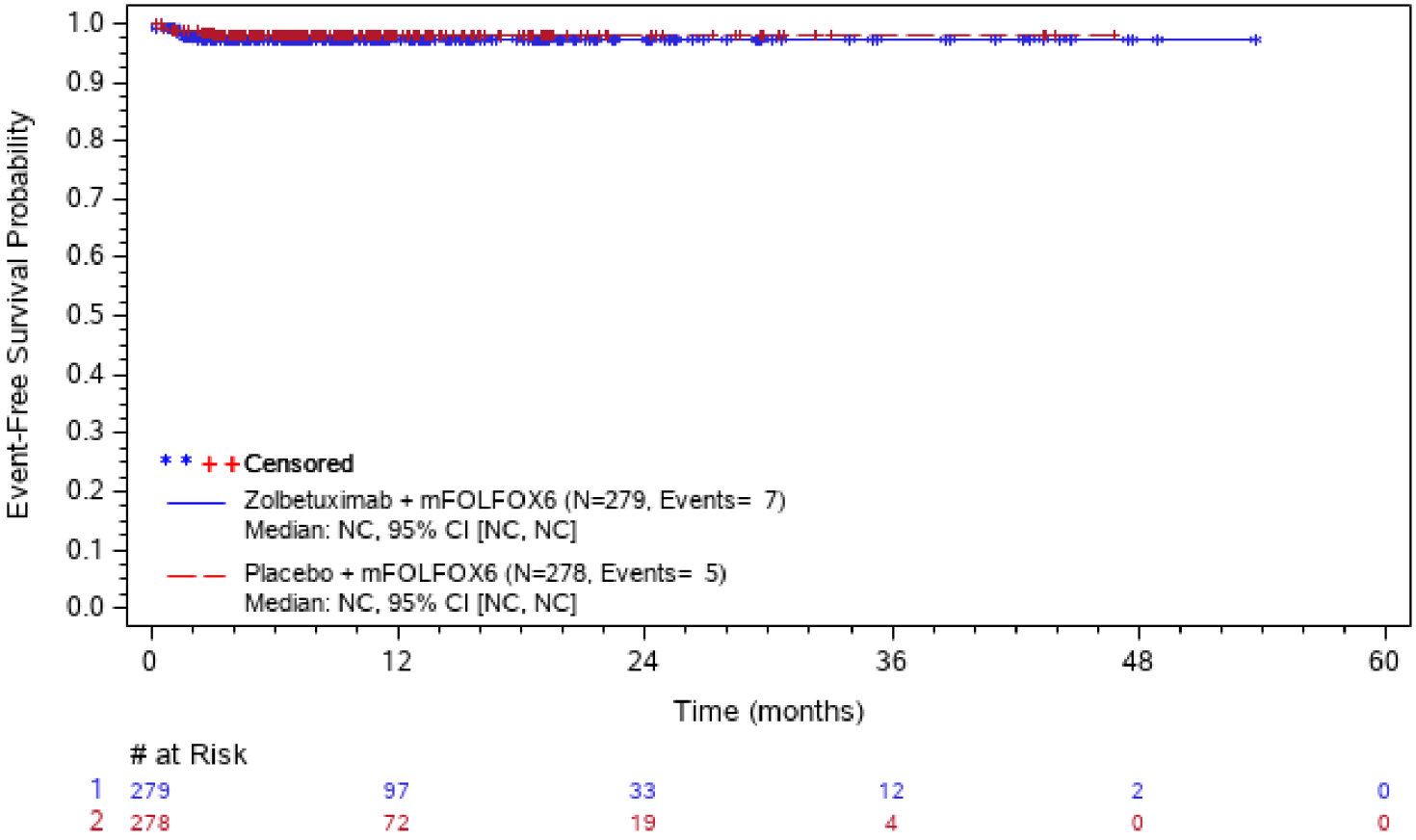
Figure 301.3.2001.70: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (PT) - Safety Analysis Set



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.

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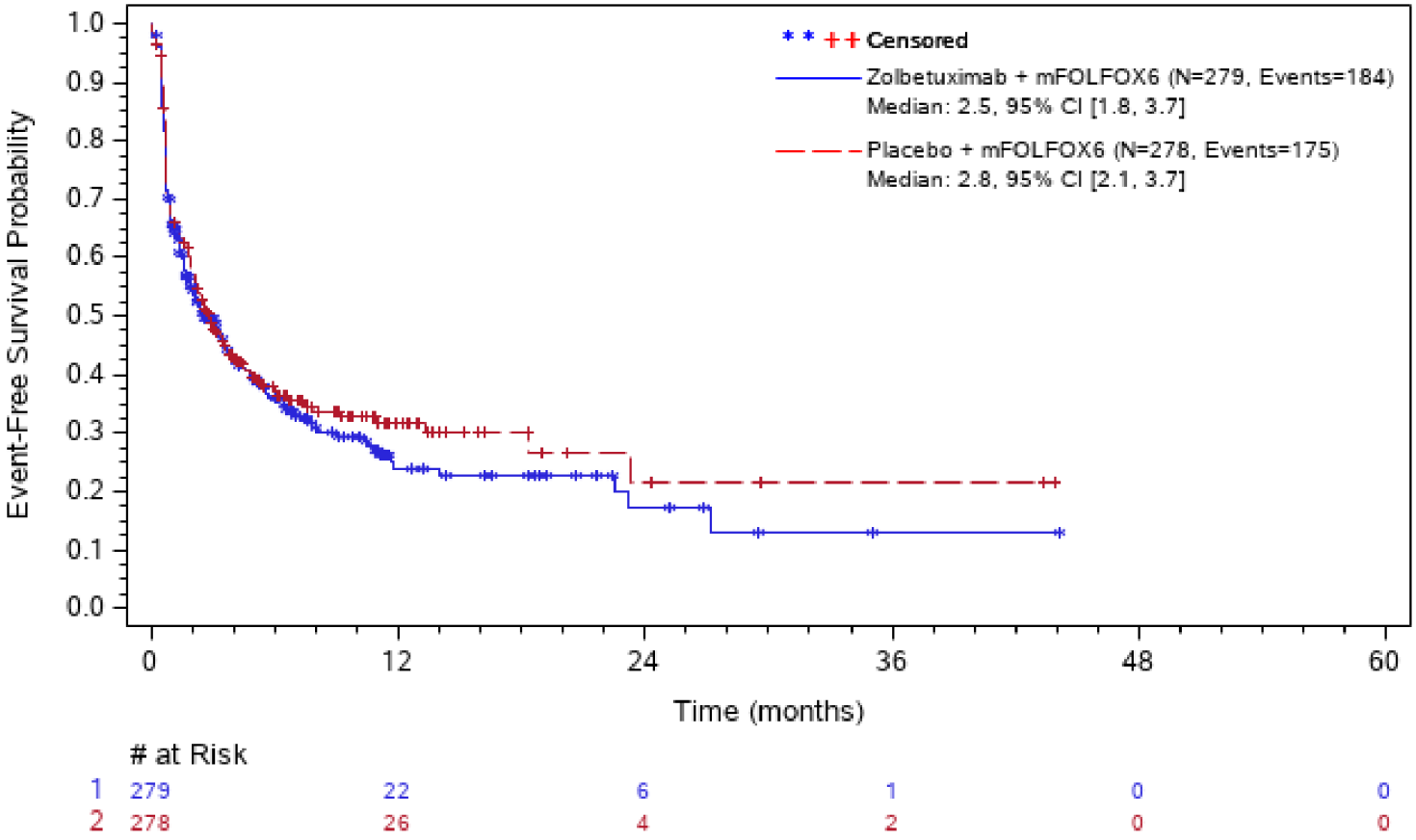
Figure 301.3.2001.71: Kaplan-Meier Plot of Time to first TEAE - Investigations (SOC) - Safety Analysis Set



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: 08SEP23

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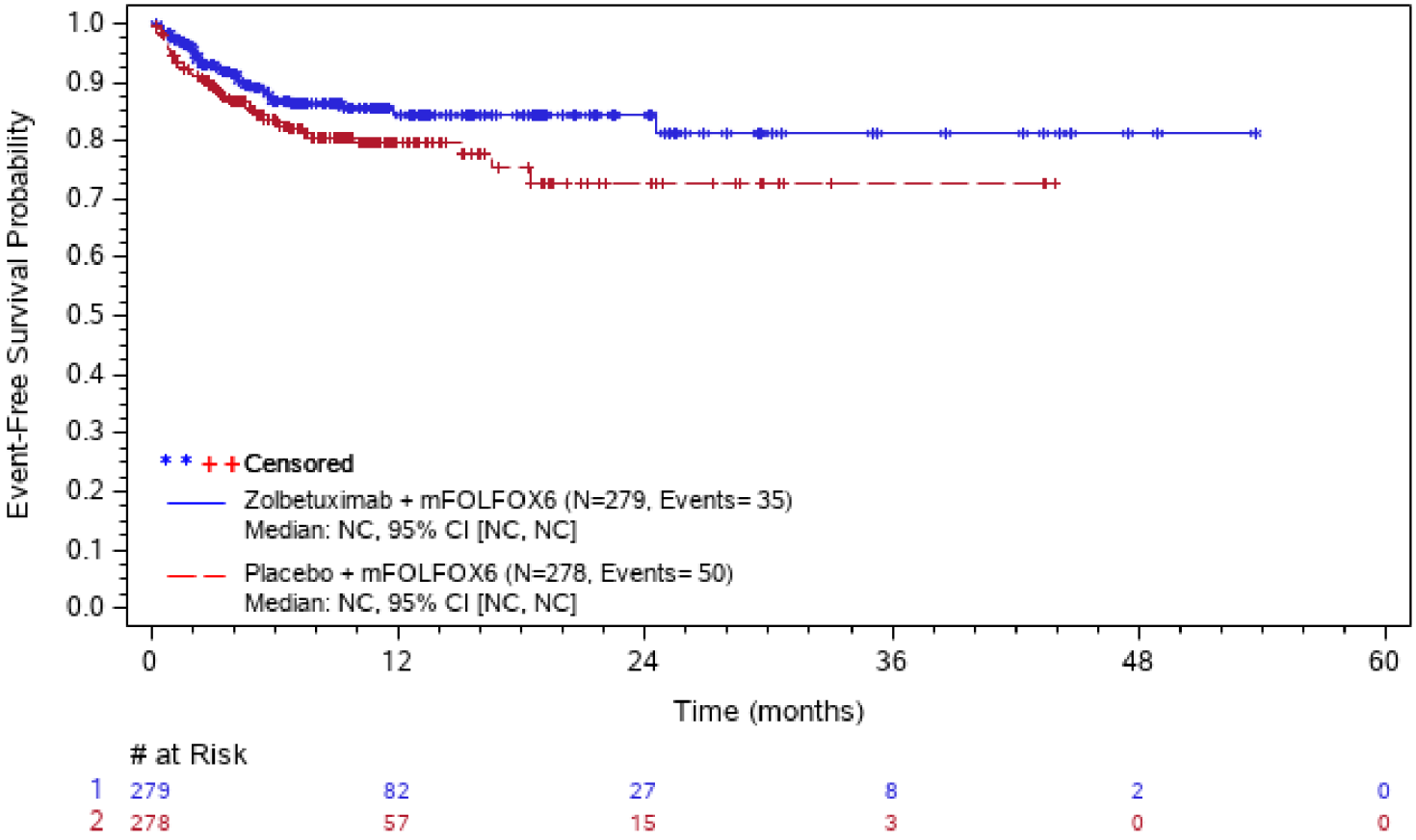
Figure 301.3.2001.72: Kaplan-Meier Plot of Time to first TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set



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: 08SEP23

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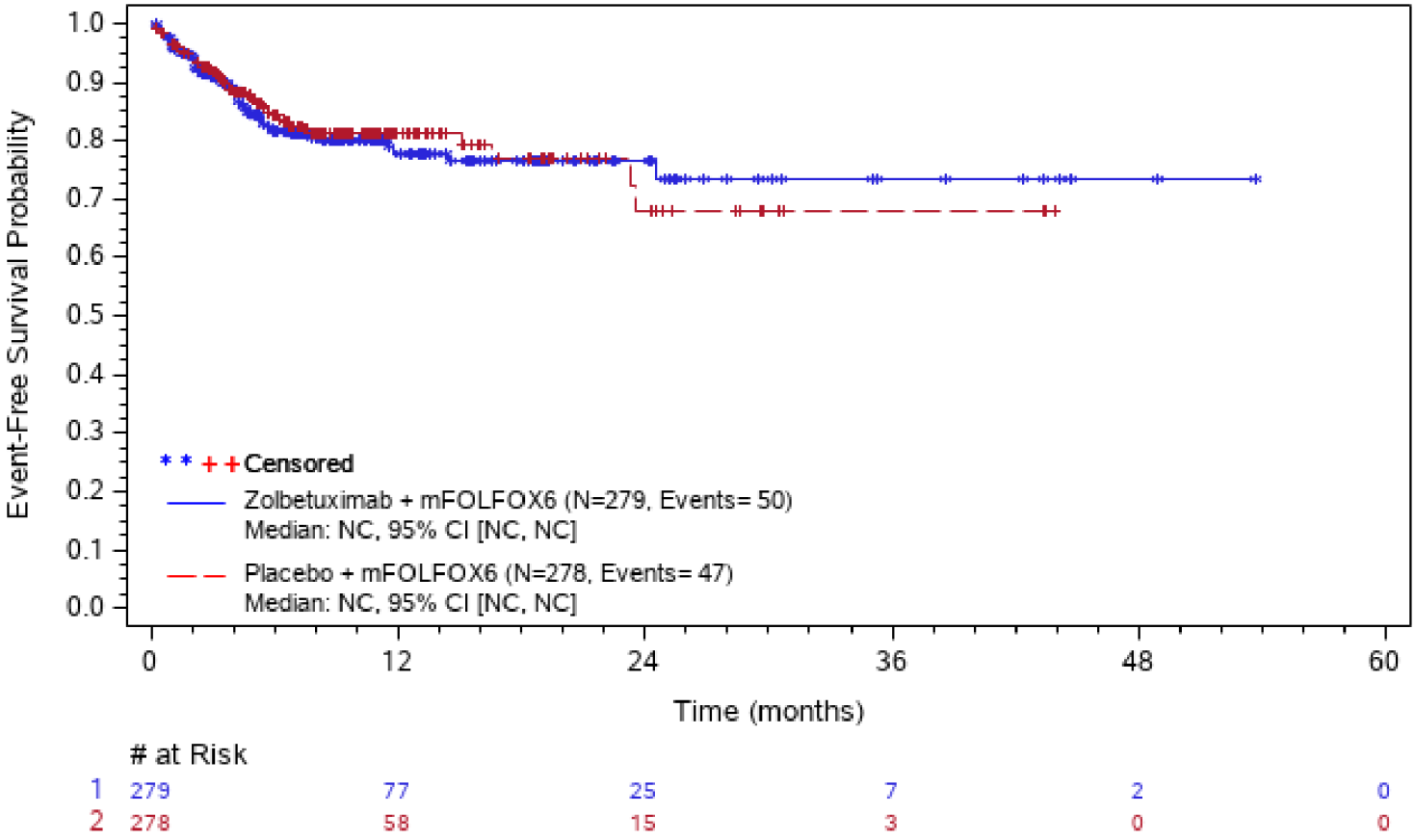
Figure 301.3.2001.73: Kaplan-Meier Plot of Time to first TEAE - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set



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.

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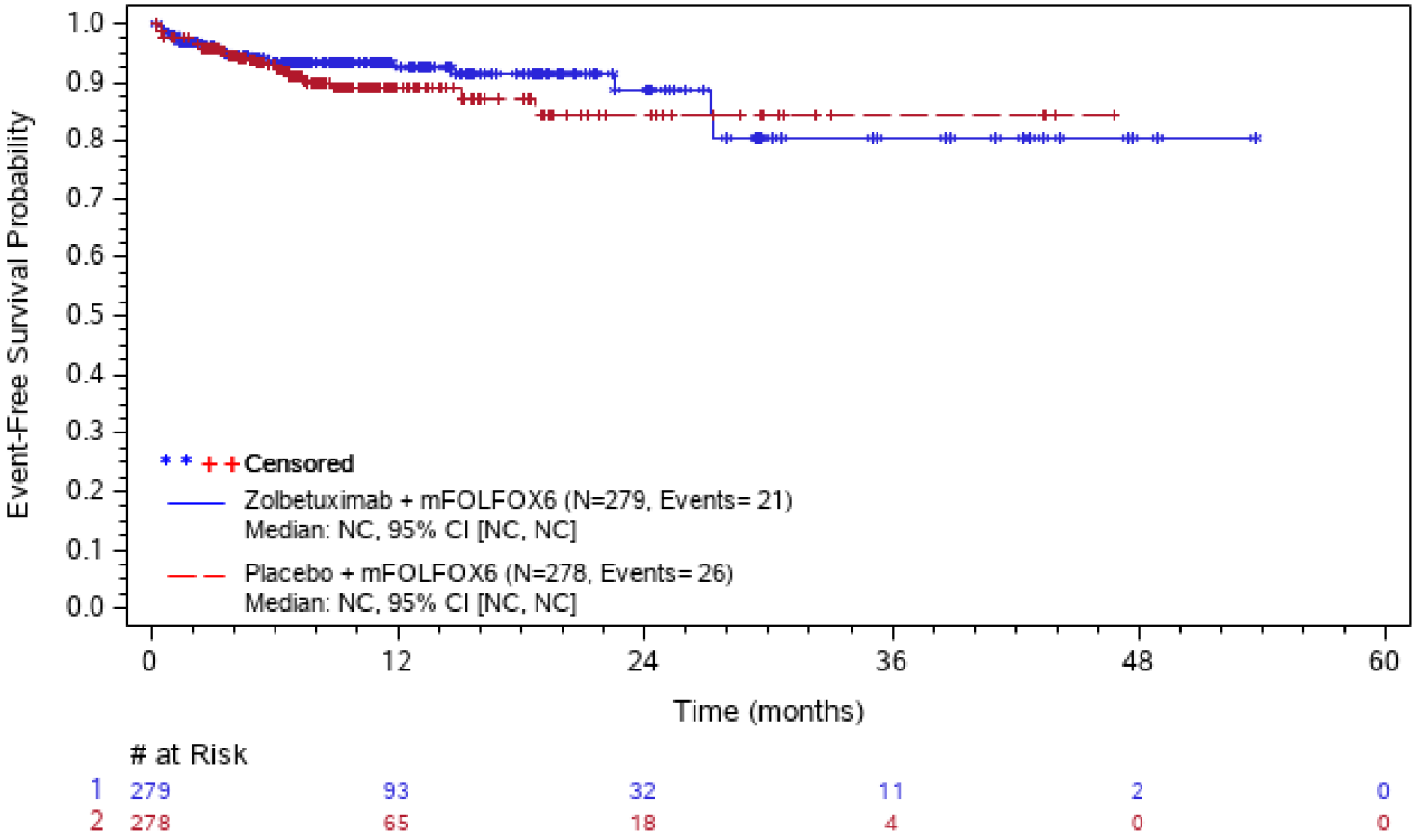
Figure 301.3.2001.74: Kaplan-Meier Plot of Time to first TEAE - Blood Alkaline Phosphatase Increased (PT) - Safety Analysis Set



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.

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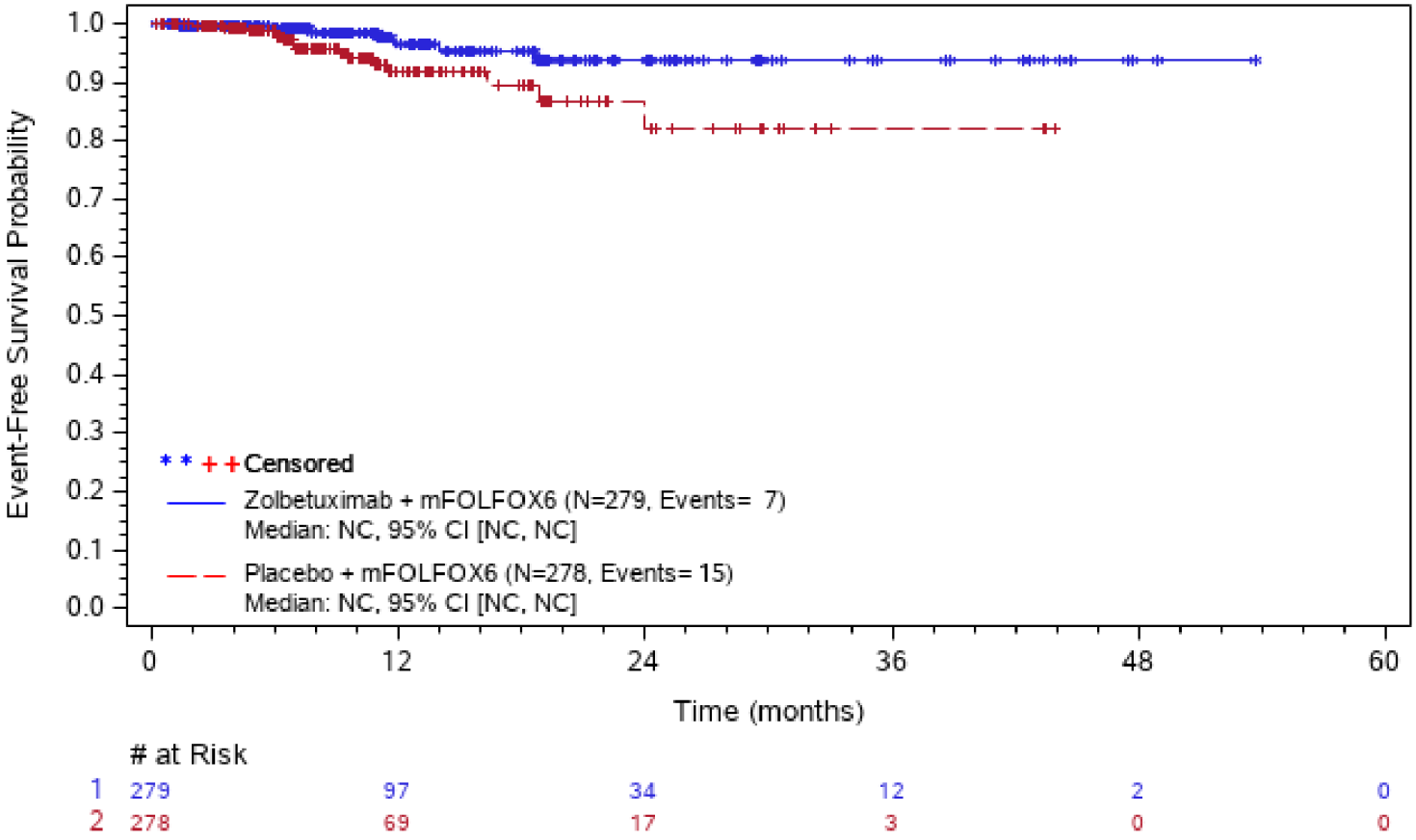
Figure 301.3.2001.75: Kaplan-Meier Plot of Time to first TEAE - Blood Bilirubin Increased (PT) - Safety Analysis Set



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.

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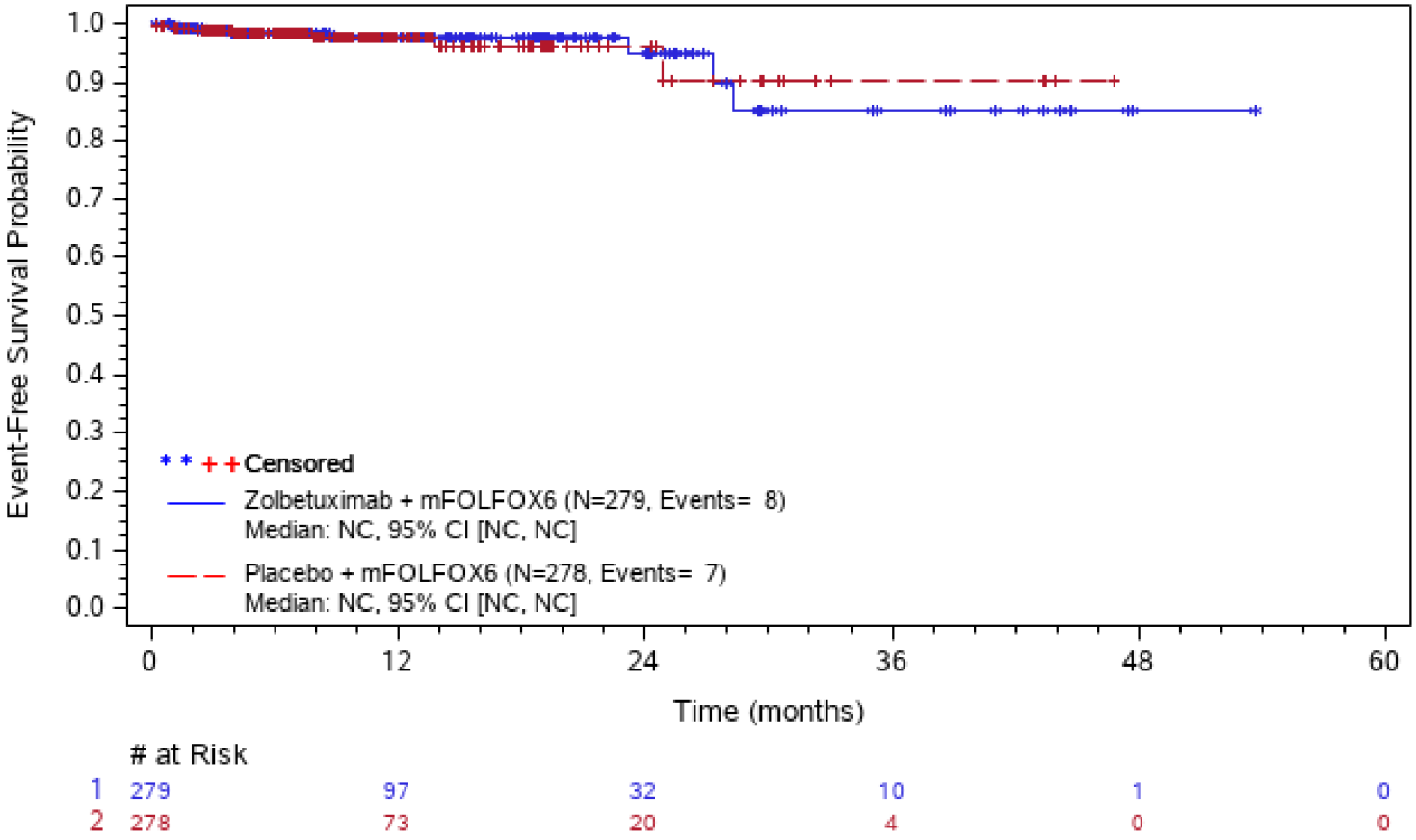
Figure 301.3.2001.76: Kaplan-Meier Plot of Time to first TEAE - Blood Creatinine Increased (PT) - Safety Analysis Set



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.

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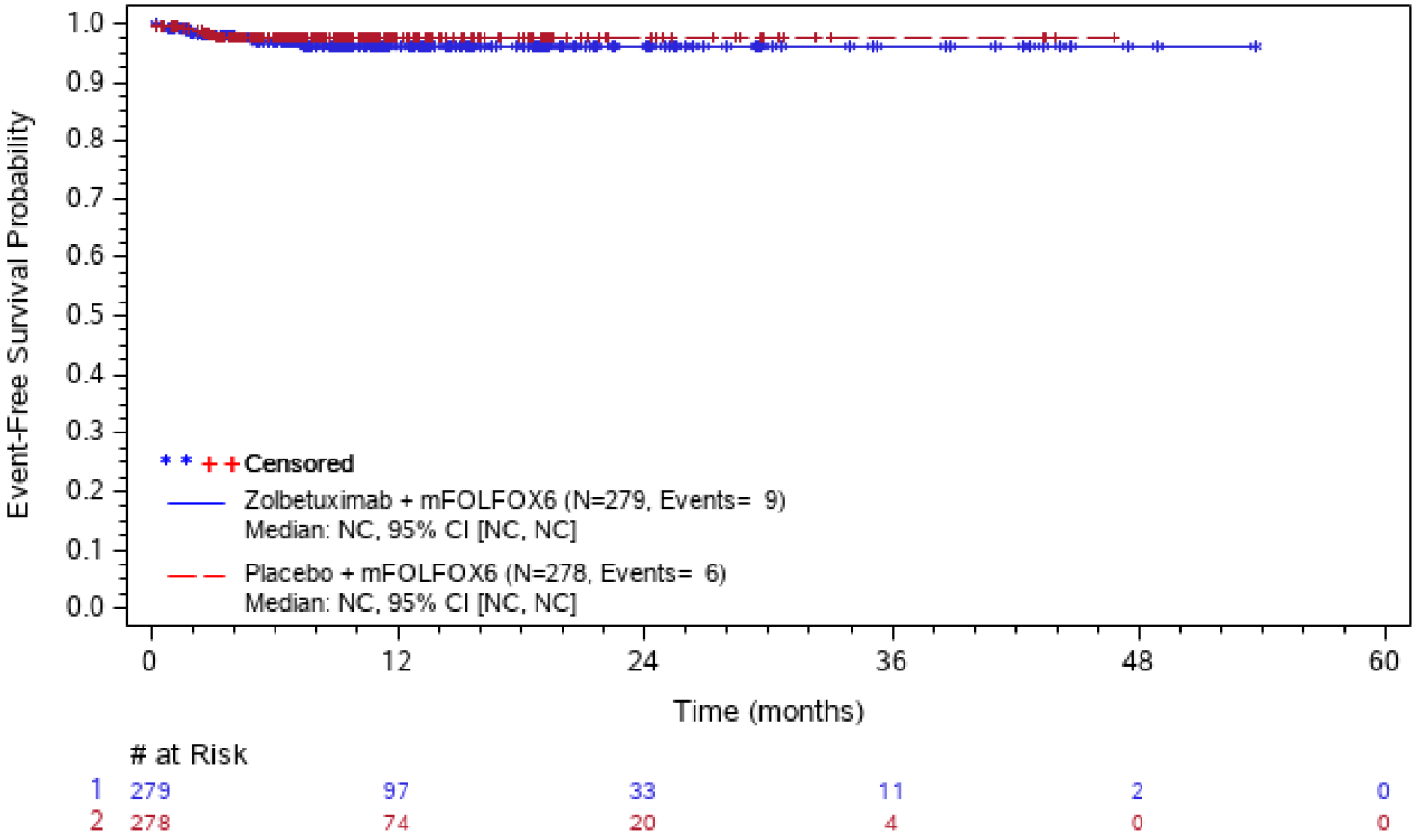
Figure 301.3.2001.77: Kaplan-Meier Plot of Time to first TEAE - Electrocardiogram Qt Prolonged (PT) - Safety Analysis Set



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.

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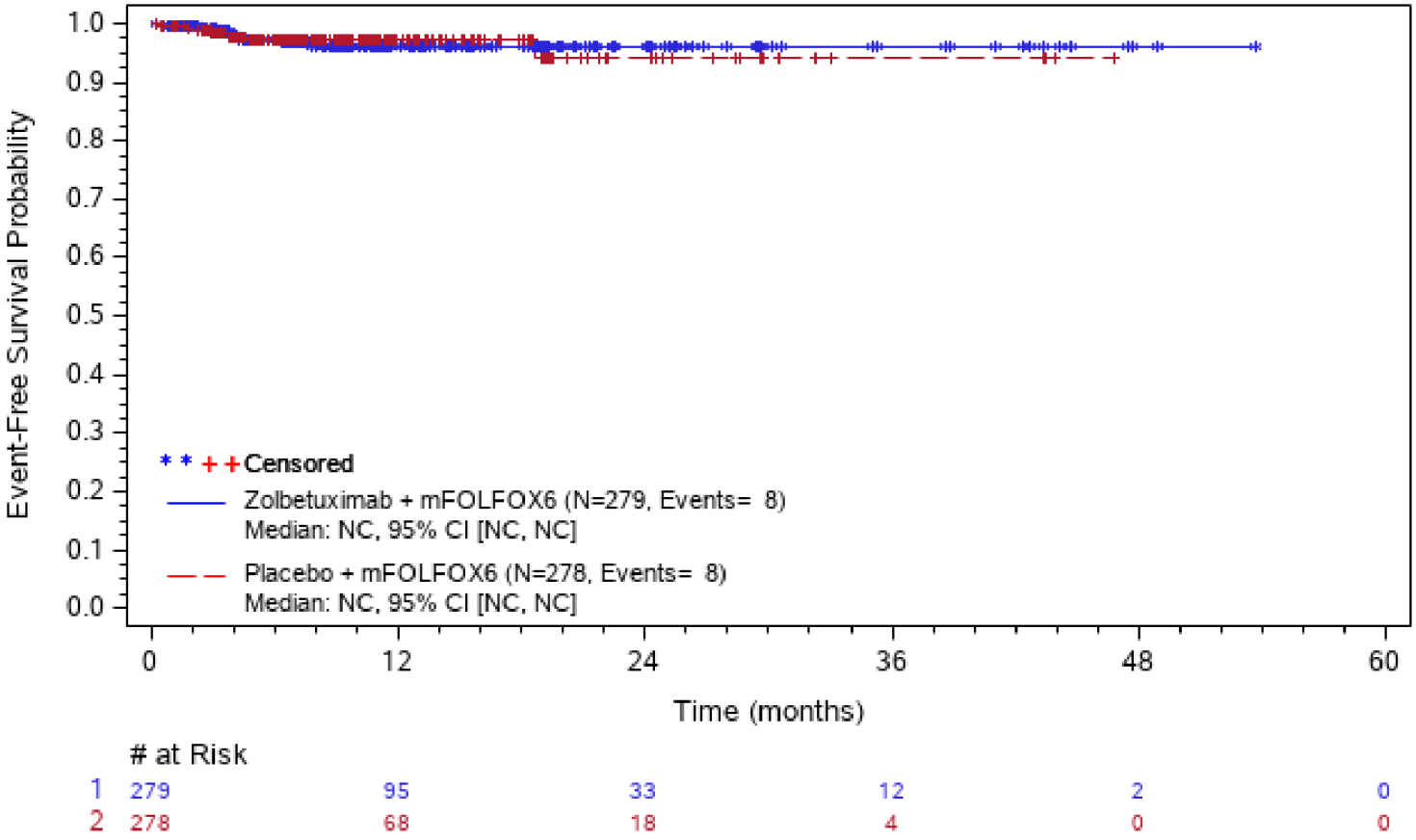
Figure 301.3.2001.78: Kaplan-Meier Plot of Time to first TEAE - Gamma-Glutamyltransferase Increased (PT) - Safety Analysis Set



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.

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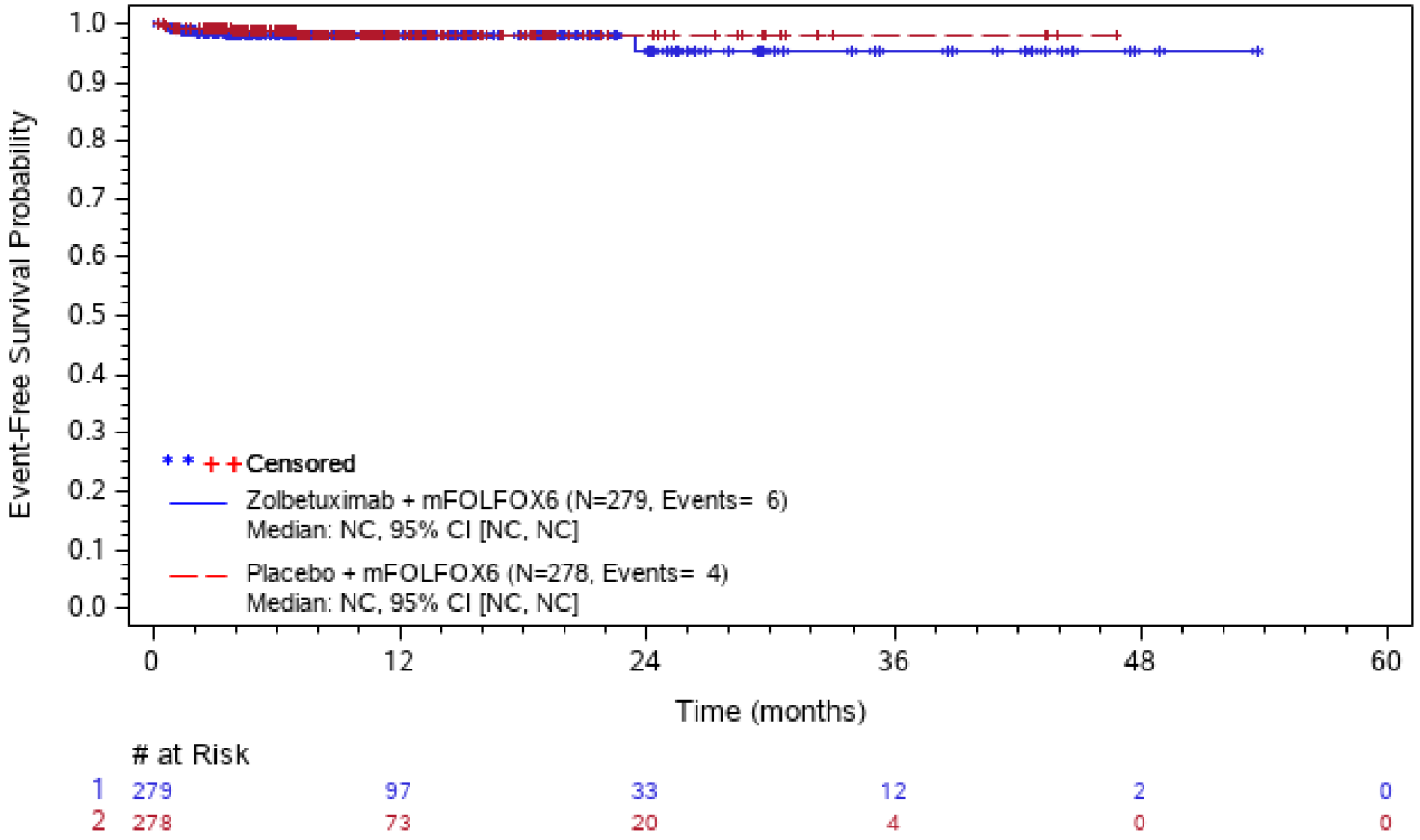
Figure 301.3.2001.79: Kaplan-Meier Plot of Time to first TEAE - Lymphocyte Count Decreased (PT) - Safety Analysis Set



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.

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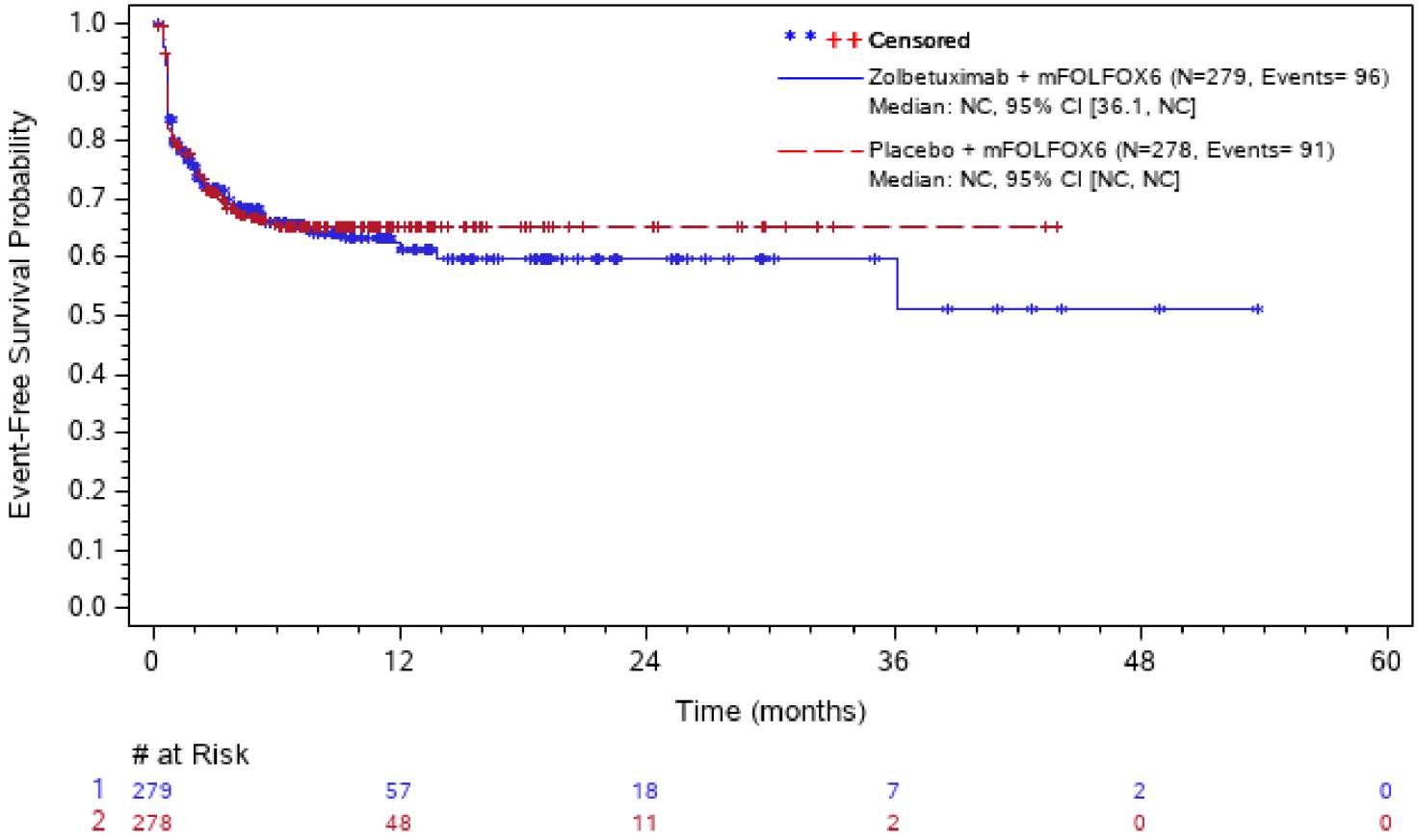
Figure 301.3.2001.80: Kaplan-Meier Plot of Time to first TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set

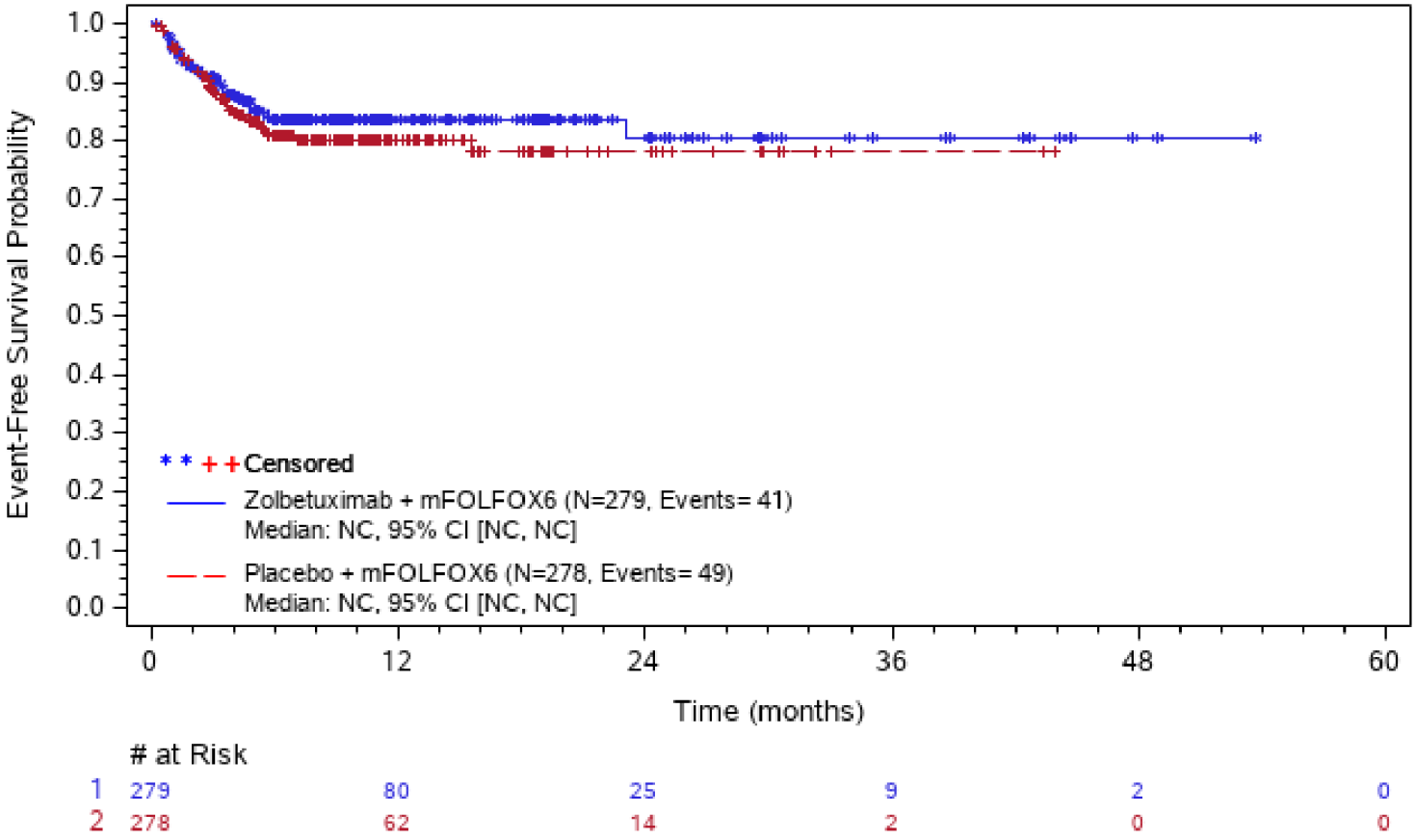


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.81: Kaplan-Meier Plot of Time to first TEAE - Platelet Count Decreased (PT) - Safety Analysis Set

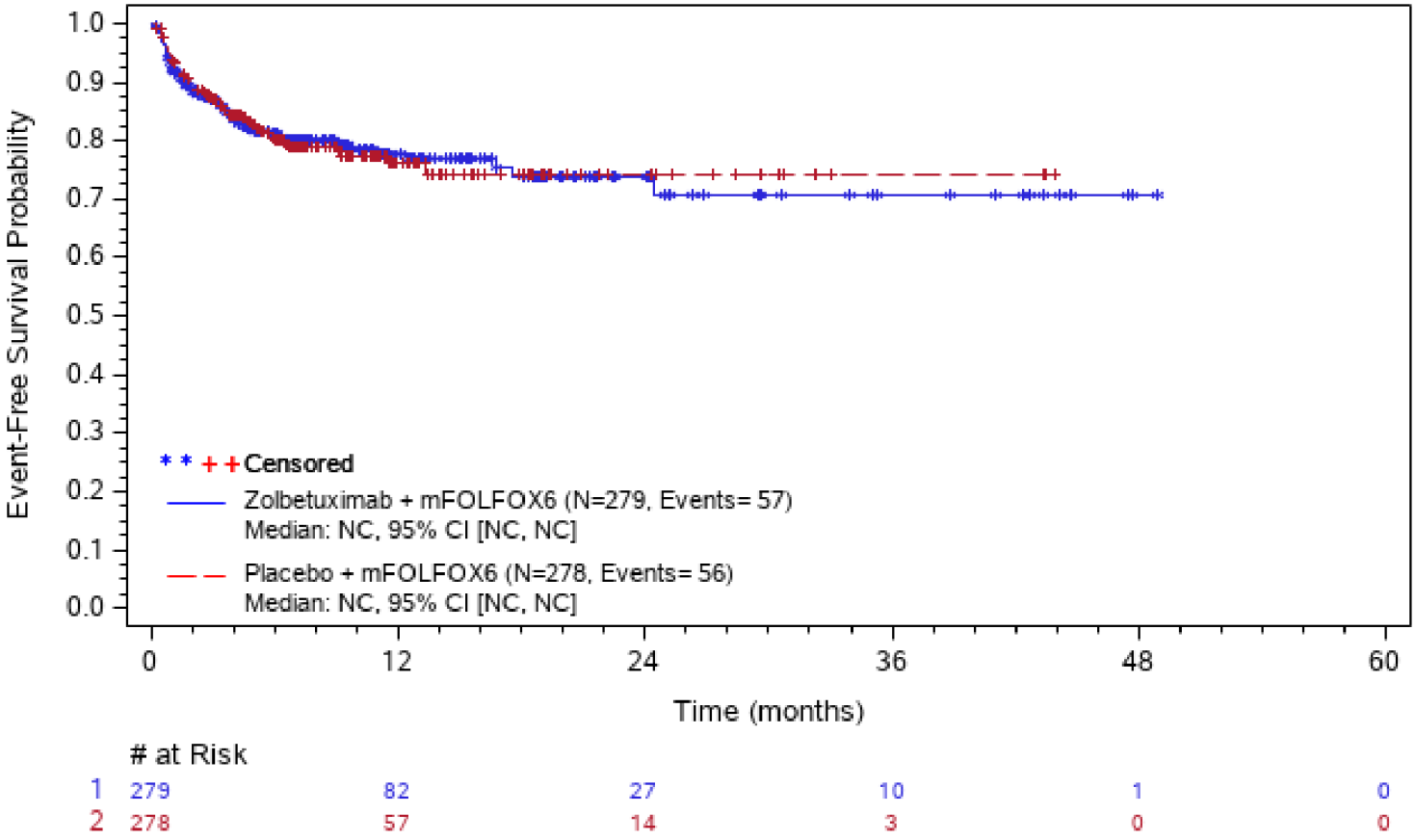


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.82: Kaplan-Meier Plot of Time to first TEAE - Weight Decreased (PT) - Safety Analysis Set

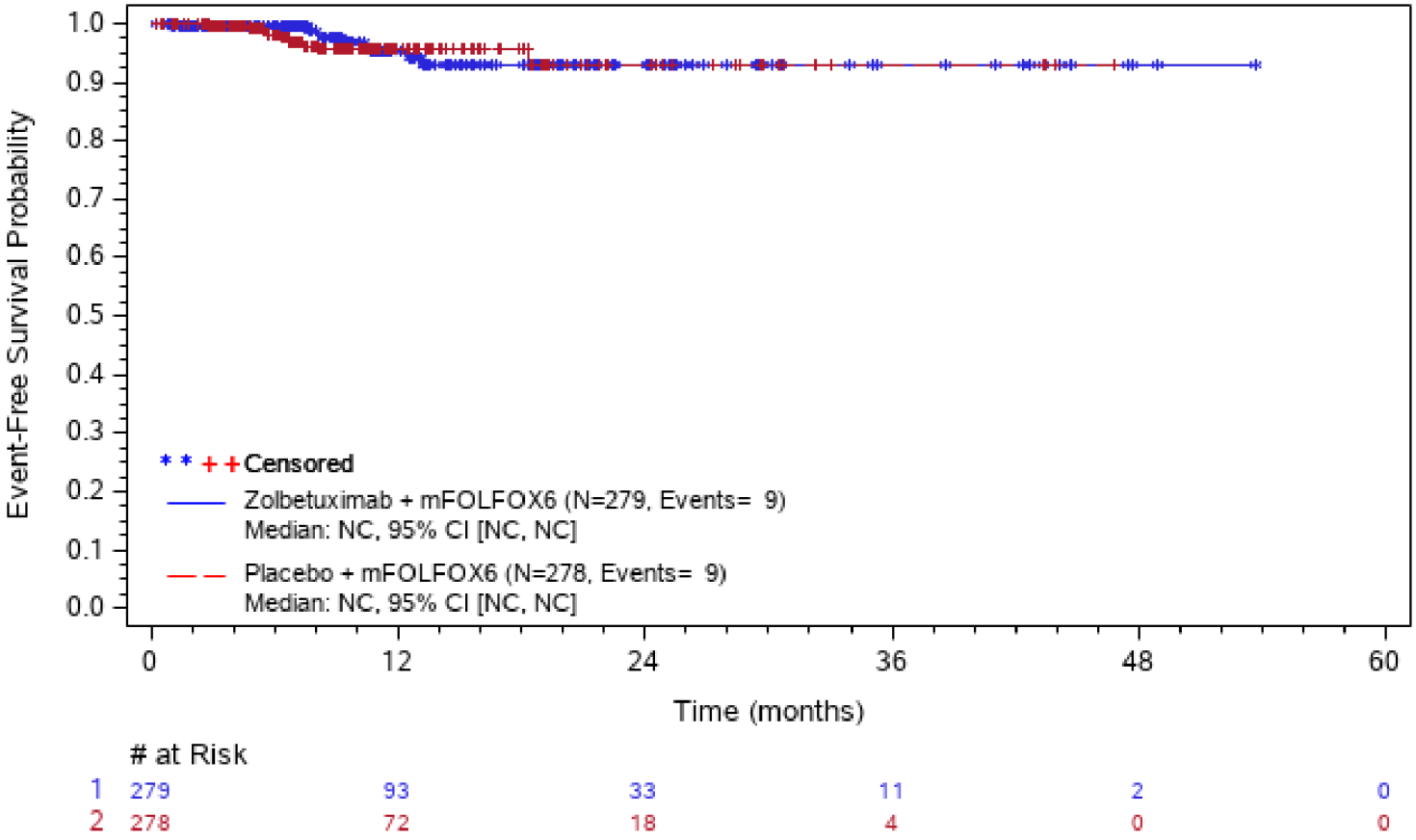


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.83: Kaplan-Meier Plot of Time to first TEAE - Weight Increased (PT) - Safety Analysis Set

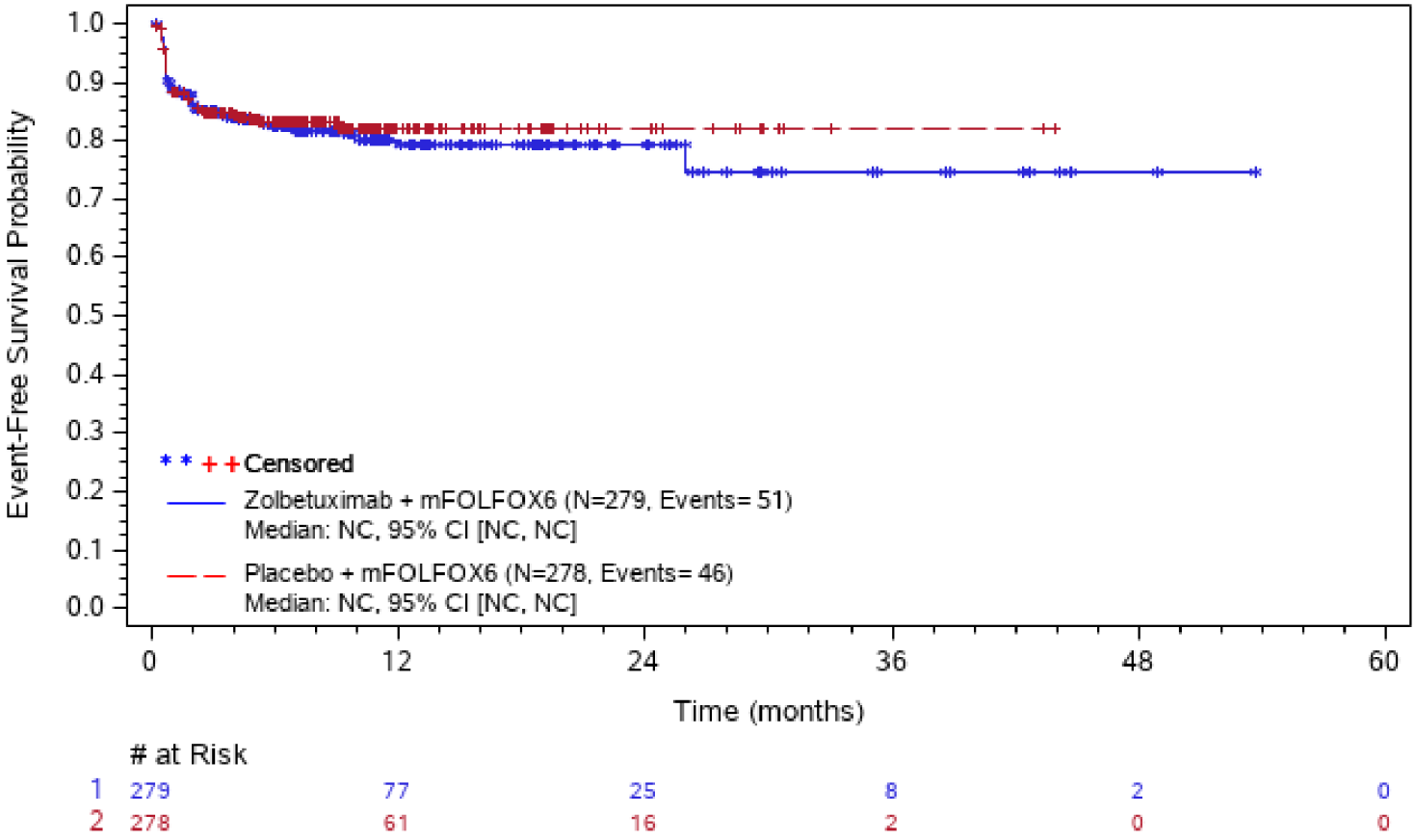


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.84: Kaplan-Meier Plot of Time to first TEAE - White Blood Cell Count 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.

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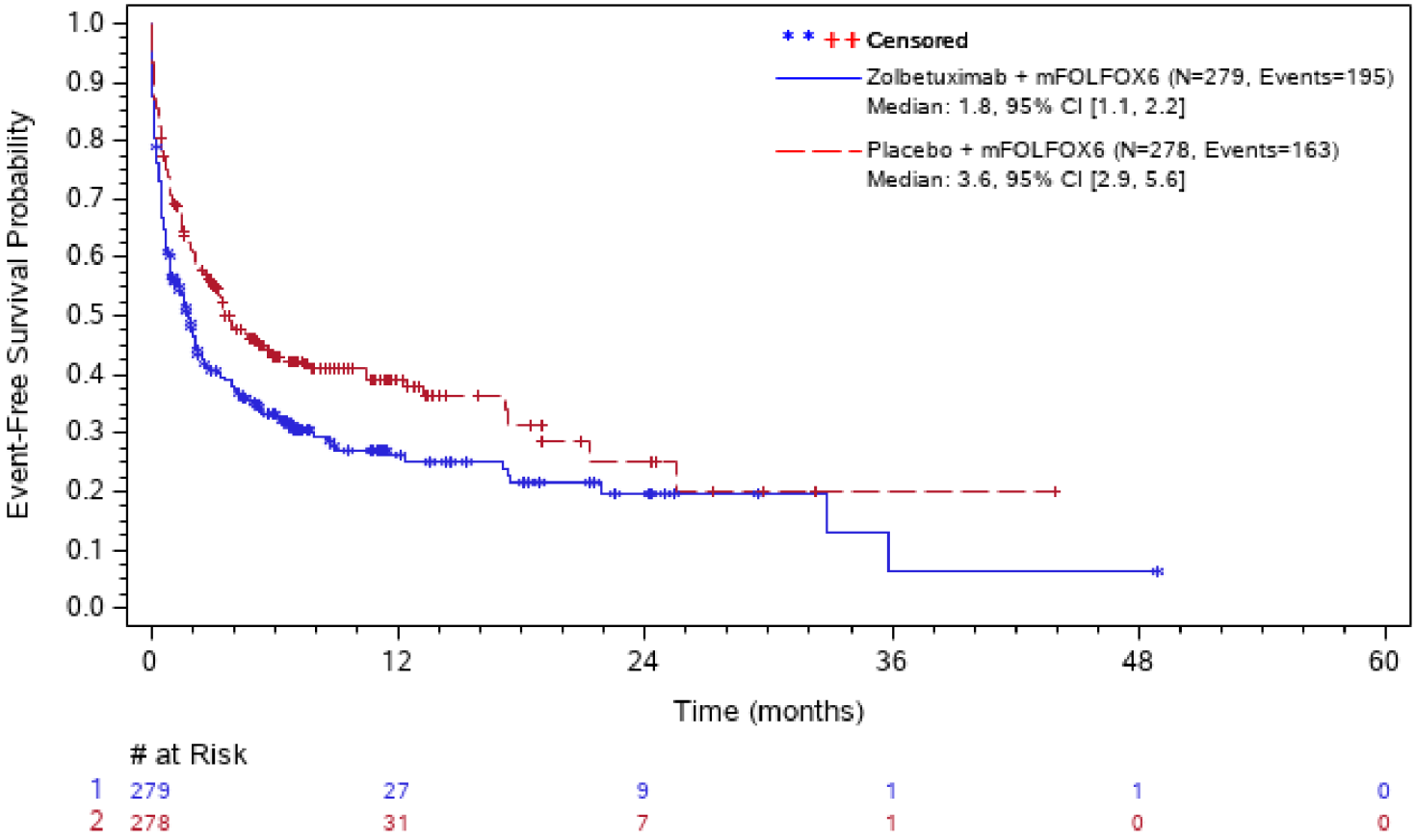
Figure 301.3.2001.85: Kaplan-Meier Plot of Time to first TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set



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: 08SEP23

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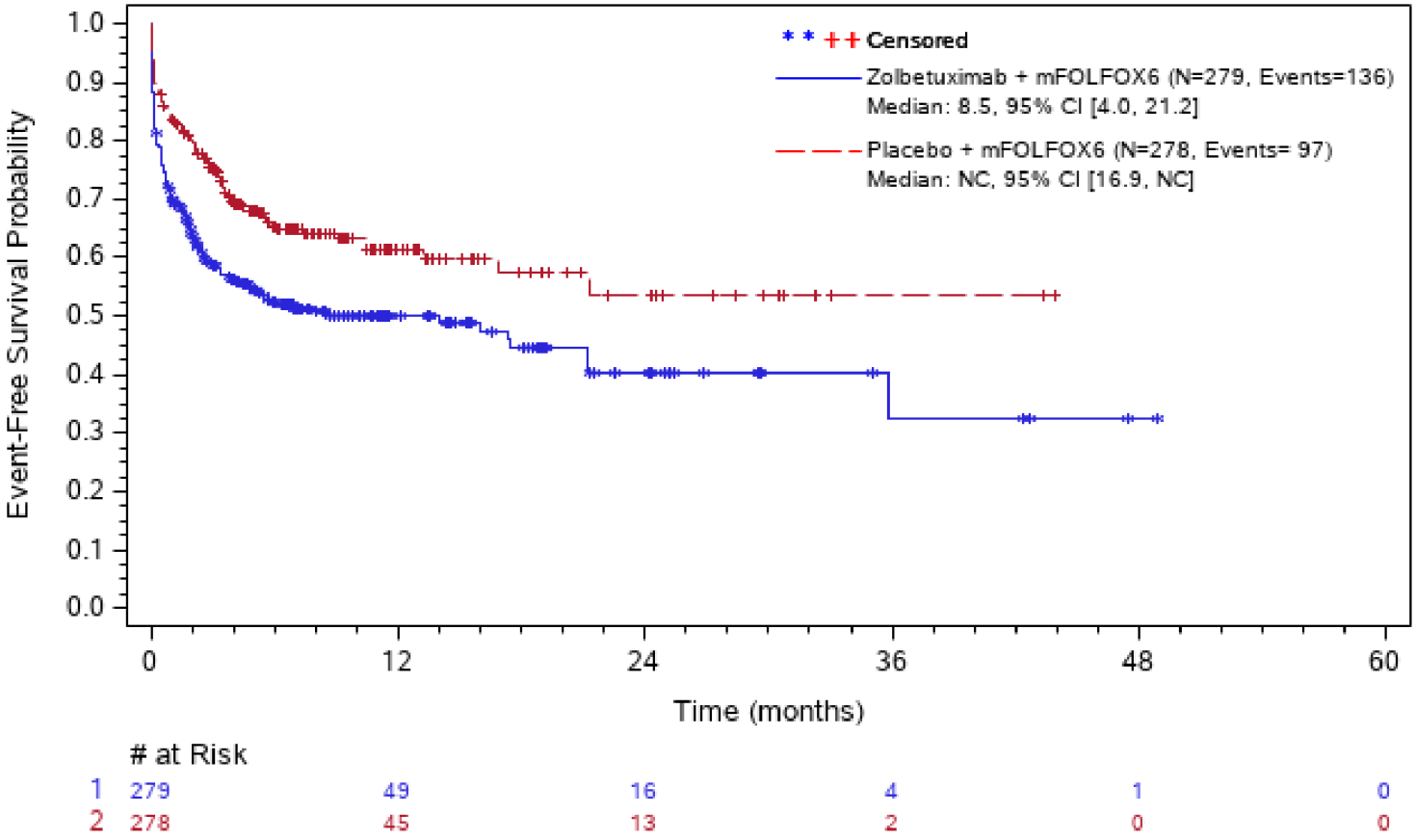
Figure 301.3.2001.86: Kaplan-Meier Plot of Time to first TEAE - Decreased Appetite (PT) - Safety Analysis Set



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.

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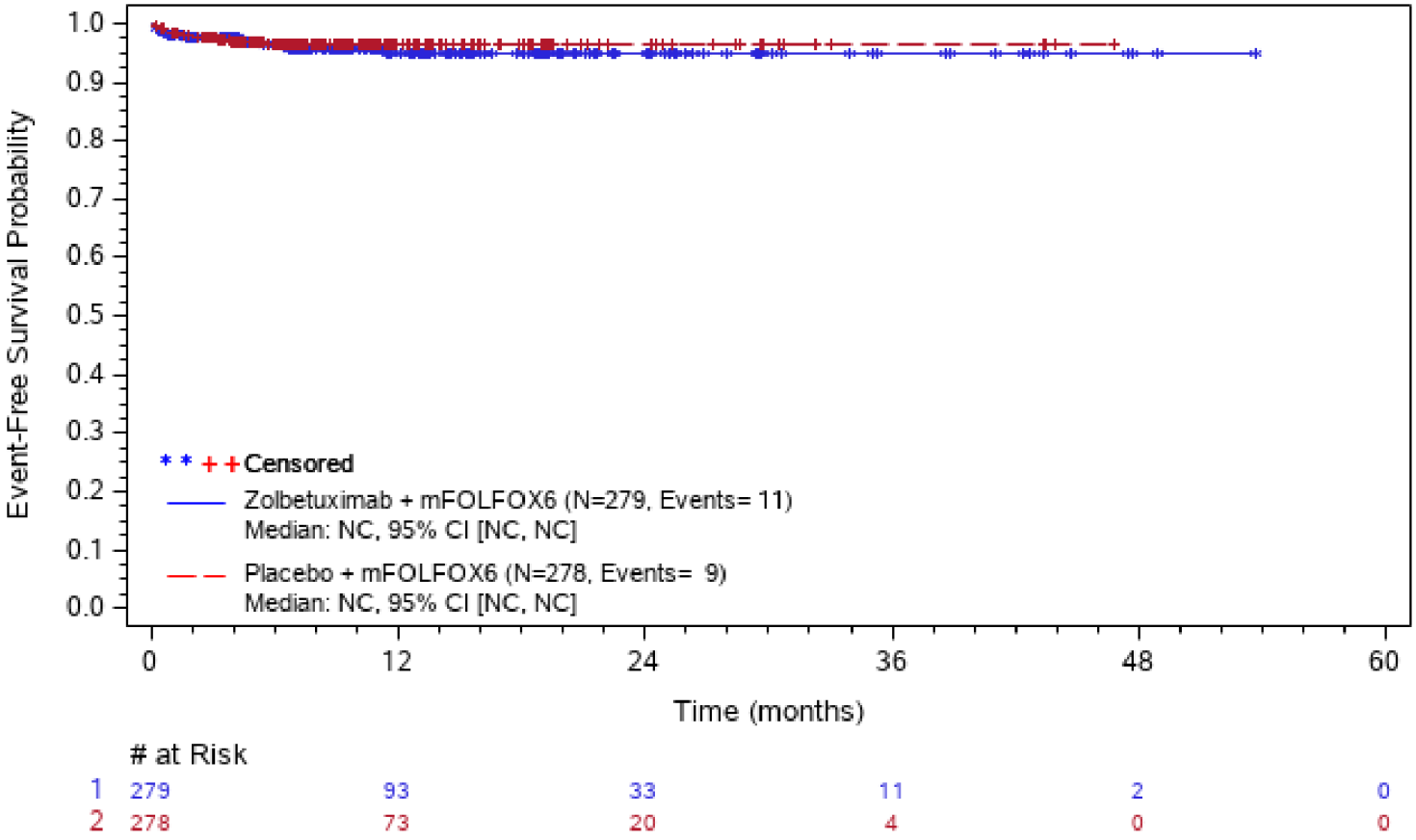
Figure 301.3.2001.87: Kaplan-Meier Plot of Time to first TEAE - Dehydration (PT) - Safety Analysis Set



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: 08SEP23

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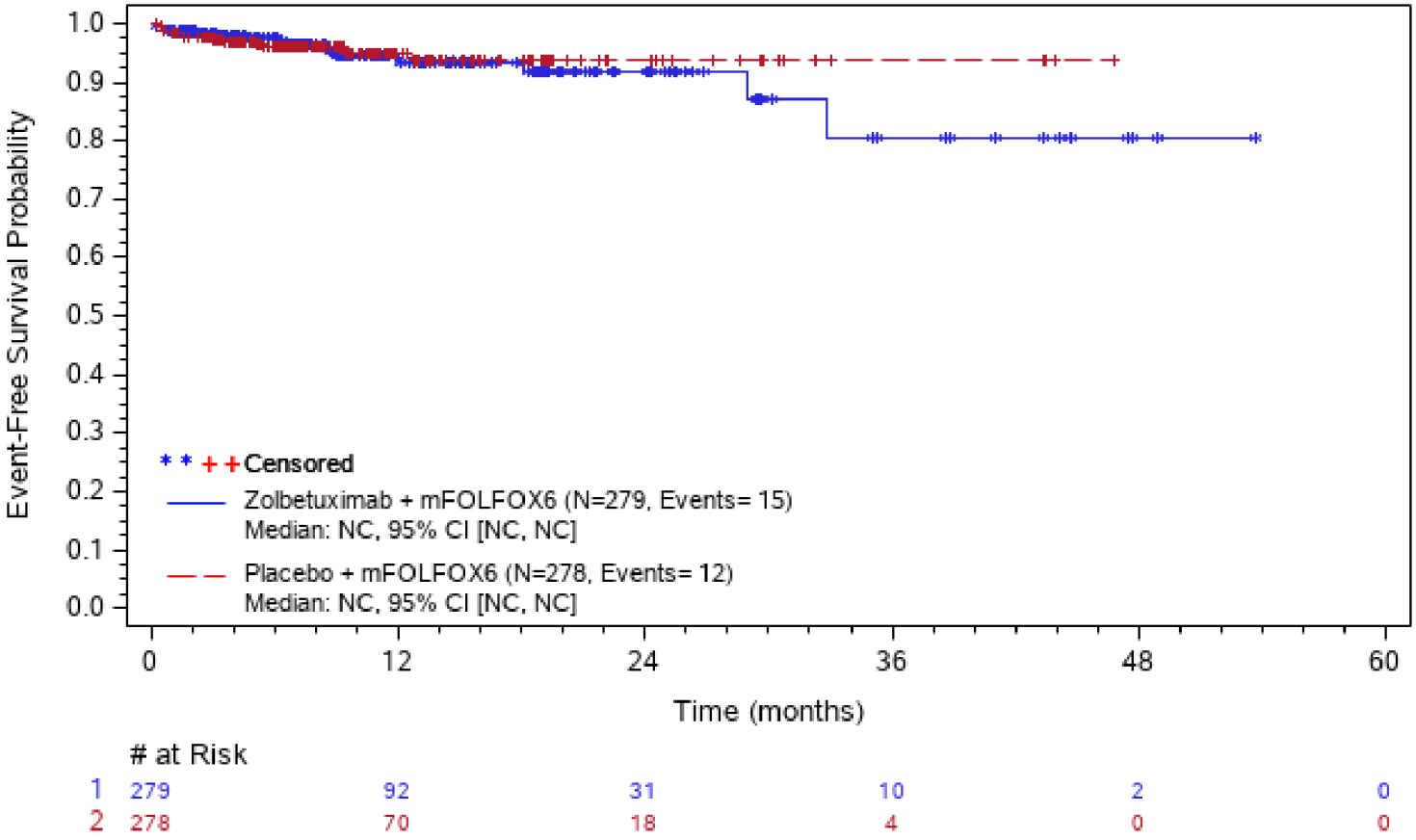
Figure 301.3.2001.88: Kaplan-Meier Plot of Time to first TEAE - Hyperglycaemia (PT) - Safety Analysis Set



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.

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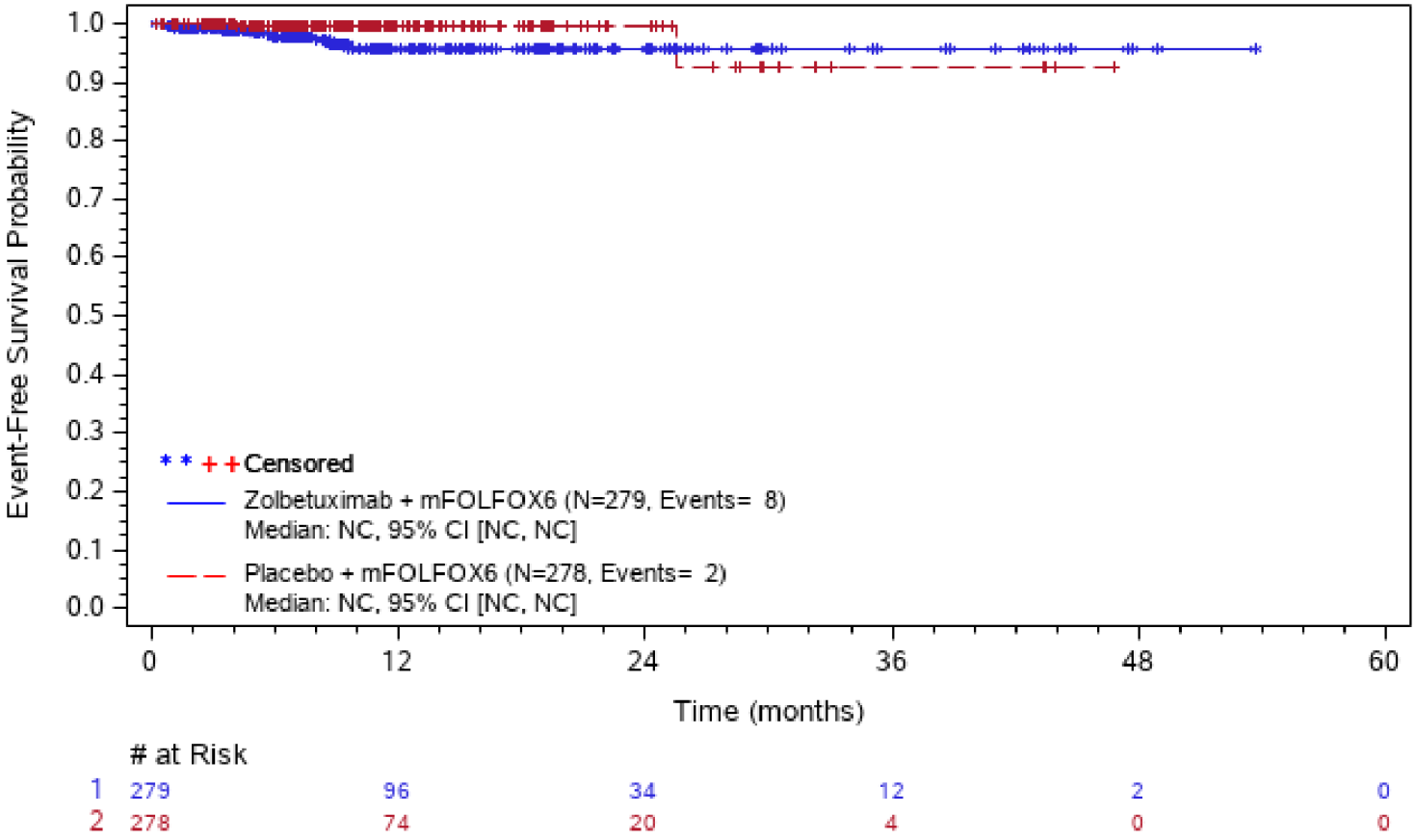
Figure 301.3.2001.89: Kaplan-Meier Plot of Time to first TEAE - Hyperkalaemia (PT) - Safety Analysis Set



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.

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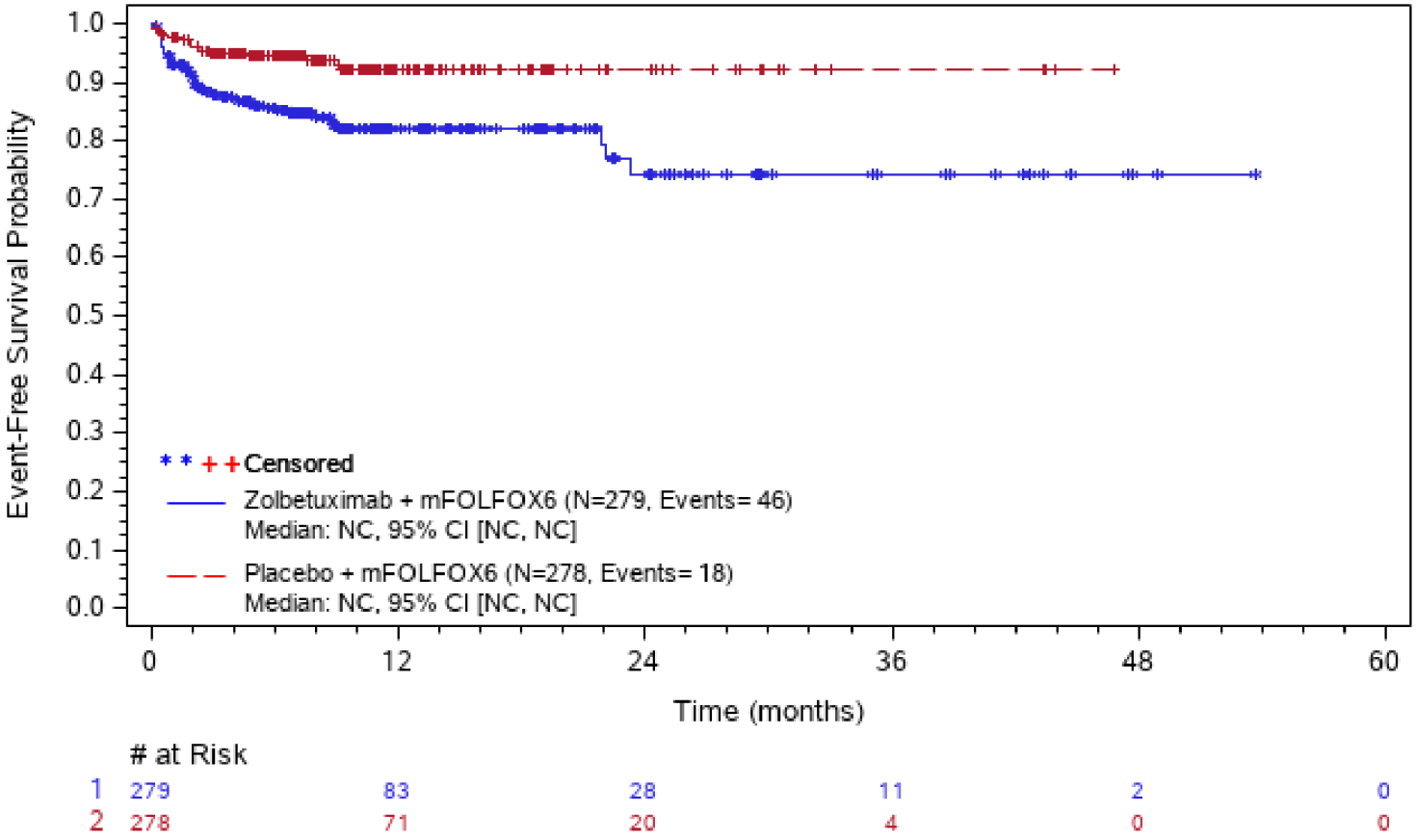
Figure 301.3.2001.90: Kaplan-Meier Plot of Time to first TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set



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.

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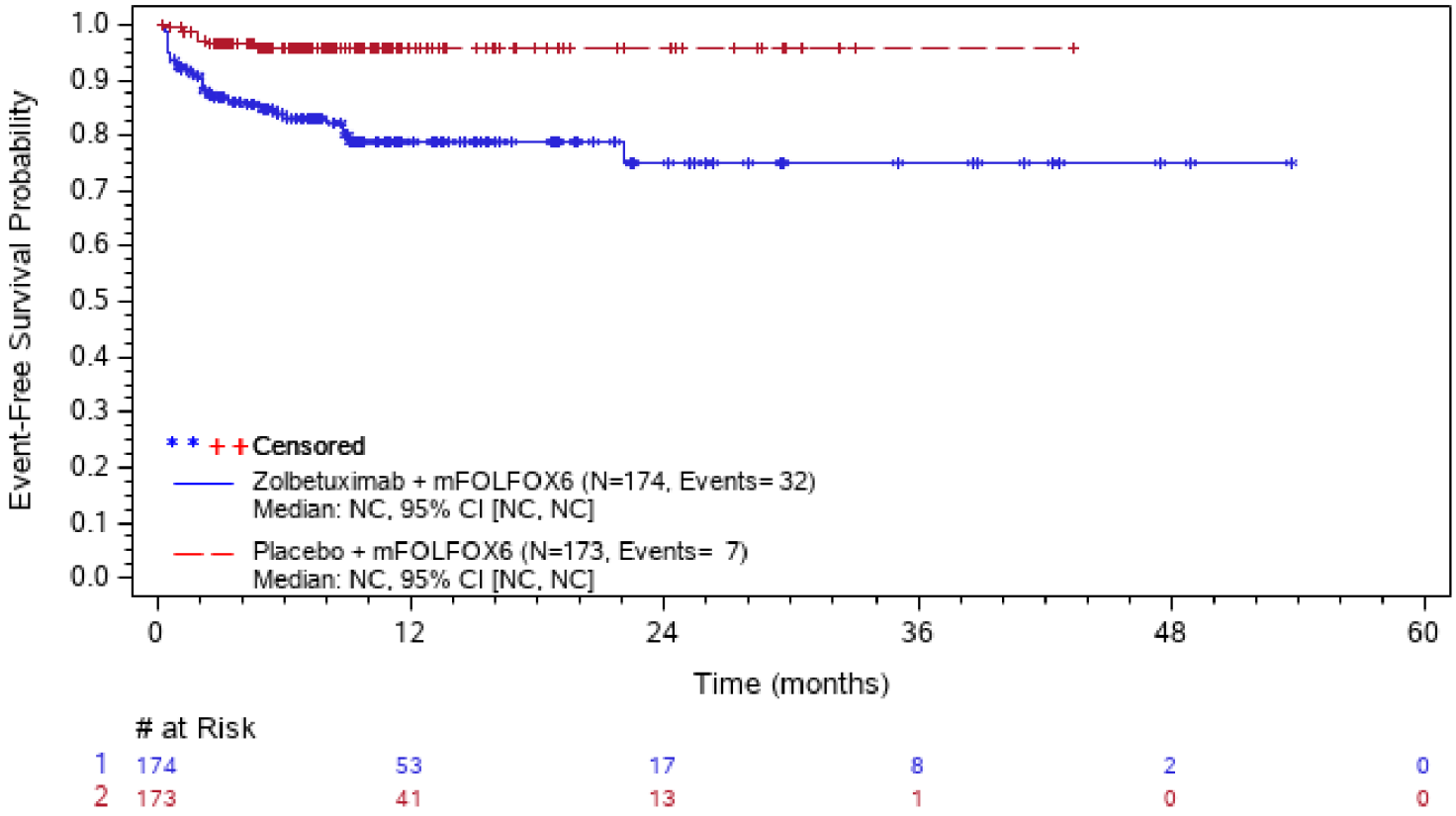
Figure 301.3.2001.90.2: Kaplan-Meier Plot of Time to first TEAE by Sex - Hypoalbuminaemia (PT) - Safety Analysis Set

Sex: Male



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.

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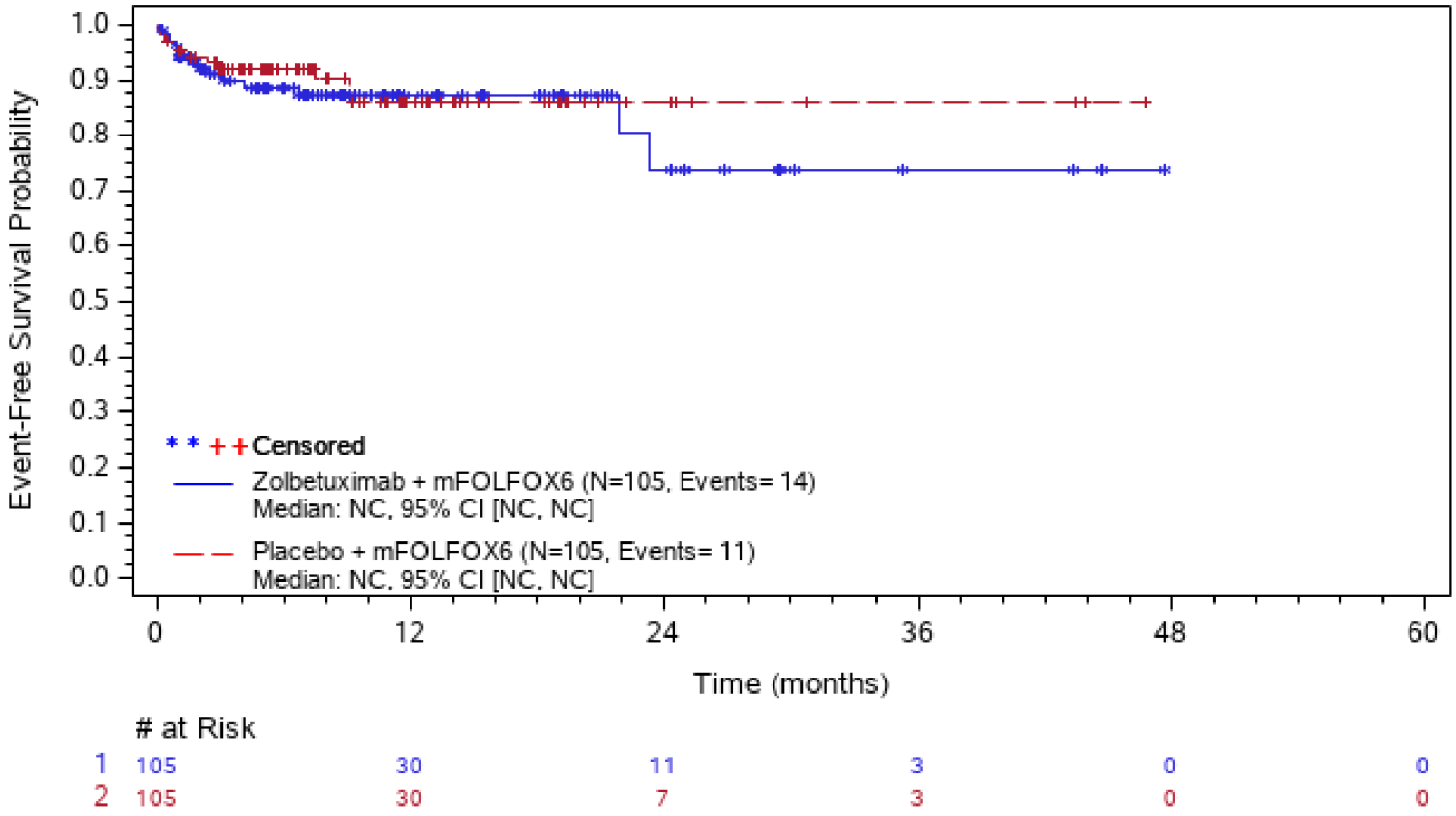
Figure 301.3.2001.90.2: Kaplan-Meier Plot of Time to first TEAE by Sex - Hypoalbuminaemia (PT) - Safety Analysis Set

Sex: Female



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.

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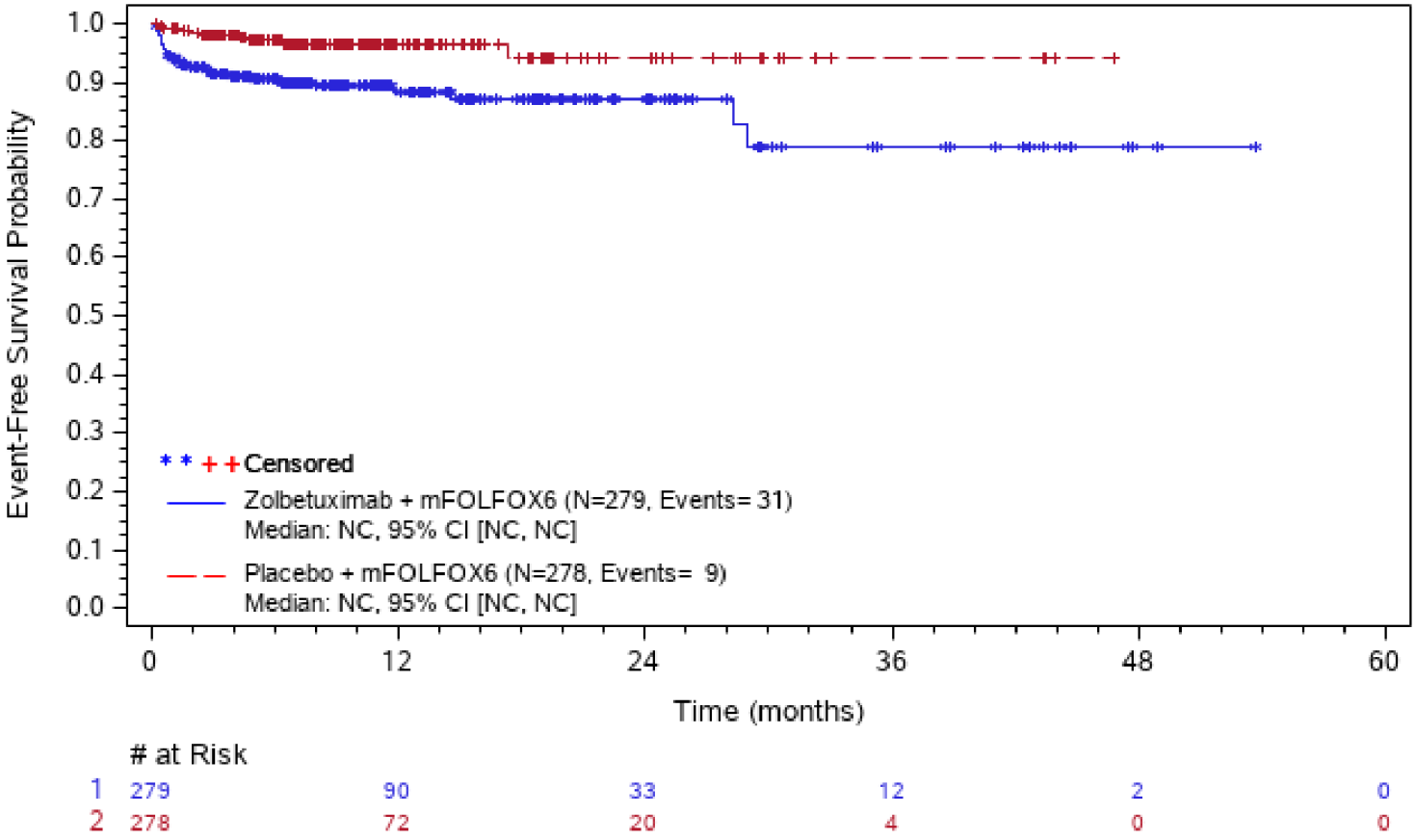
Figure 301.3.2001.91: Kaplan-Meier Plot of Time to first TEAE - Hypocalcaemia (PT) - Safety Analysis Set



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.

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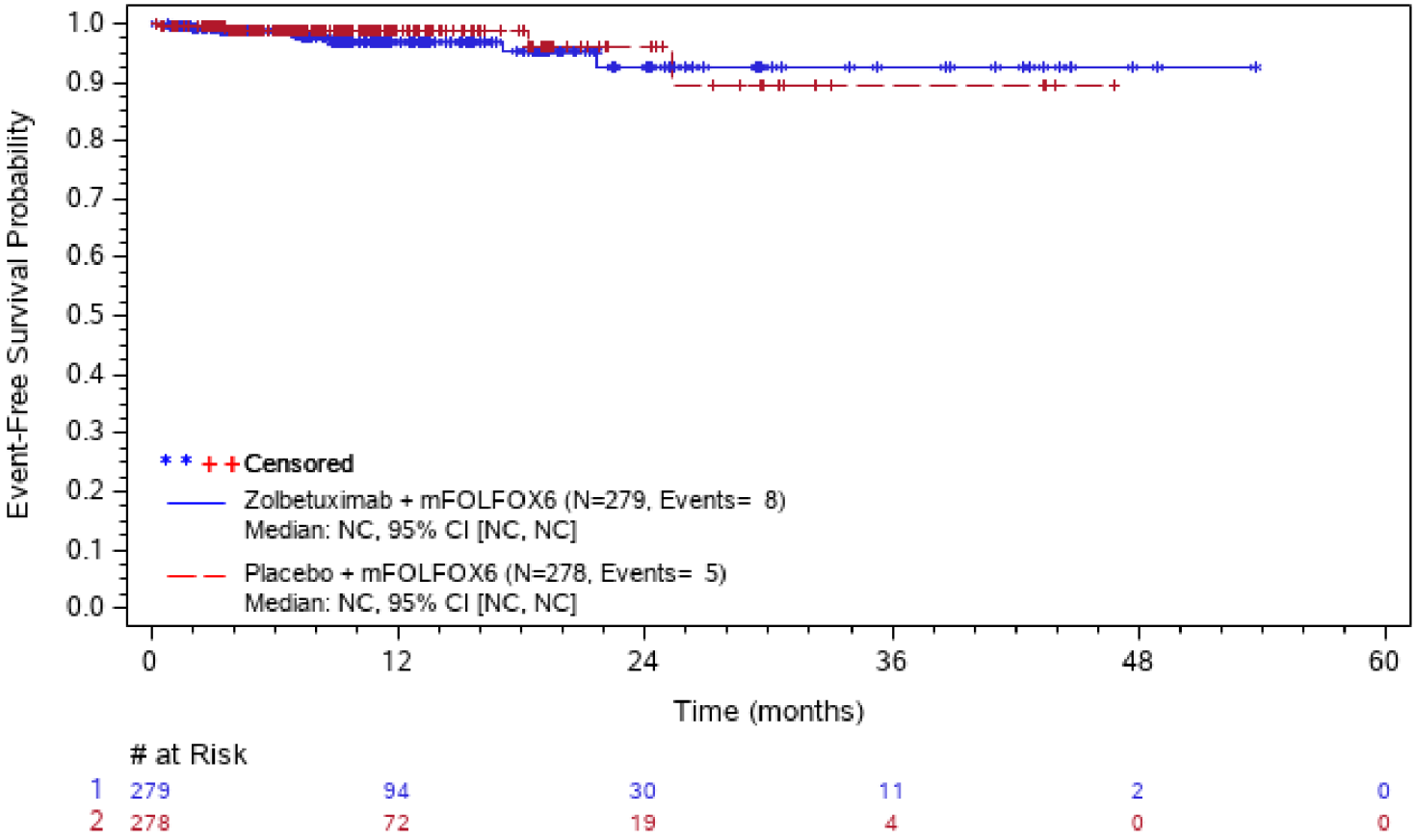
Figure 301.3.2001.92: Kaplan-Meier Plot of Time to first TEAE - Hypoglycaemia (PT) - Safety Analysis Set



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.

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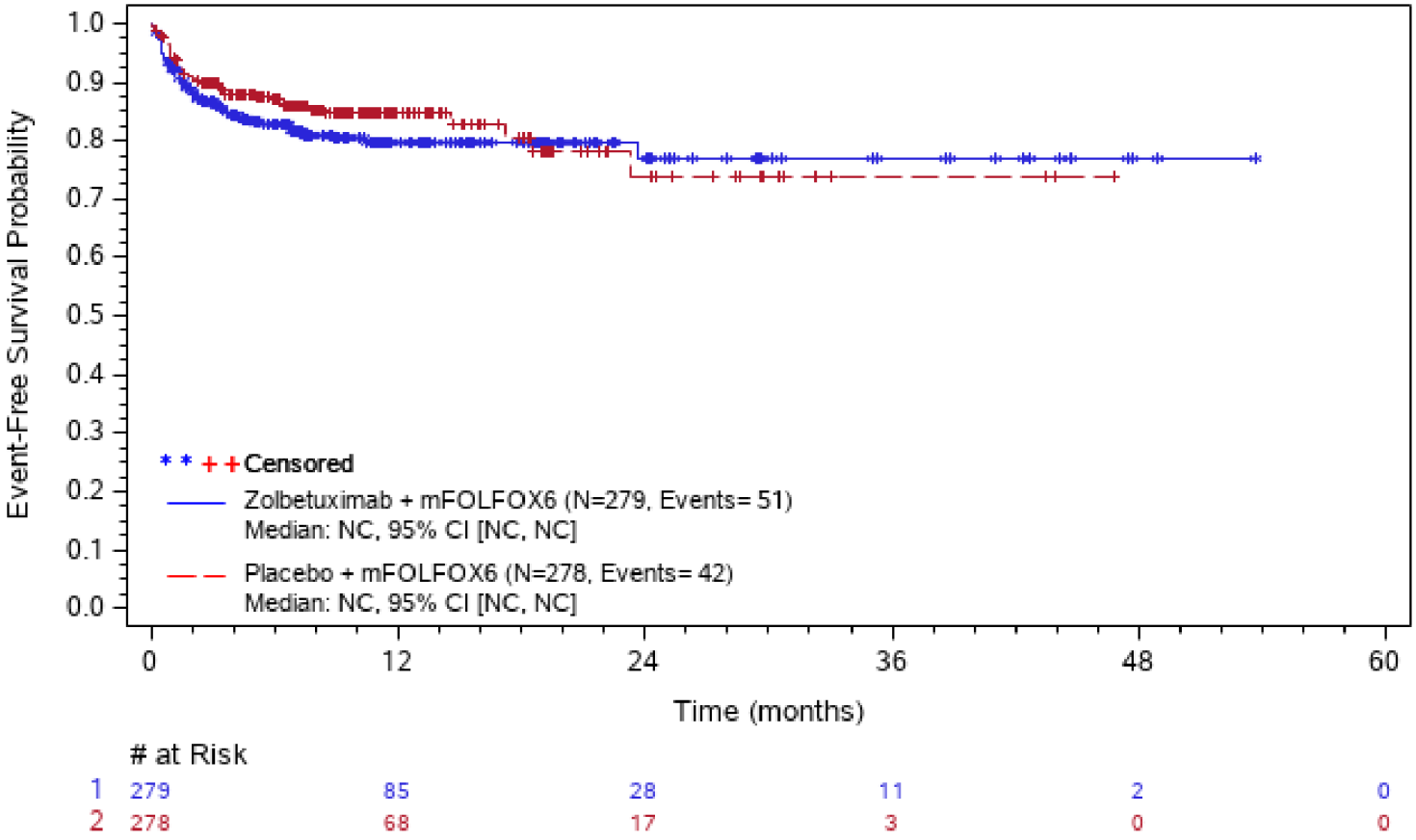
Figure 301.3.2001.93: Kaplan-Meier Plot of Time to first TEAE - Hypokalaemia (PT) - Safety Analysis Set



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.

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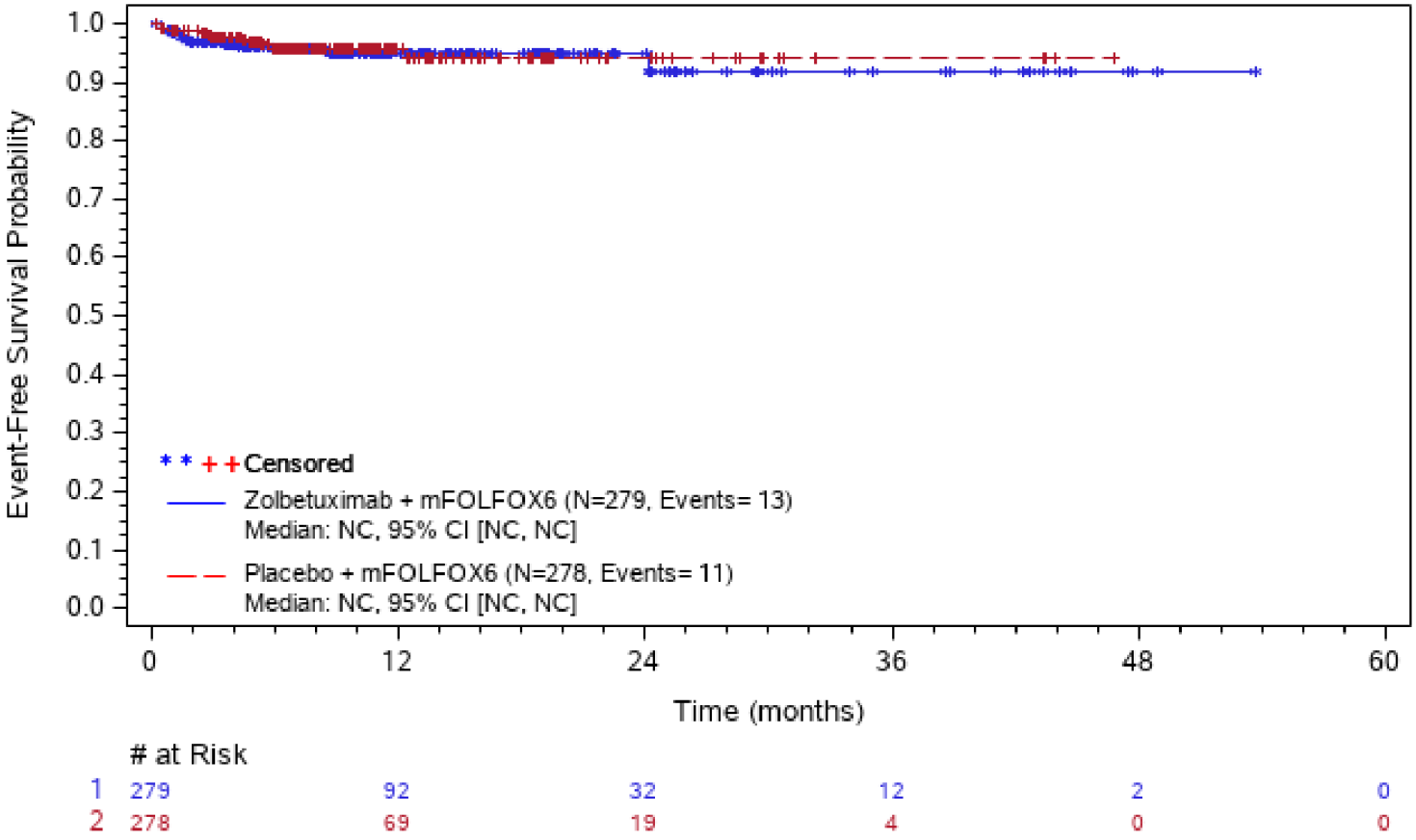
Figure 301.3.2001.94: Kaplan-Meier Plot of Time to first TEAE - Hypomagnesaemia (PT) - Safety Analysis Set



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.

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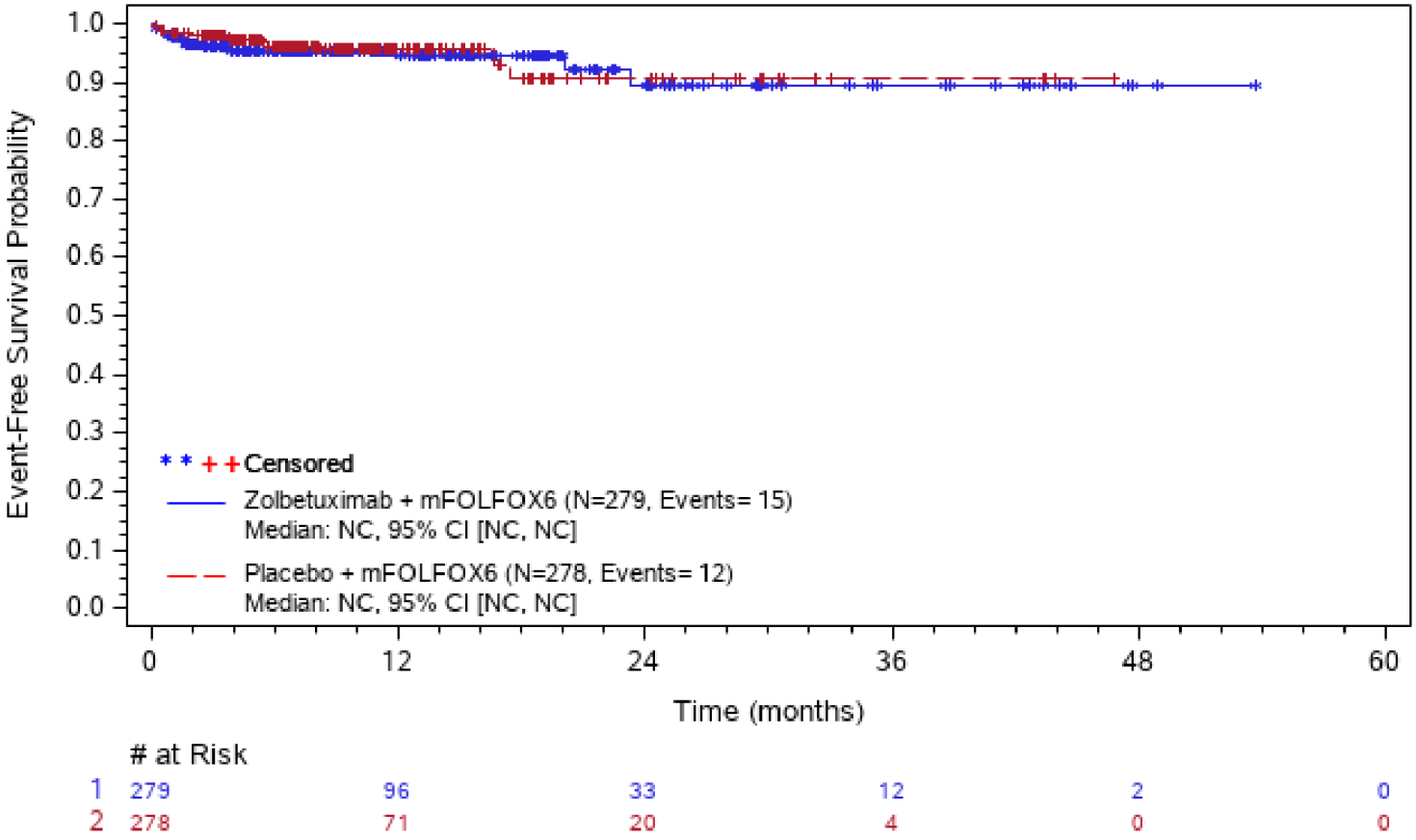
Figure 301.3.2001.95: Kaplan-Meier Plot of Time to first TEAE - Hyponatraemia (PT) - Safety Analysis Set



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.

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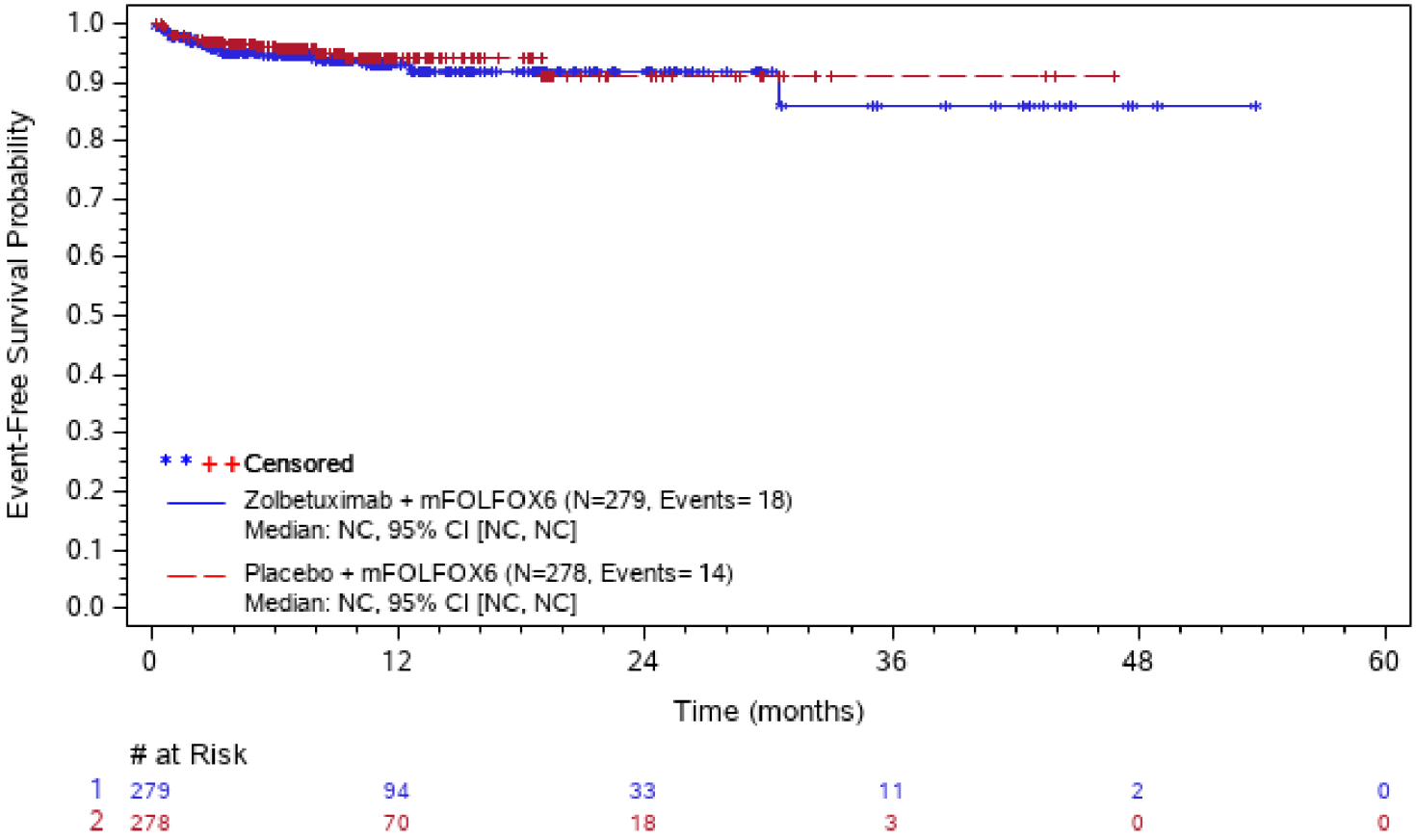
Figure 301.3.2001.96: Kaplan-Meier Plot of Time to first TEAE - Hypophosphataemia (PT) - Safety Analysis Set



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.

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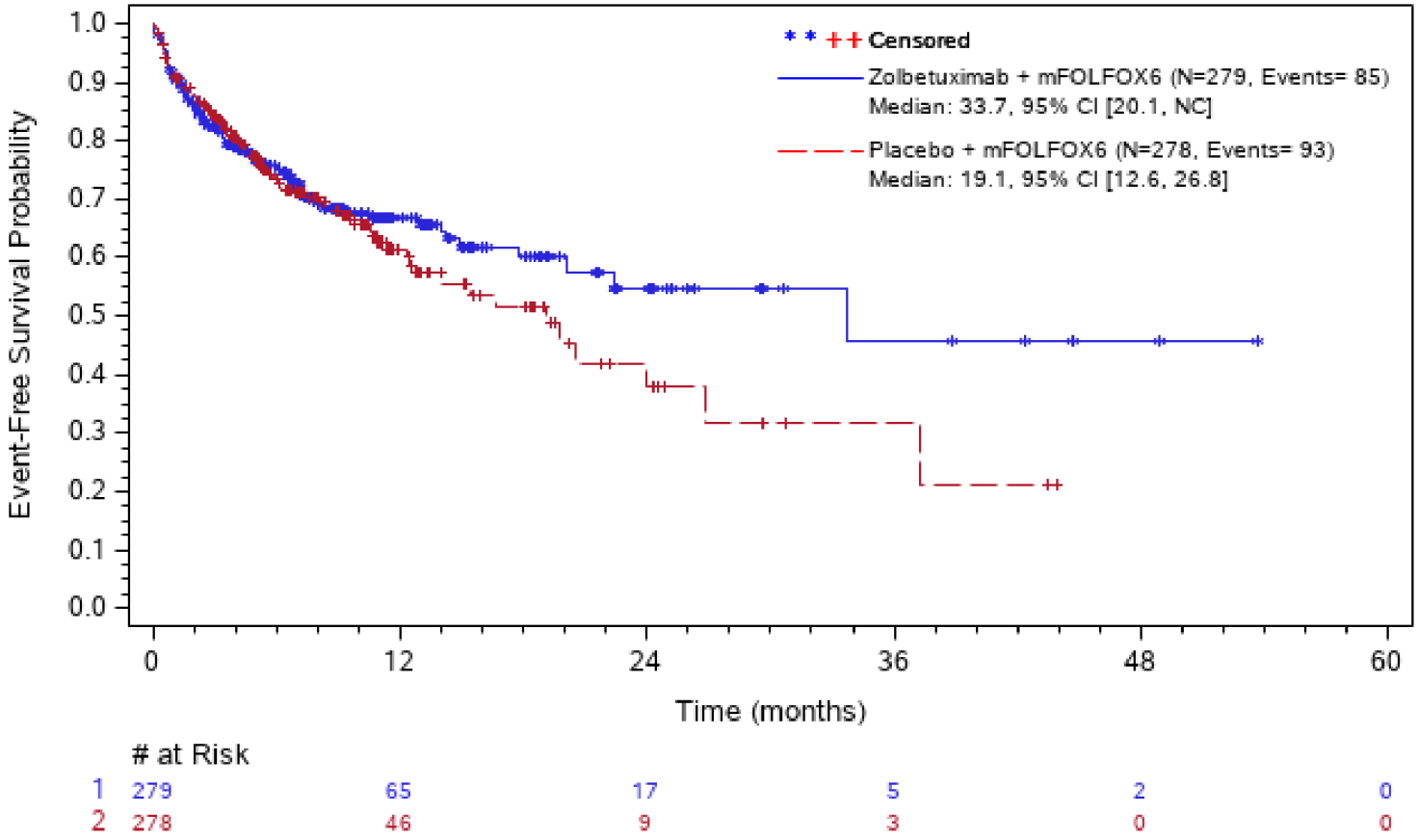
Figure 301.3.2001.97: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal And Connective Tissue Disorders (SOC) - Safety Analysis Set



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.

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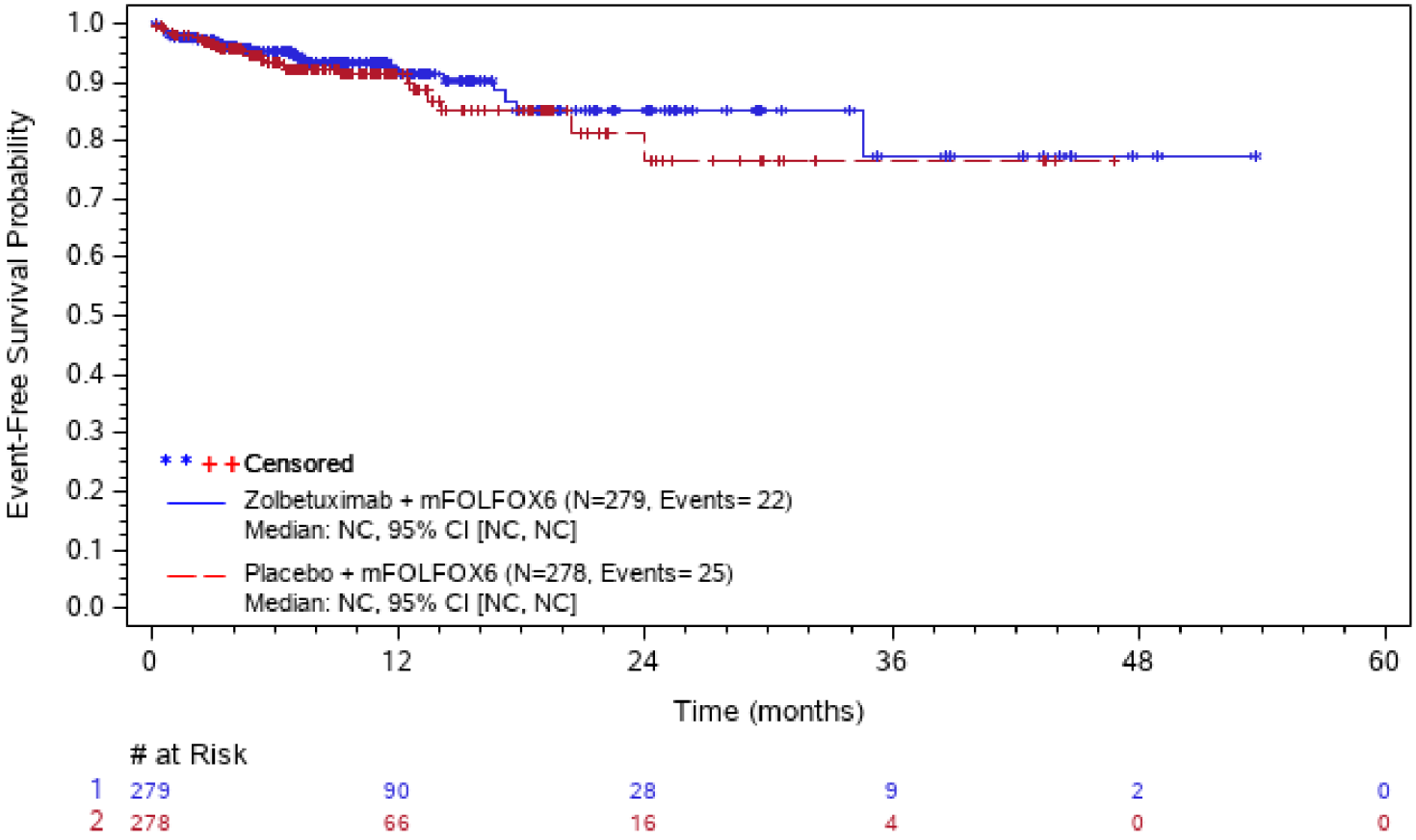
Figure 301.3.2001.98: Kaplan-Meier Plot of Time to first TEAE - Arthralgia (PT) - Safety Analysis Set



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.

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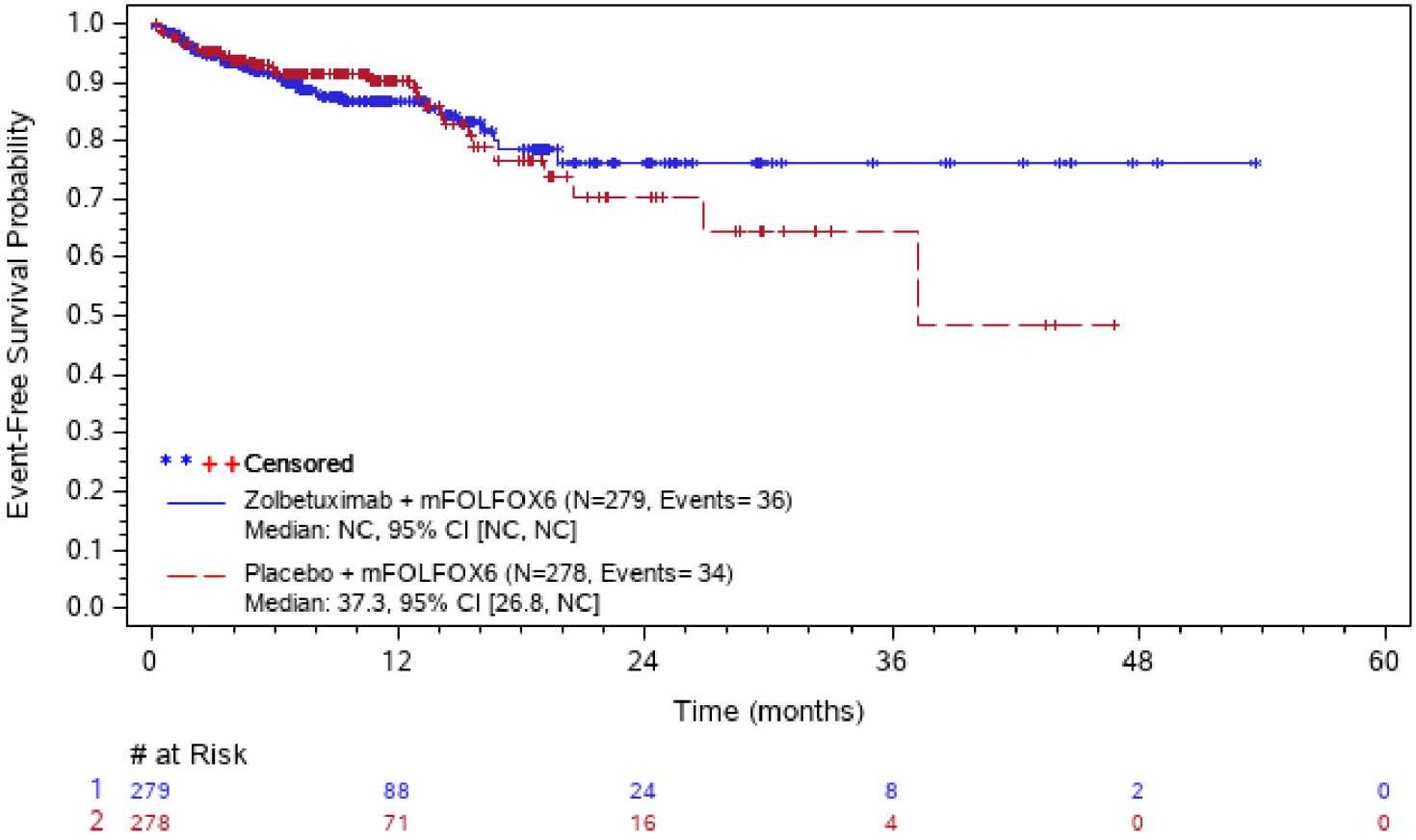
Figure 301.3.2001.99: Kaplan-Meier Plot of Time to first TEAE - Back Pain (PT) - Safety Analysis Set



# at Risk						
1	279	88	24	8	2	0
2	278	71	16	4	0	0

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: 08SEP23

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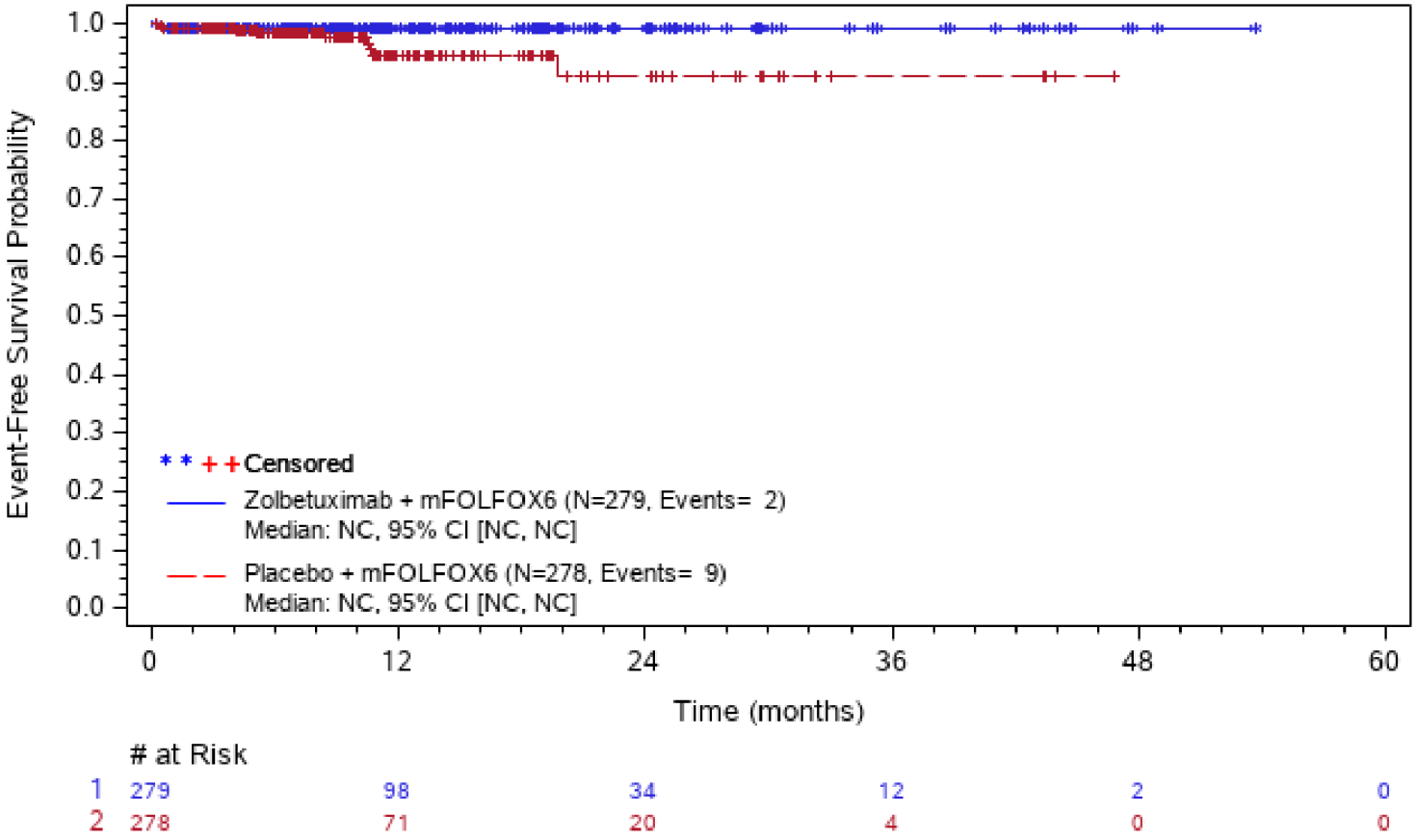
Figure 301.3.2001.100: Kaplan-Meier Plot of Time to first TEAE - Flank Pain (PT) - Safety Analysis Set



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: 08SEP23

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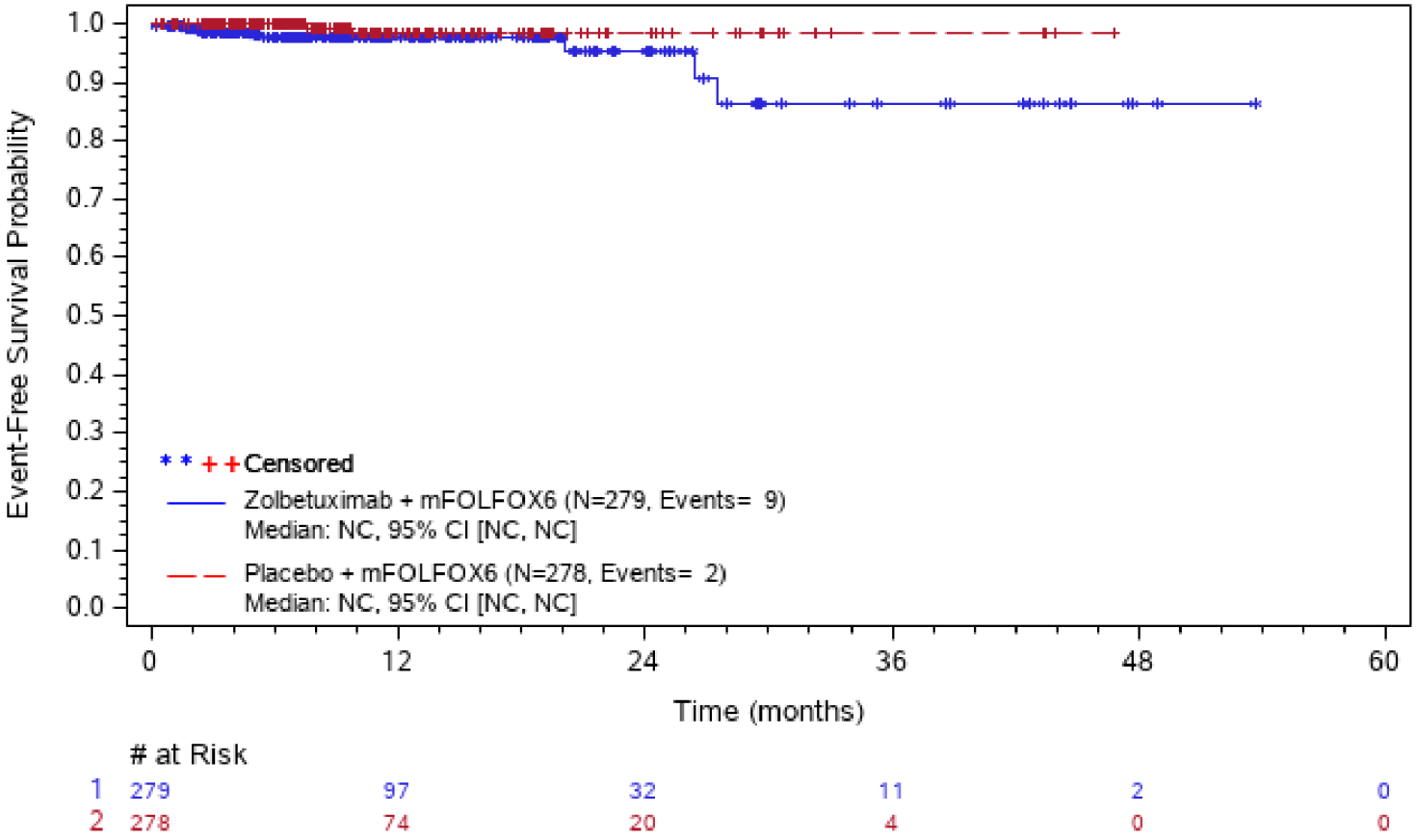
Figure 301.3.2001.101: Kaplan-Meier Plot of Time to first TEAE - Muscular Weakness (PT) - Safety Analysis Set



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.

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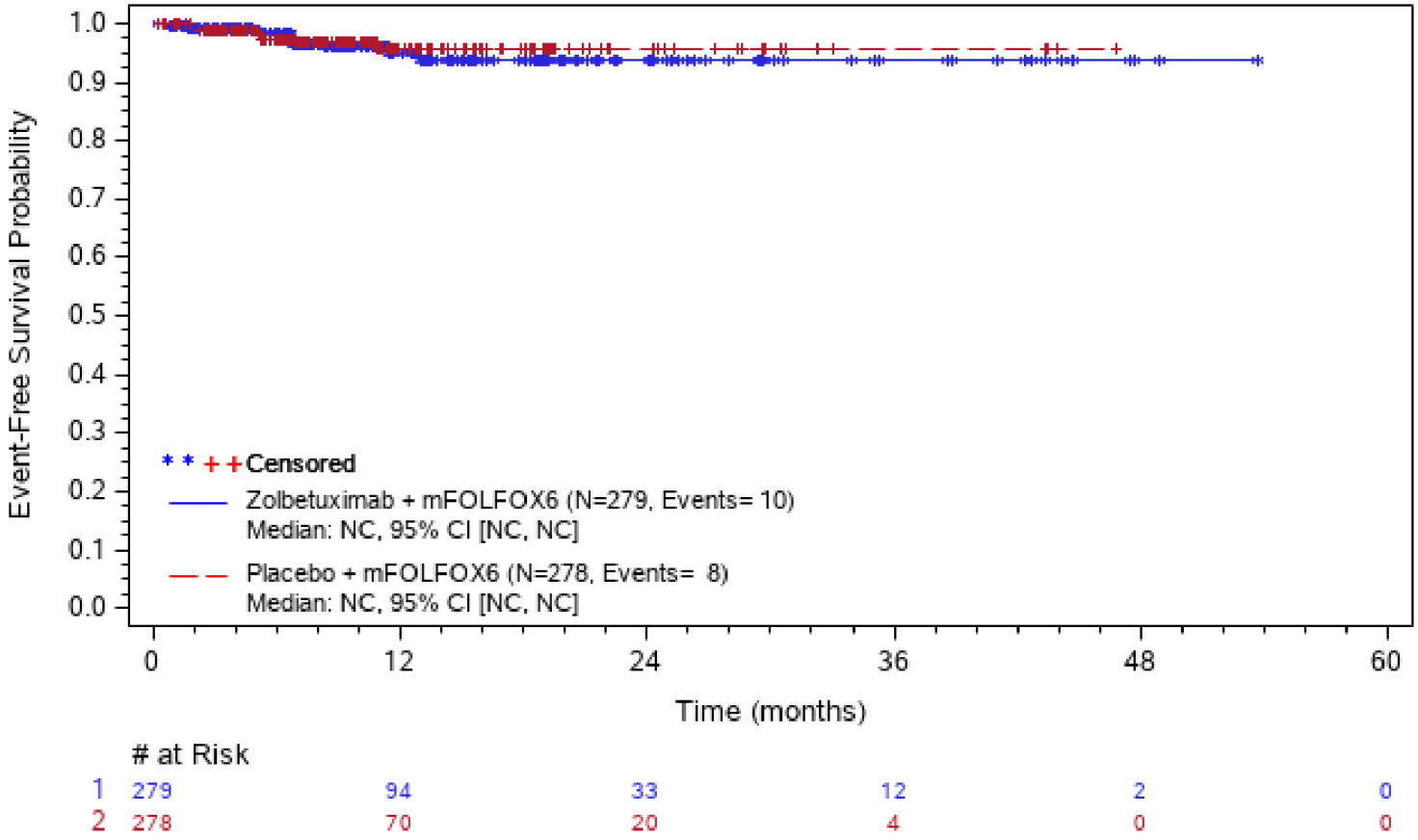
Figure 301.3.2001.102: Kaplan-Meier Plot of Time to first TEAE - Musculoskeletal Chest Pain (PT) - Safety Analysis Set

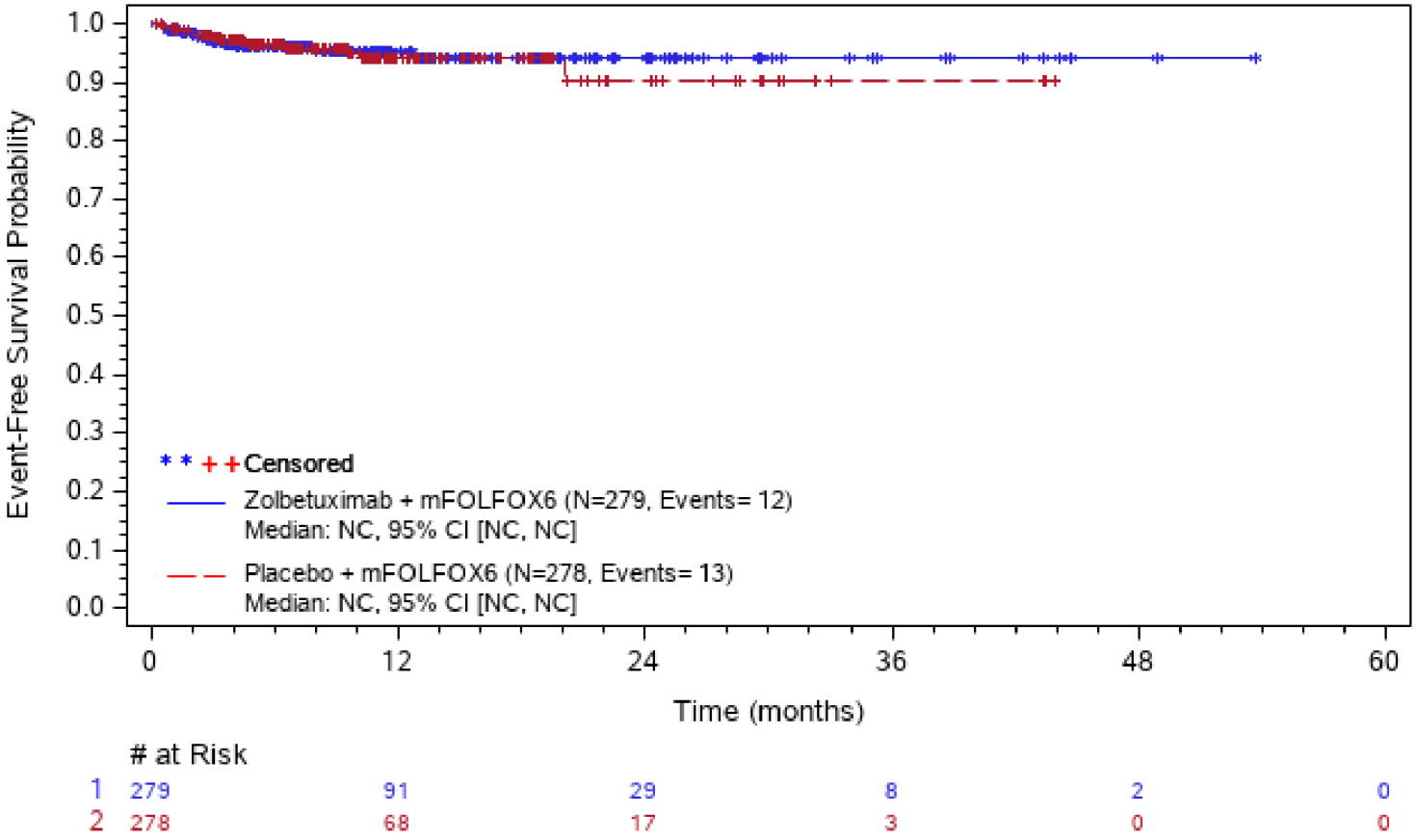


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.103: Kaplan-Meier Plot of Time to first TEAE - Myalgia (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: 08SEP23

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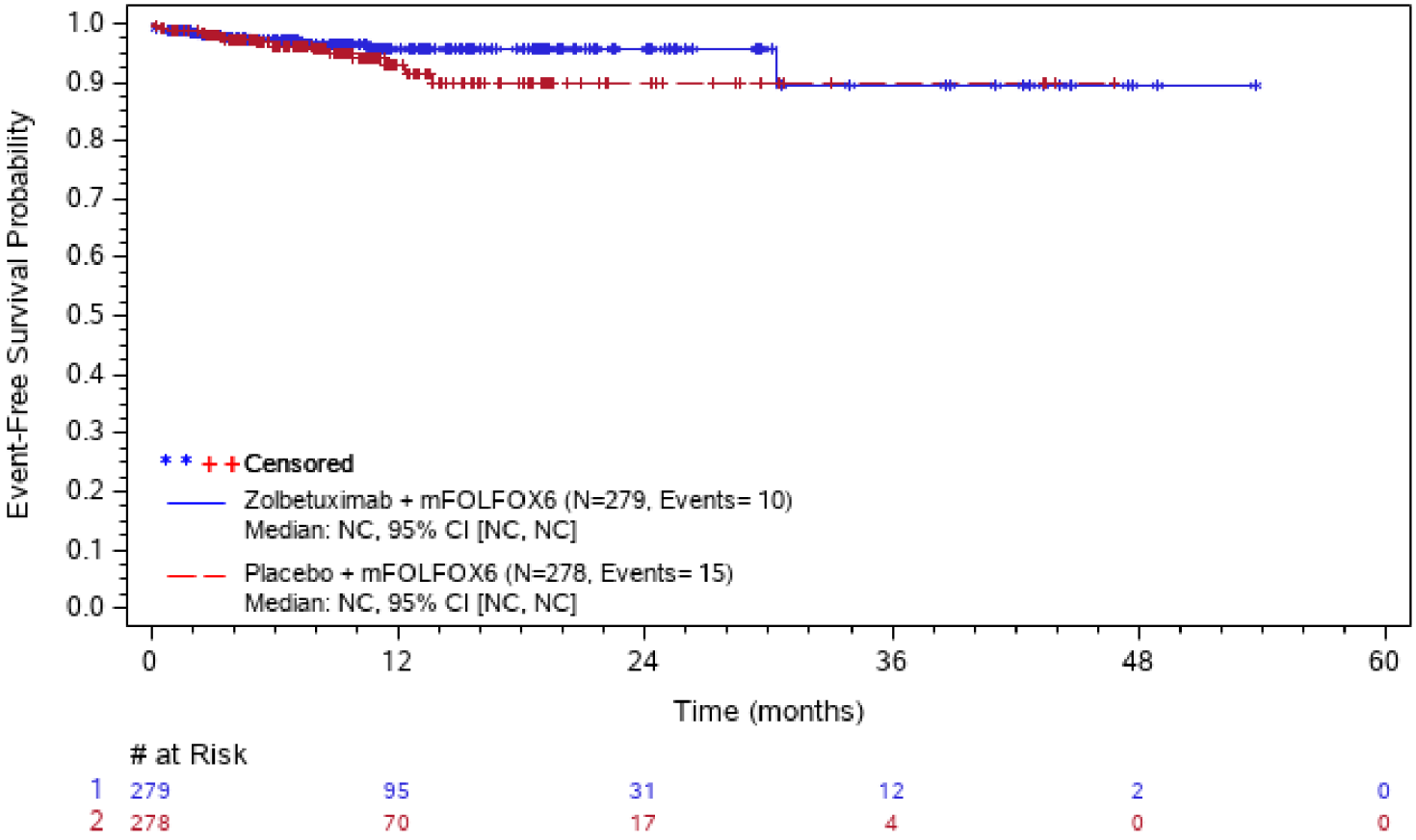
Figure 301.3.2001.104: Kaplan-Meier Plot of Time to first TEAE - Pain In Extremity (PT) - Safety Analysis Set



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: 08SEP23

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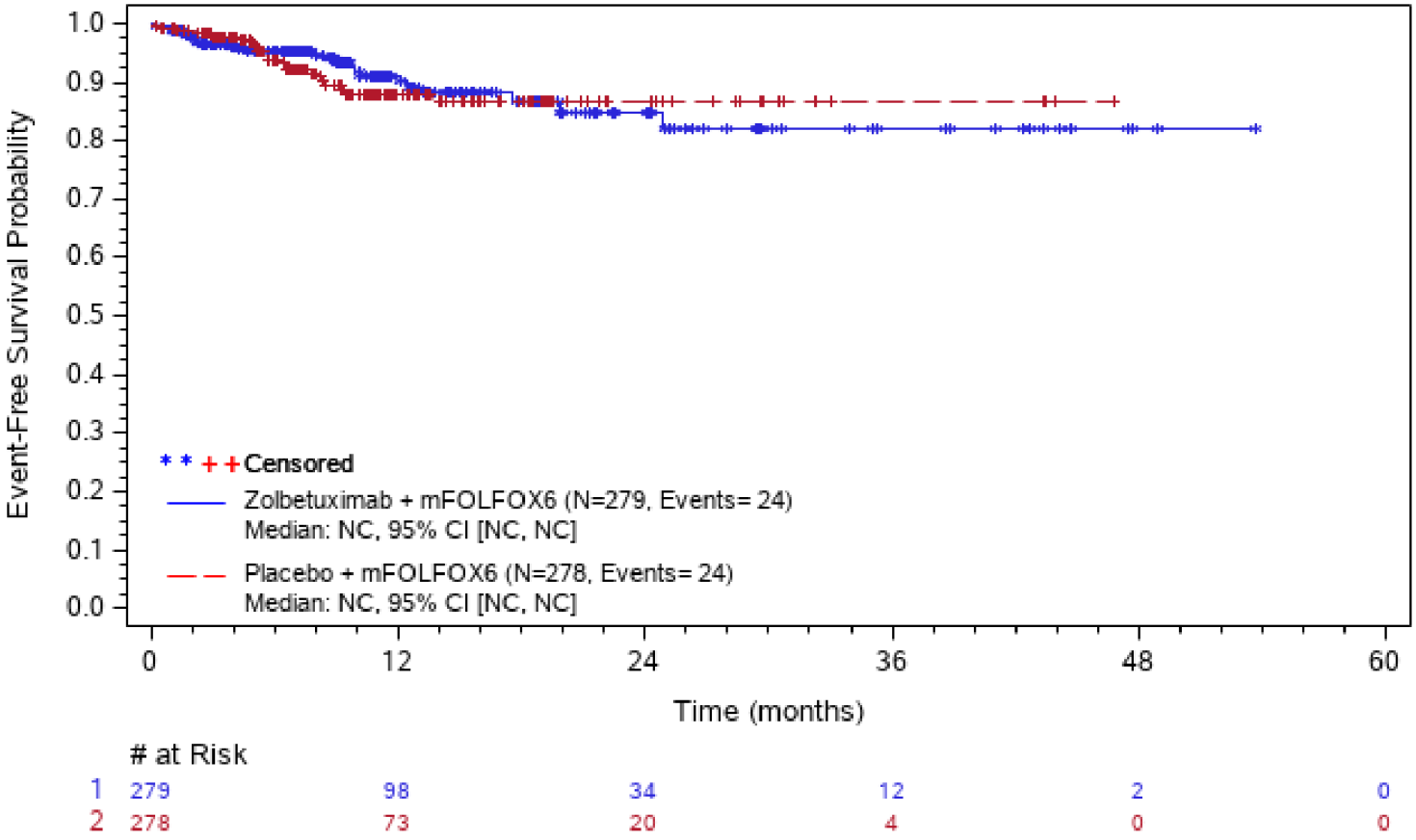
Figure 301.3.2001.105: Kaplan-Meier Plot of Time to first TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

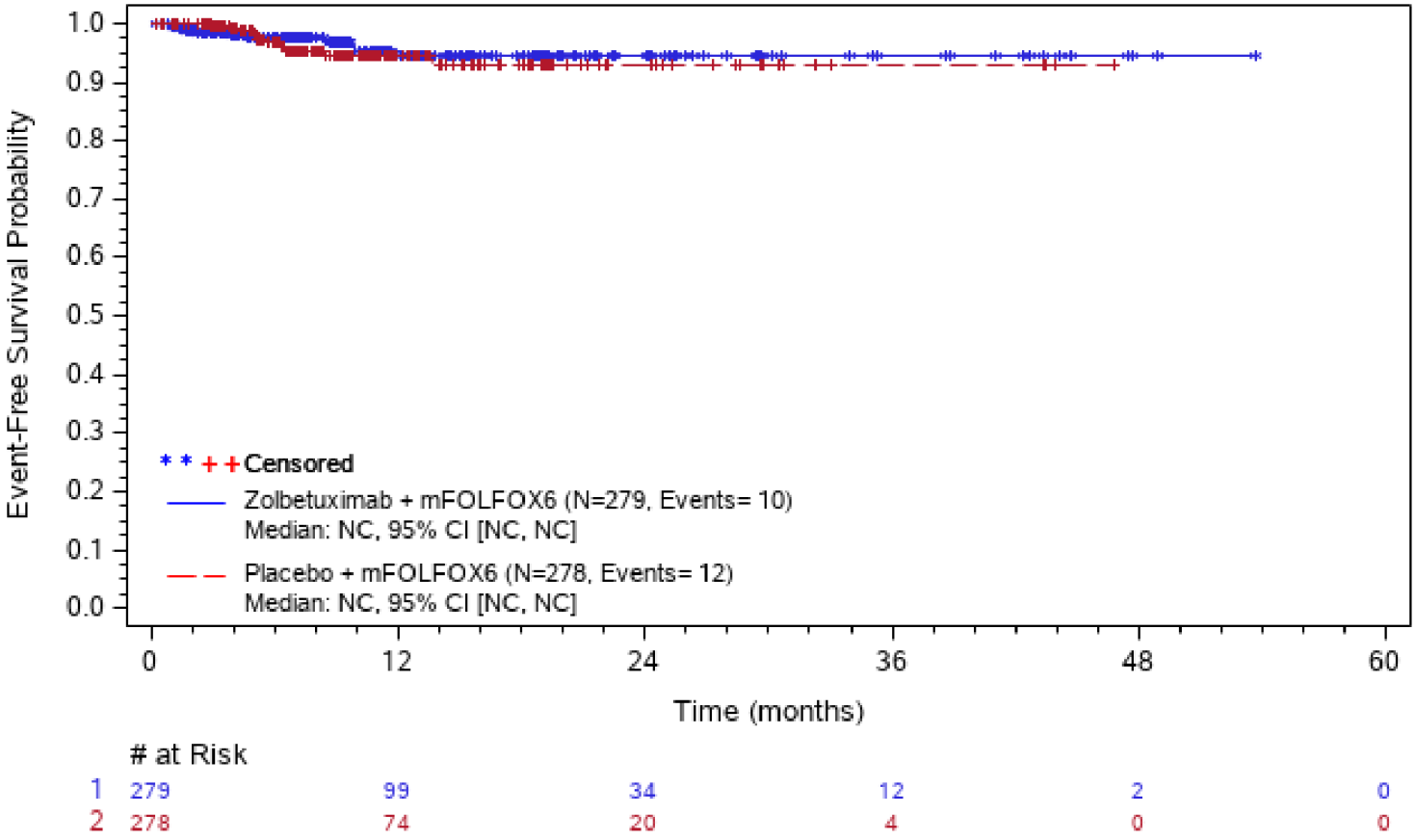


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.106: Kaplan-Meier Plot of Time to first TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set

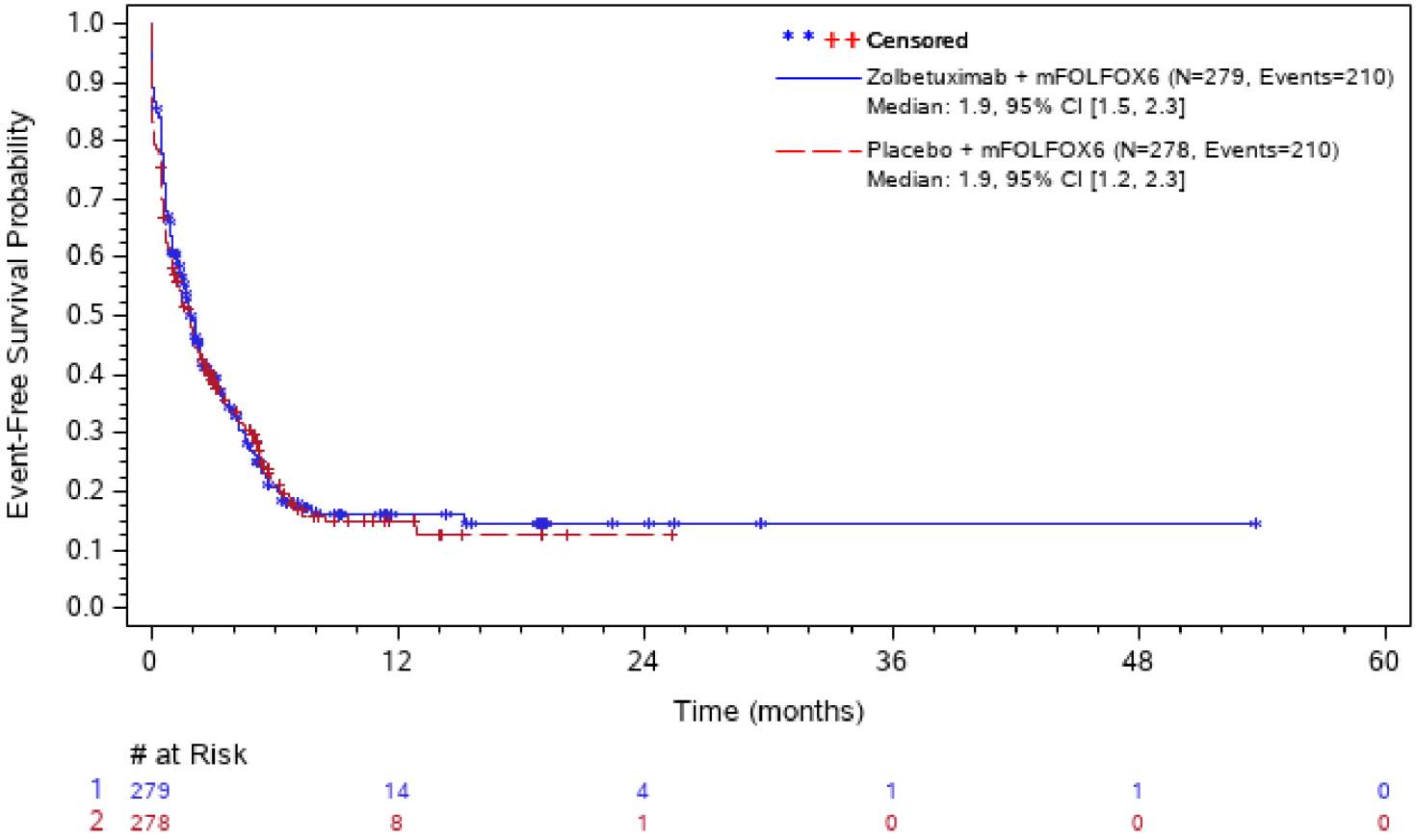


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.107: 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: 08SEP23

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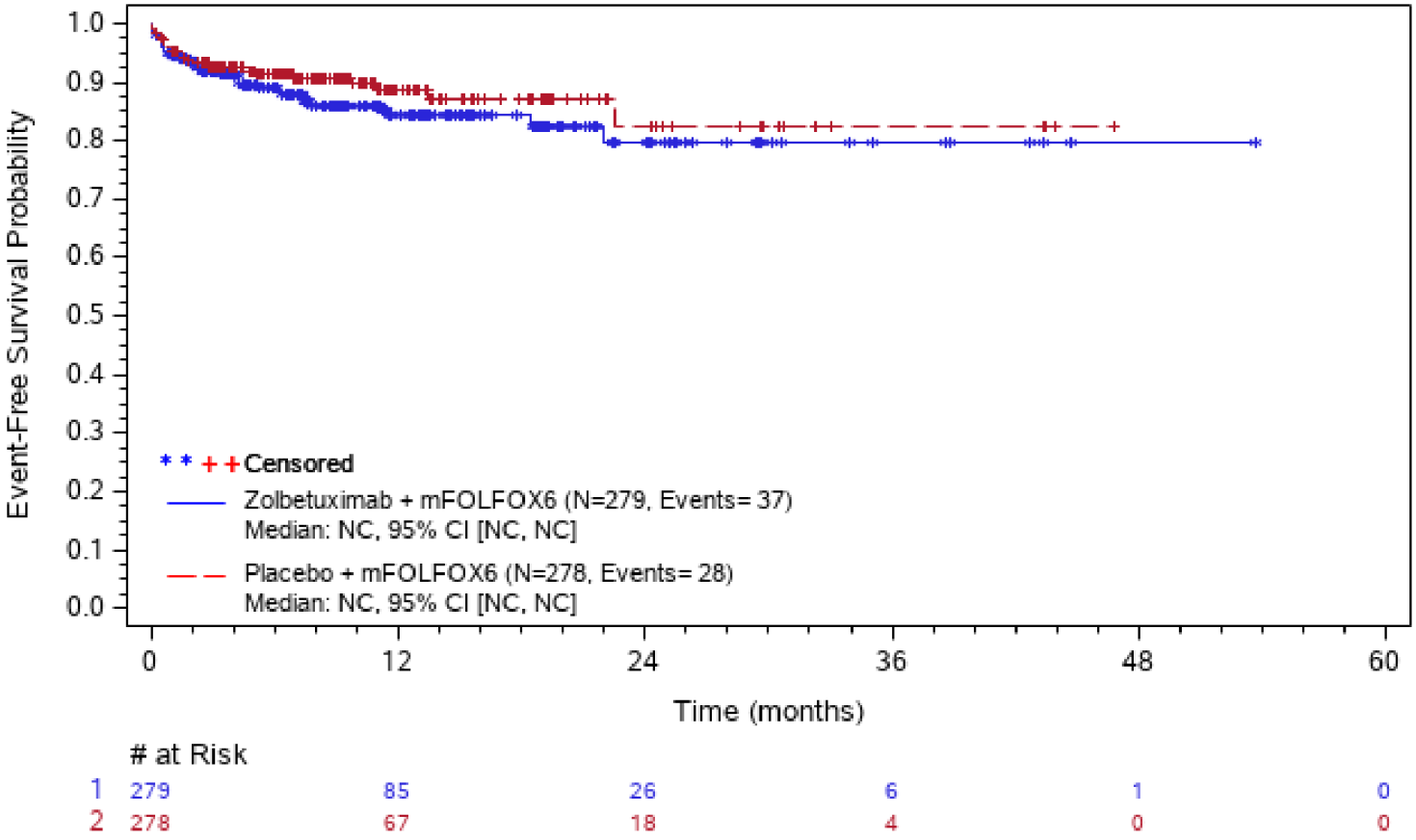
Figure 301.3.2001.108: Kaplan-Meier Plot of Time to first TEAE - Dizziness (PT) - Safety Analysis Set



# at Risk						
1	279	85	26	6	1	0
2	278	67	18	4	0	0

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: 08SEP23

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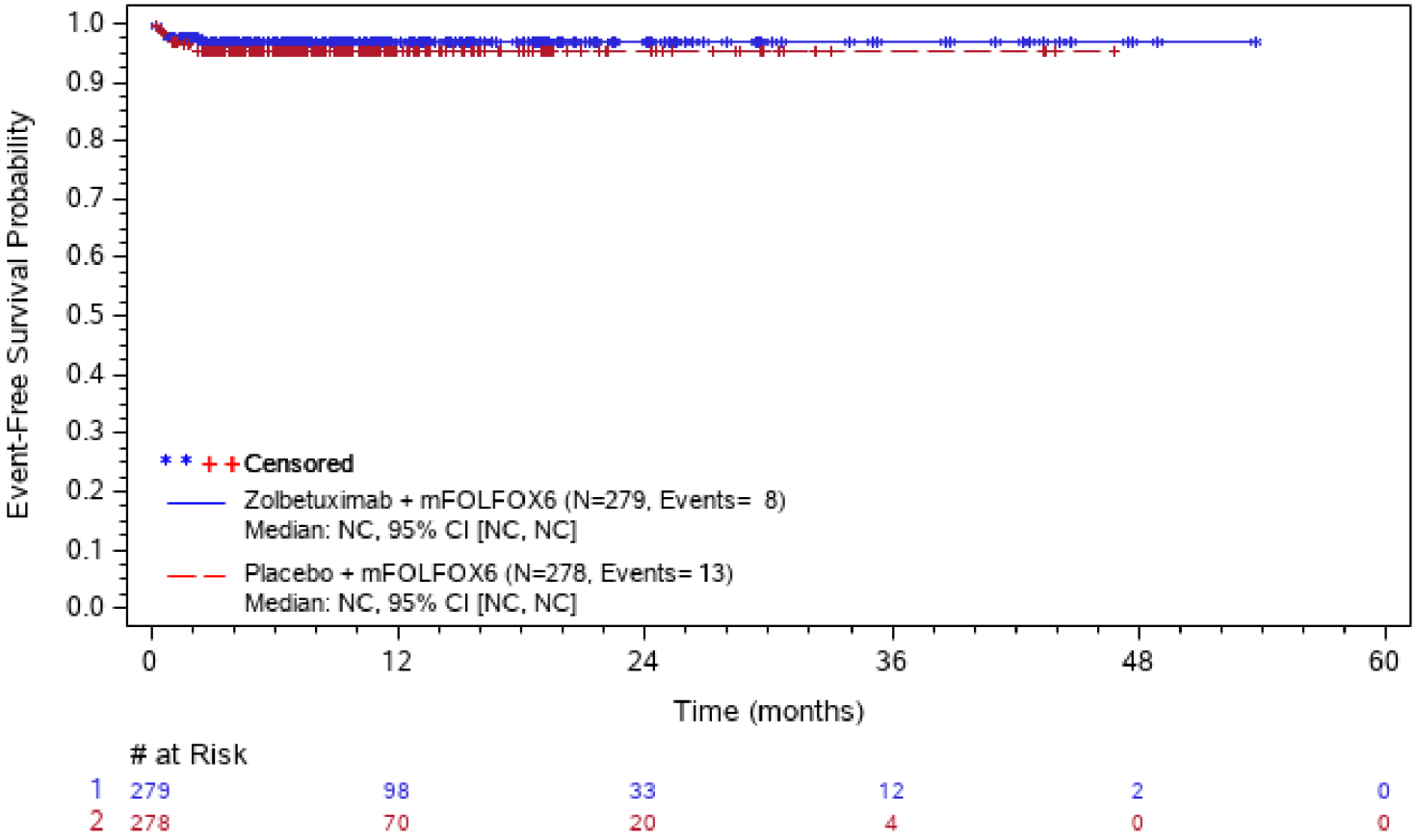
Figure 301.3.2001.109: Kaplan-Meier Plot of Time to first TEAE - Dysaesthesia (PT) - Safety Analysis Set



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.

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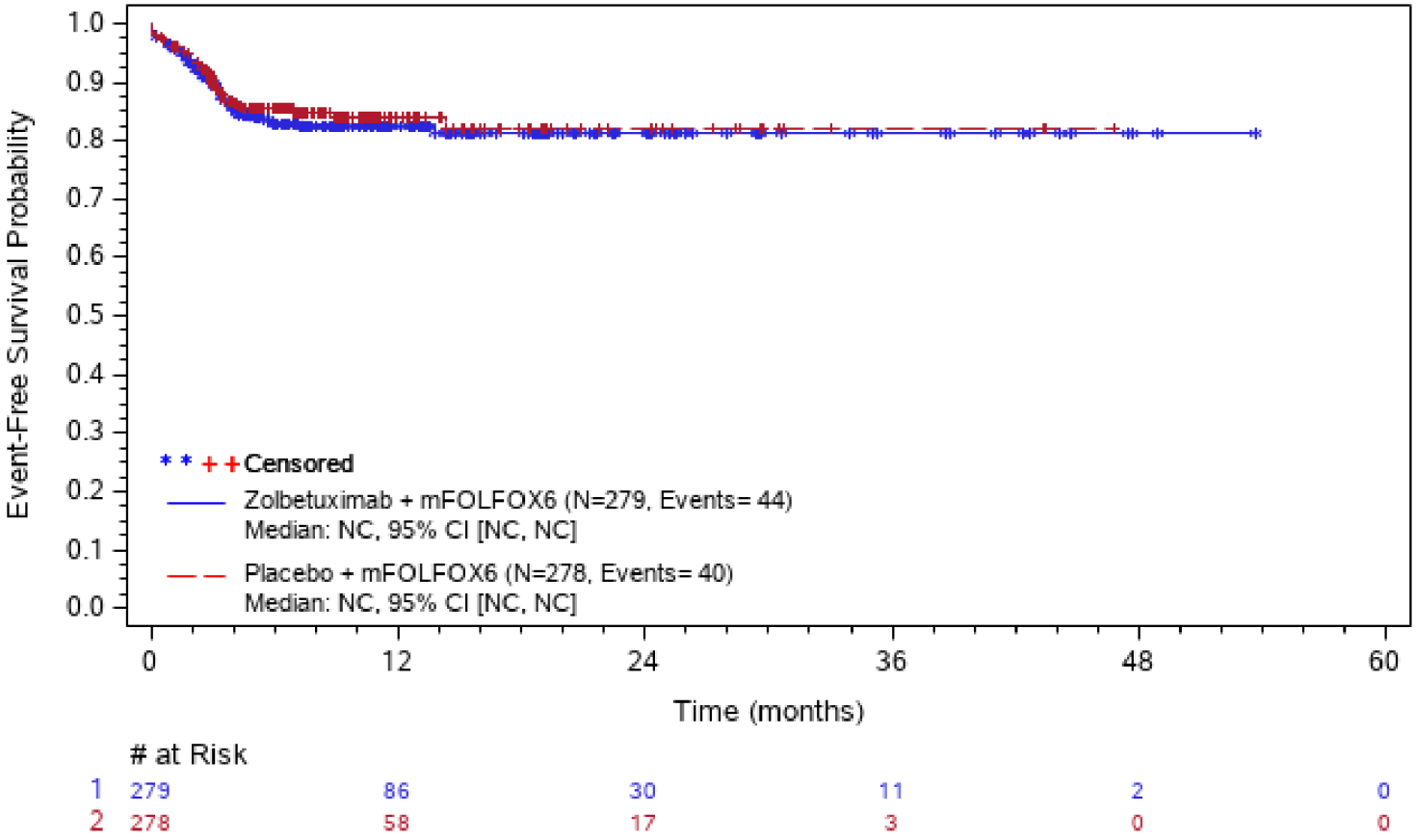
Figure 301.3.2001.110: Kaplan-Meier Plot of Time to first TEAE - Dysgeusia (PT) - Safety Analysis Set



# at Risk						
1	279	86	30	11	2	0
2	278	58	17	3	0	0

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.

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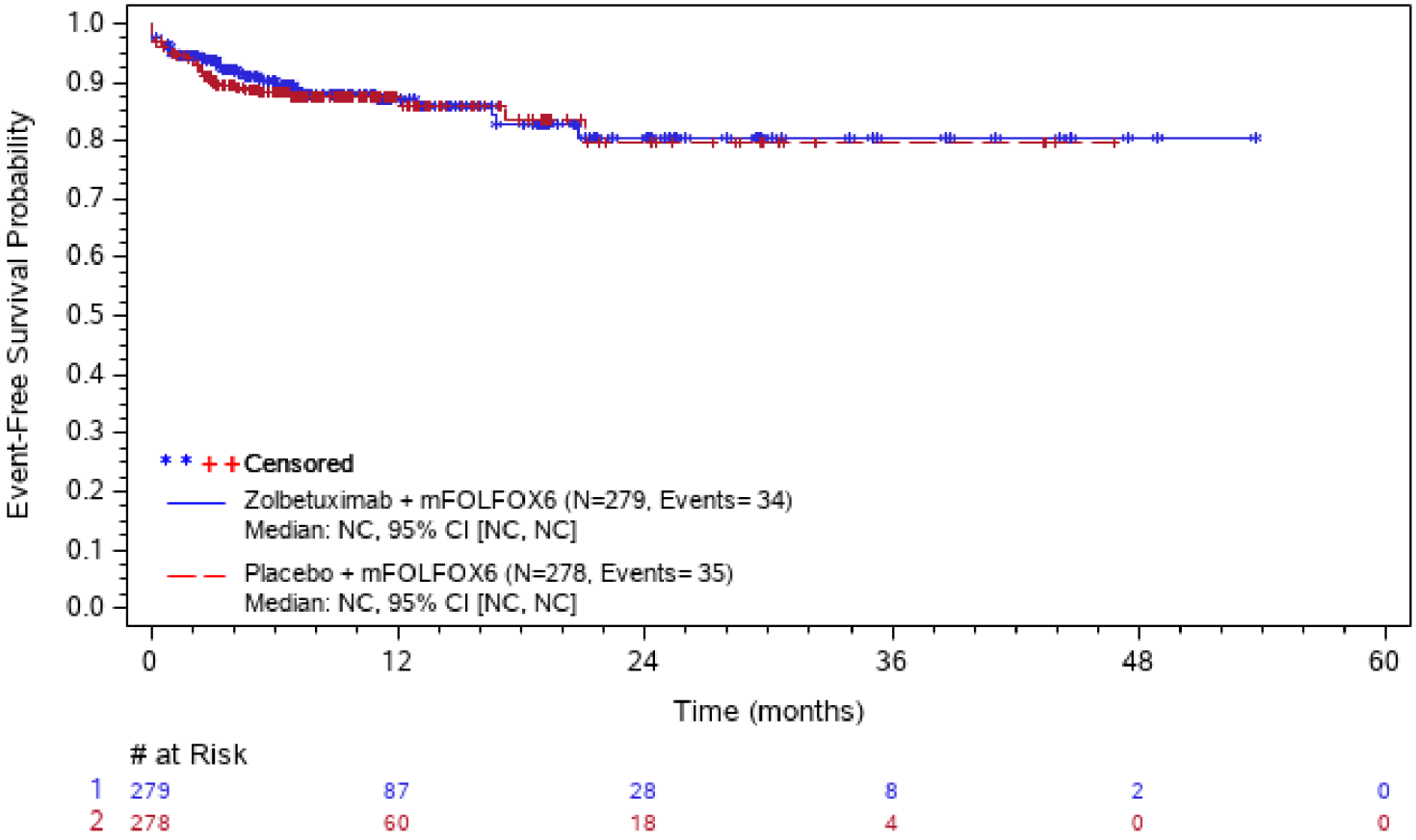
Figure 301.3.2001.111: Kaplan-Meier Plot of Time to first TEAE - Headache (PT) - Safety Analysis Set



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: 08SEP23

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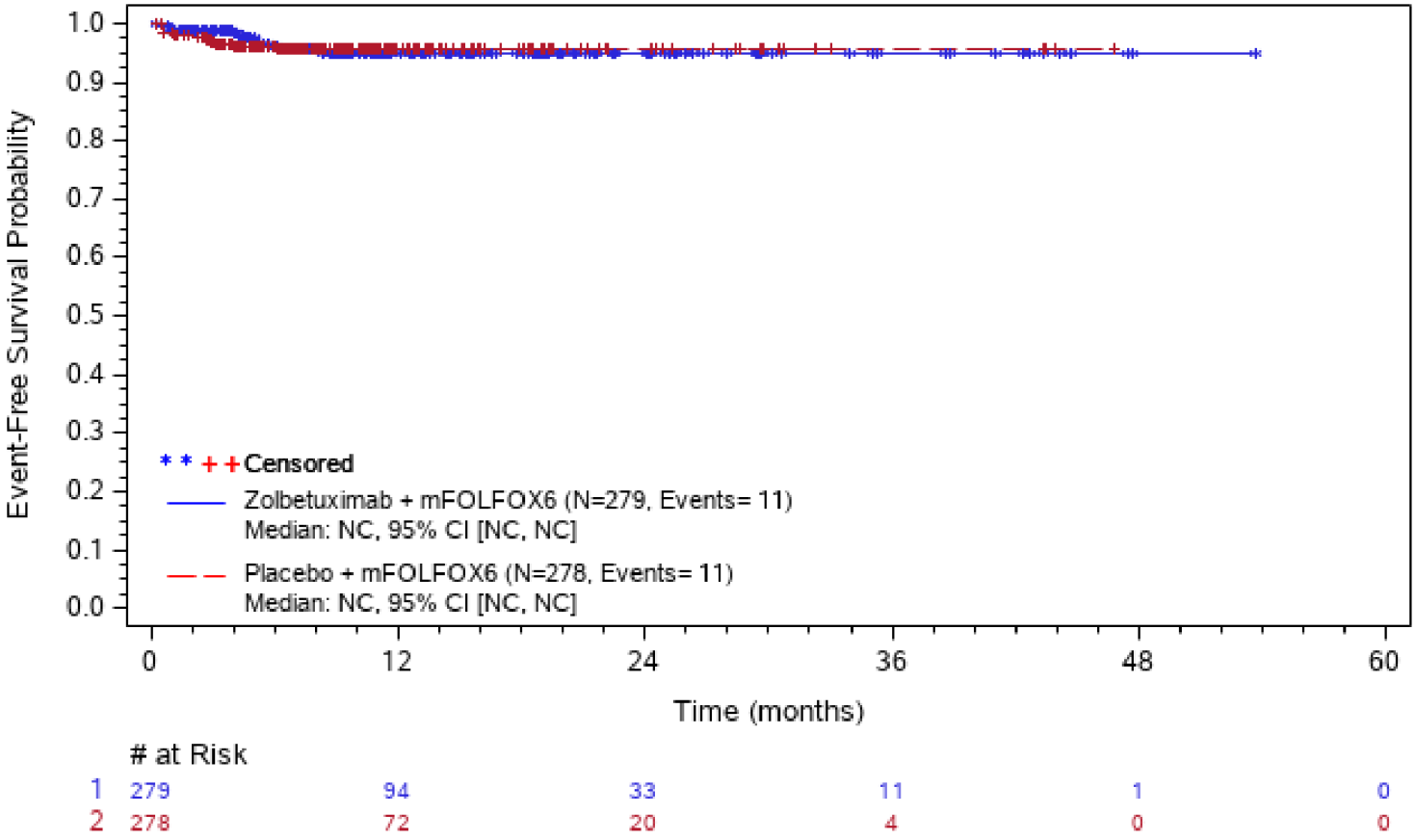
Figure 301.3.2001.112: Kaplan-Meier Plot of Time to first TEAE - Hypoaesthesia (PT) - Safety Analysis Set

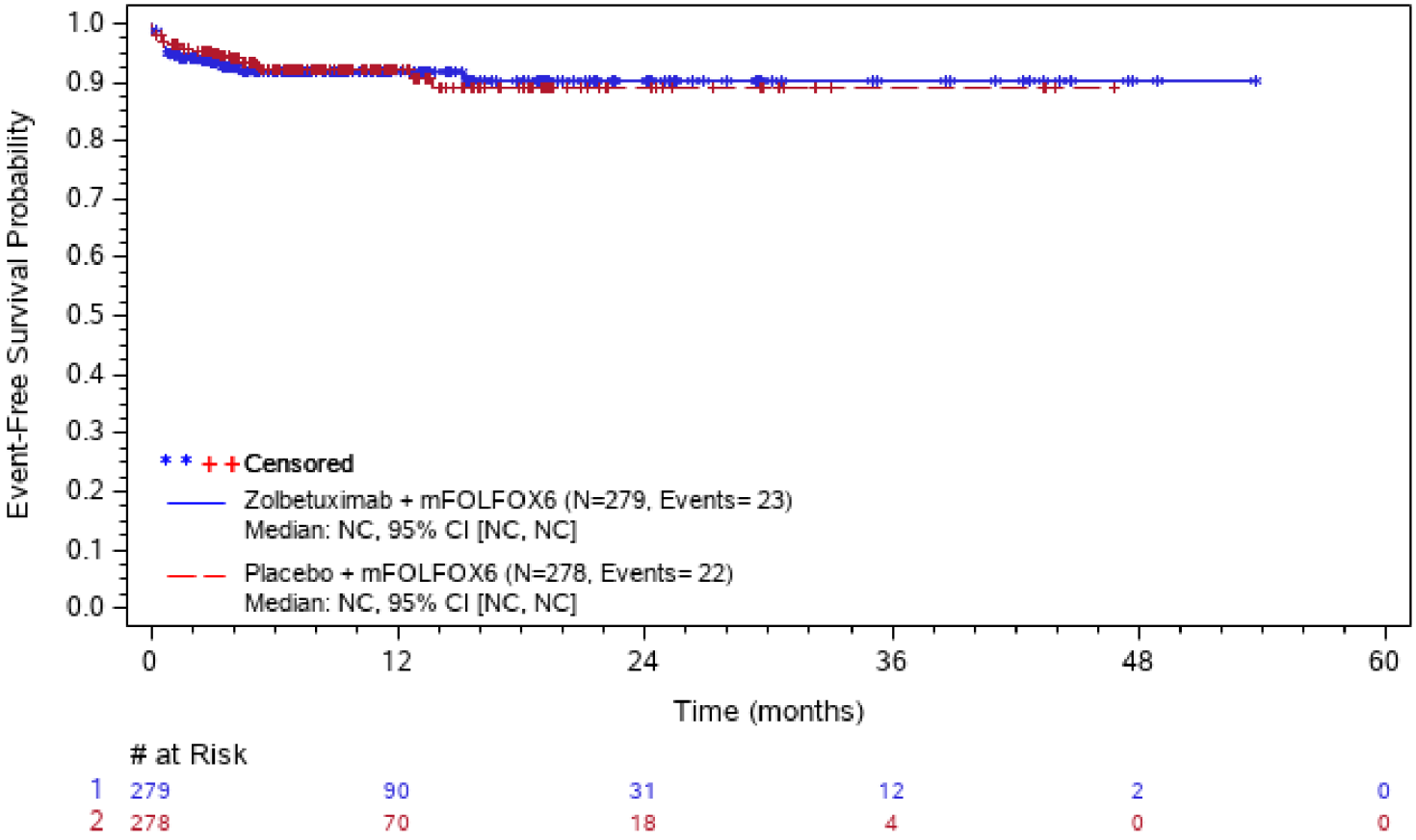


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.113: Kaplan-Meier Plot of Time to first TEAE - Neuropathy Peripheral (PT) - Safety Analysis Set

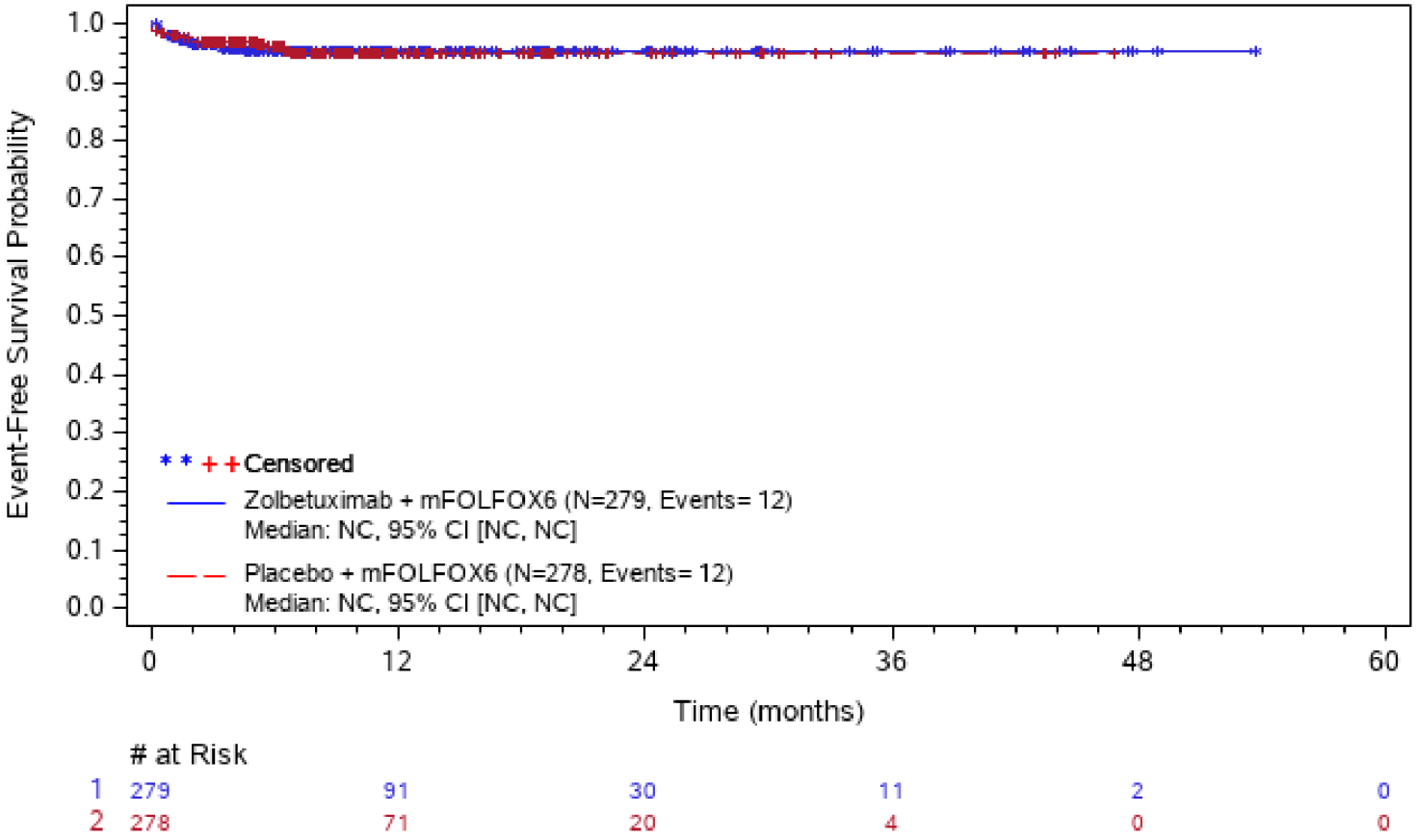


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.114: Kaplan-Meier Plot of Time to first TEAE - Neurotoxicity (PT) - Safety Analysis Set

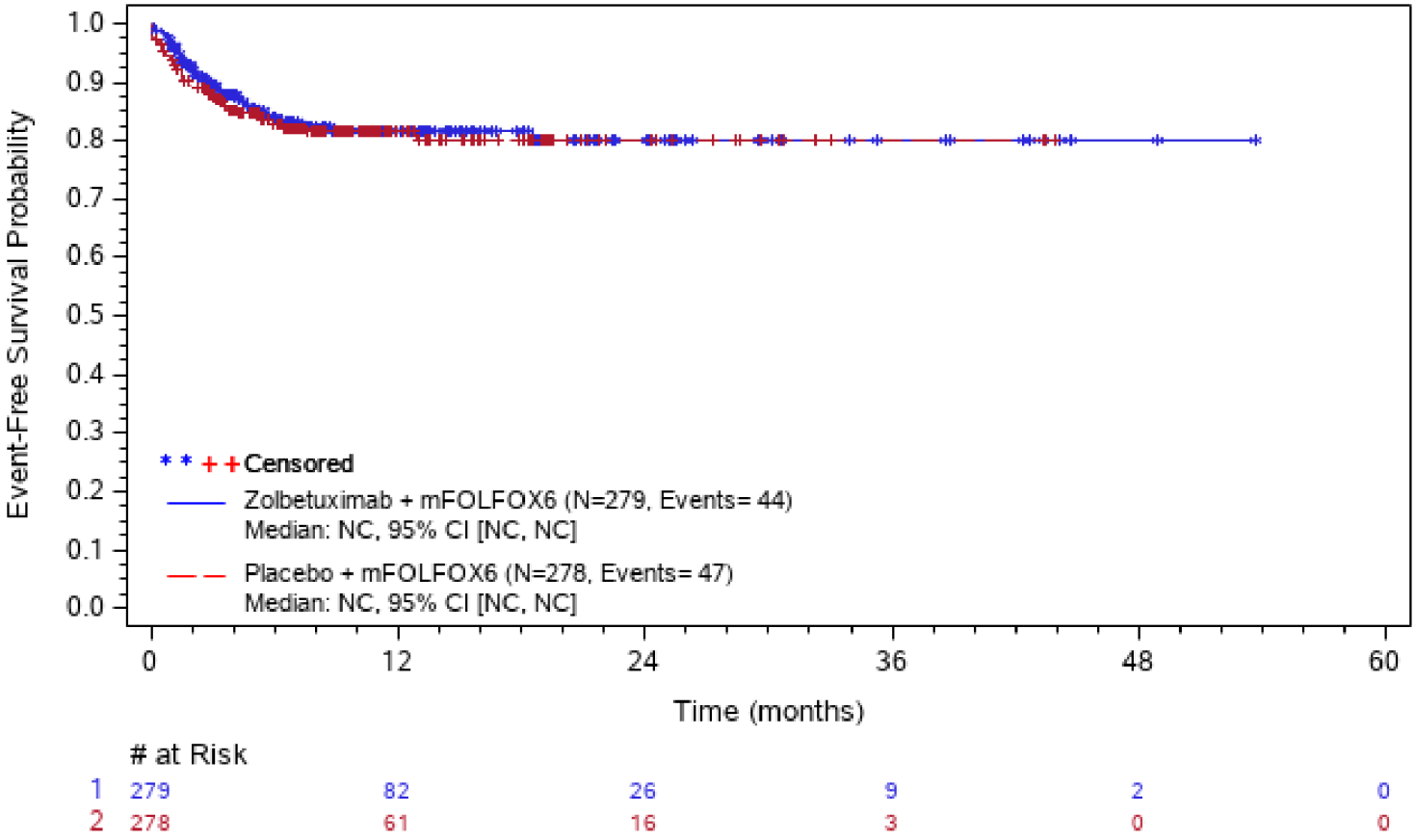


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.115: Kaplan-Meier Plot of Time to first TEAE - Paraesthesia (PT) - Safety Analysis Set

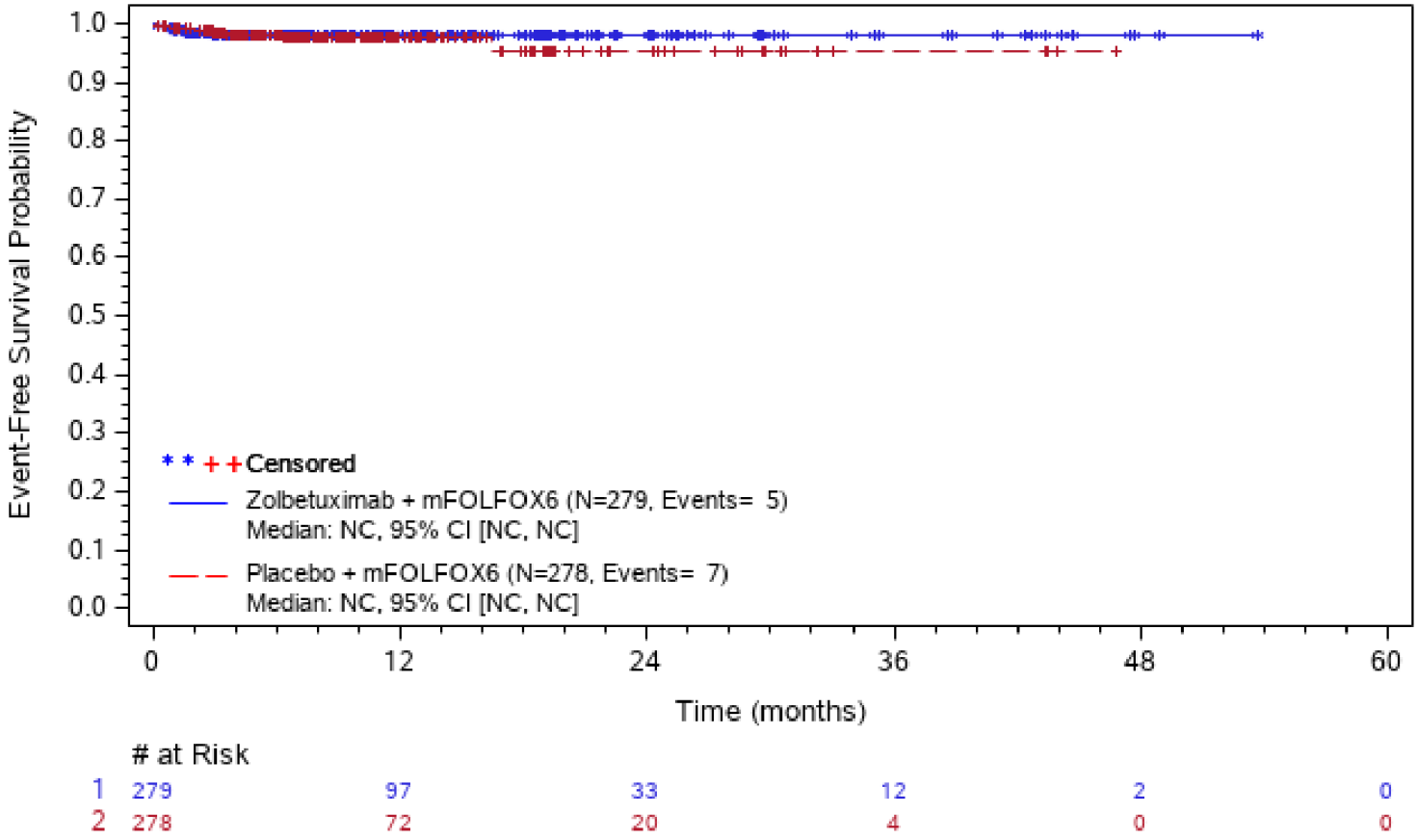


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.116: Kaplan-Meier Plot of Time to first TEAE - Peripheral Motor Neuropathy (PT) - Safety Analysis Set

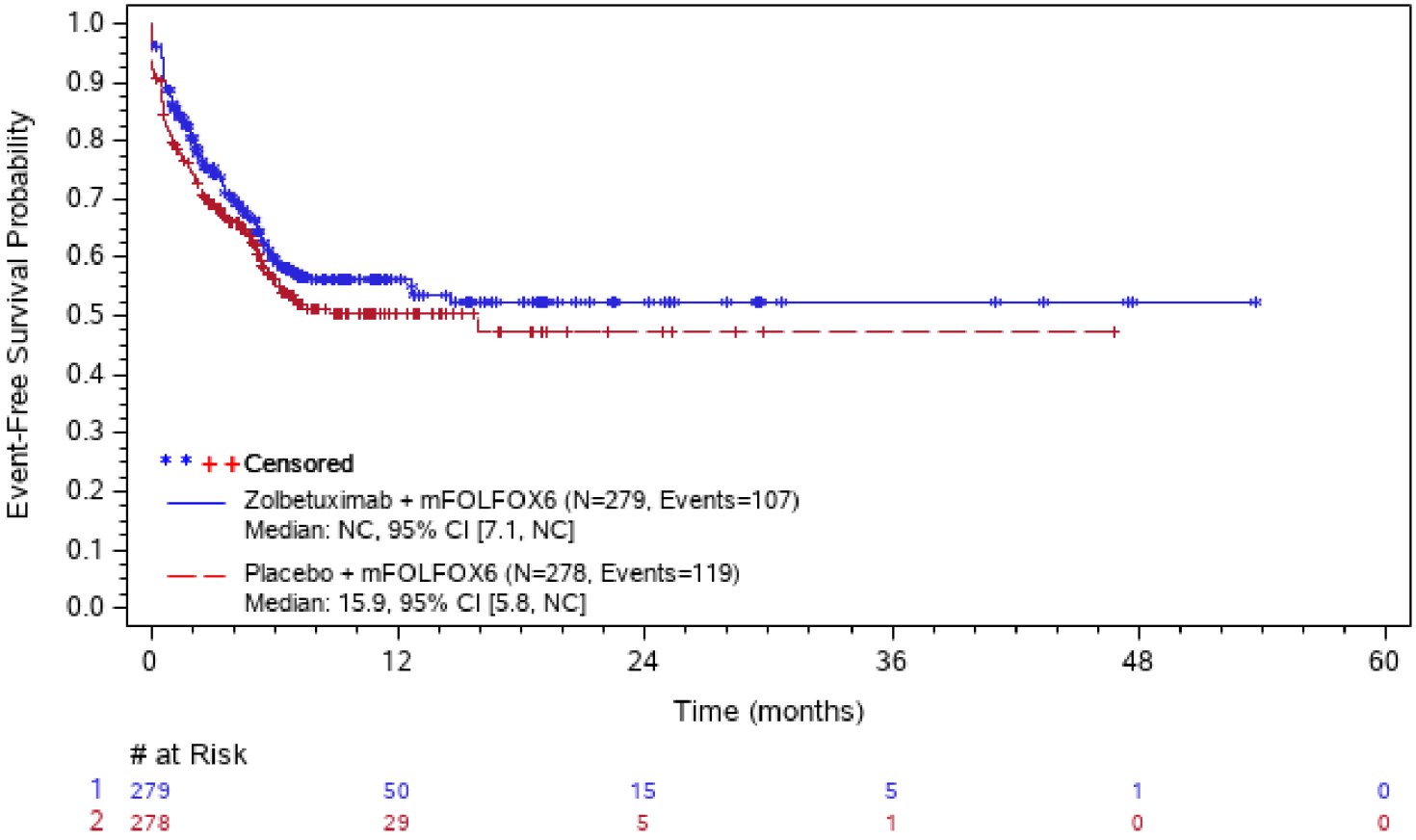


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.117: Kaplan-Meier Plot of Time to first TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

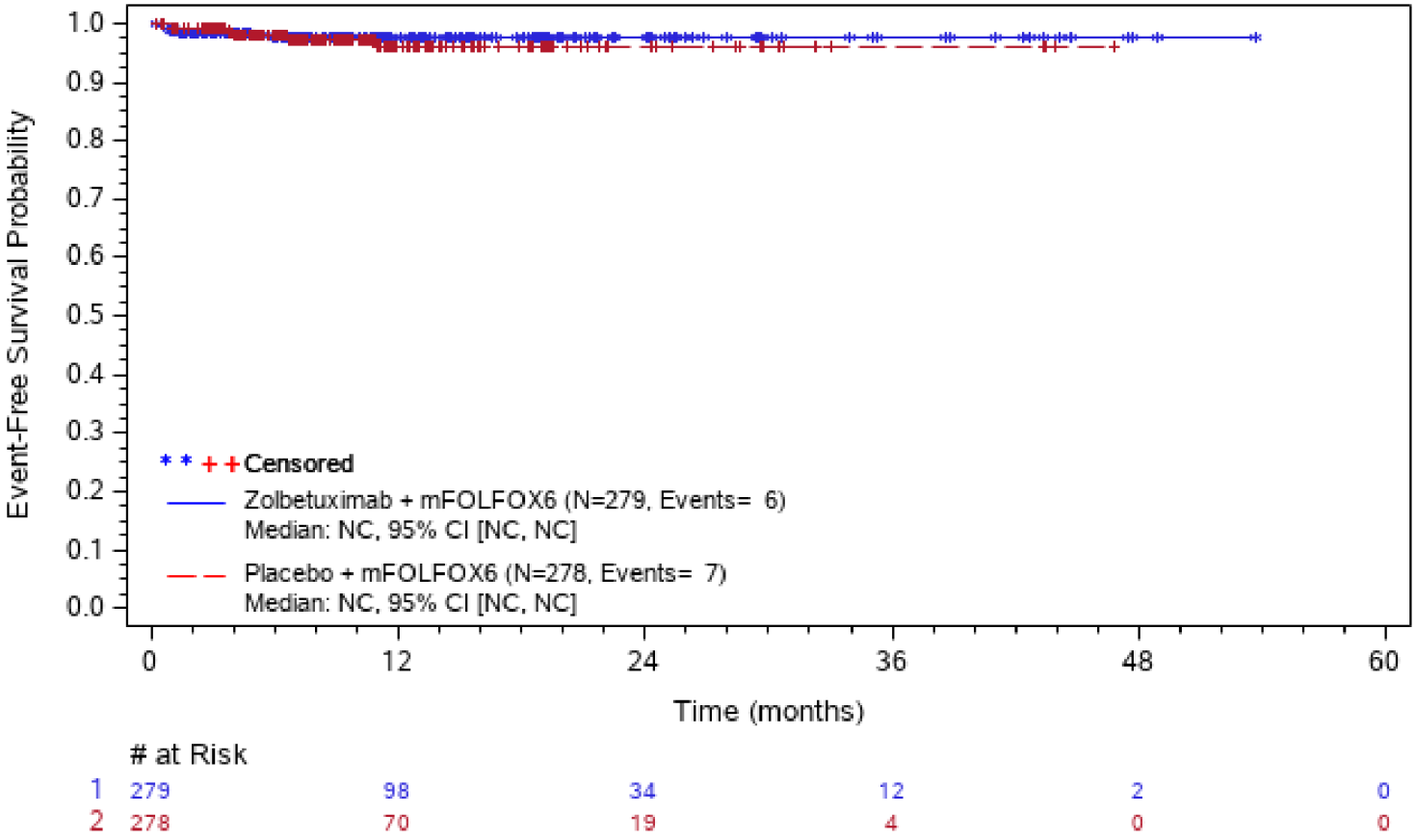


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.118: Kaplan-Meier Plot of Time to first TEAE - Syncope (PT) - Safety Analysis Set

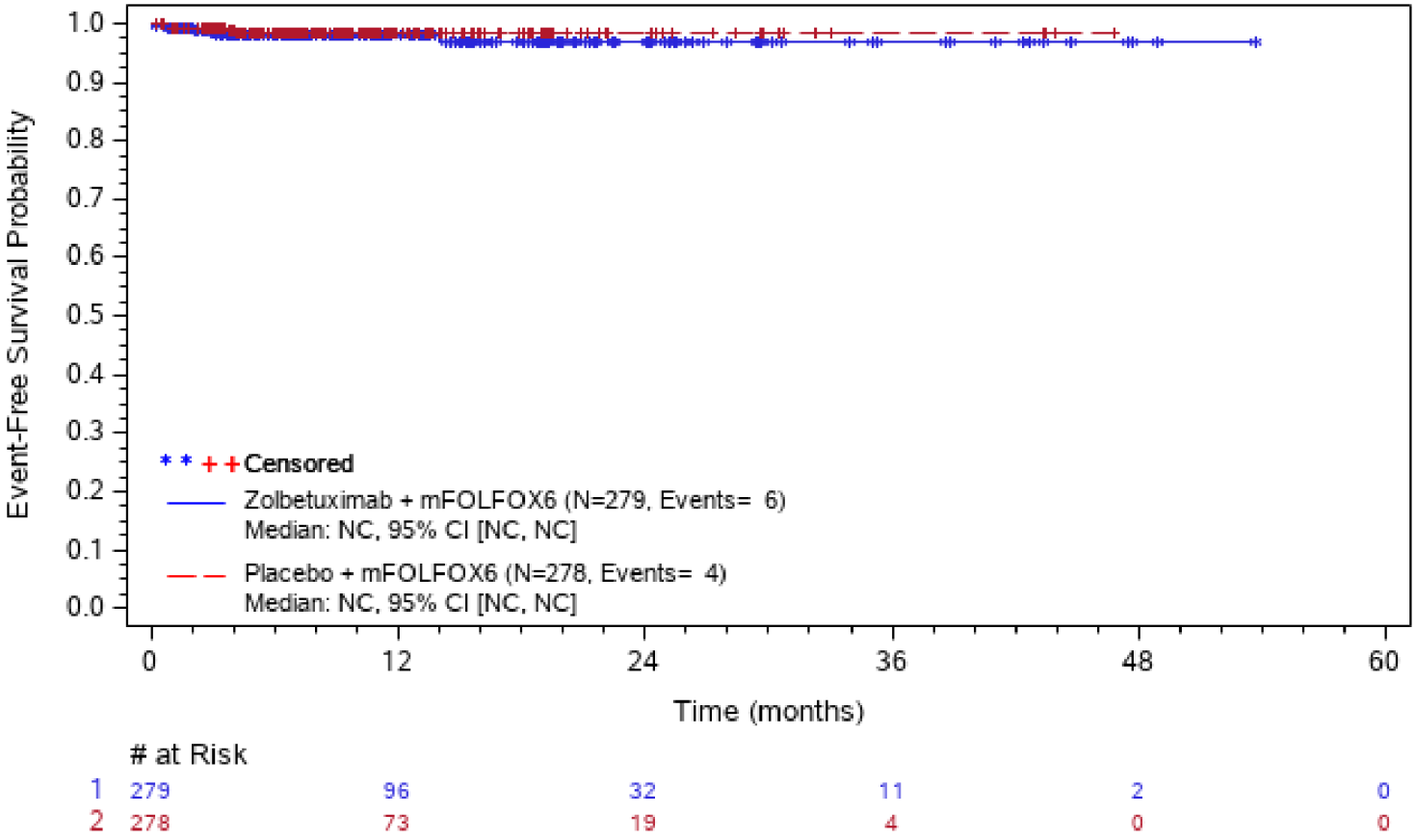


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.119: Kaplan-Meier Plot of Time to first TEAE - Taste Disorder (PT) - Safety Analysis Set

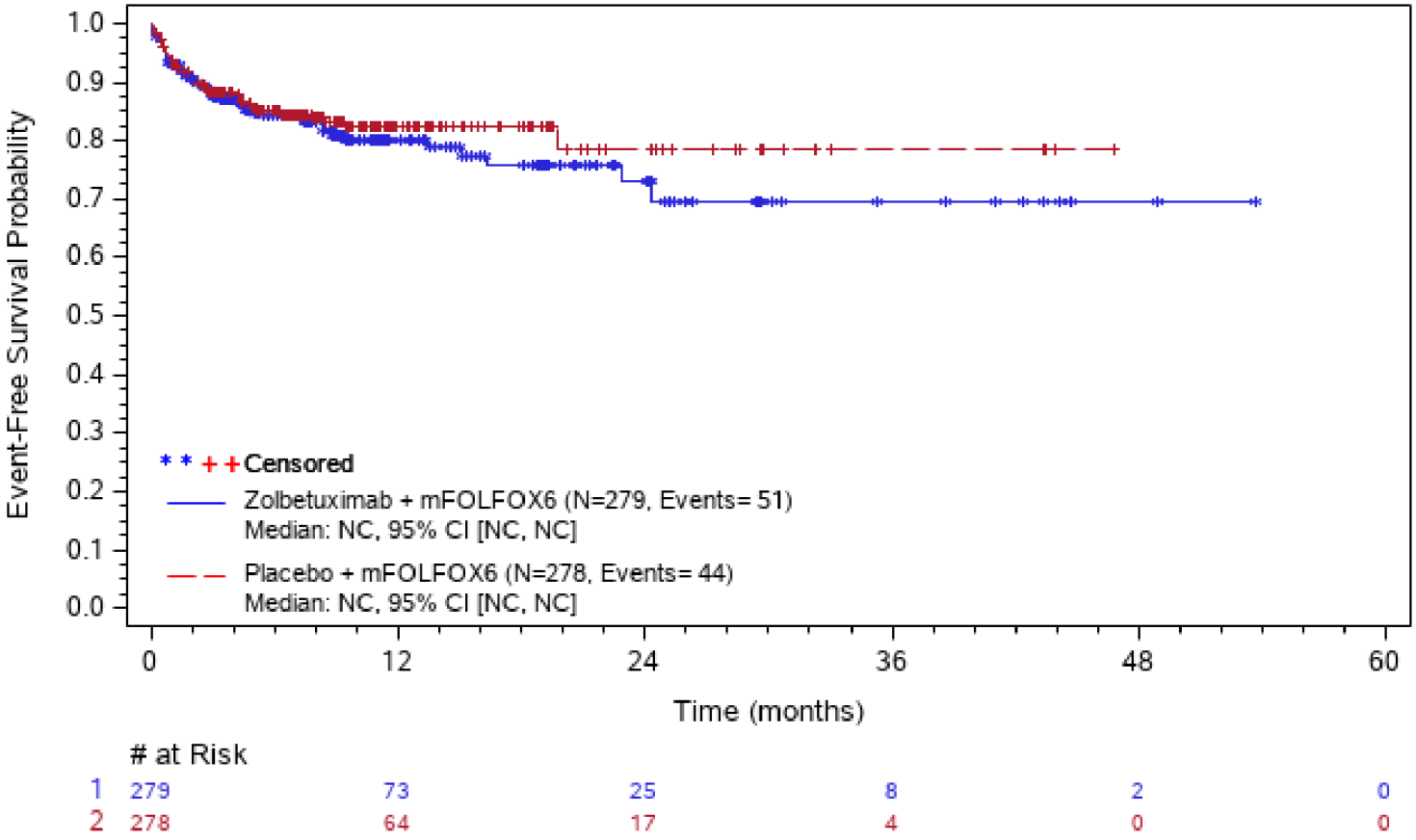


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.120: Kaplan-Meier Plot of Time to first TEAE - Psychiatric Disorders (SOC) - Safety Analysis Set

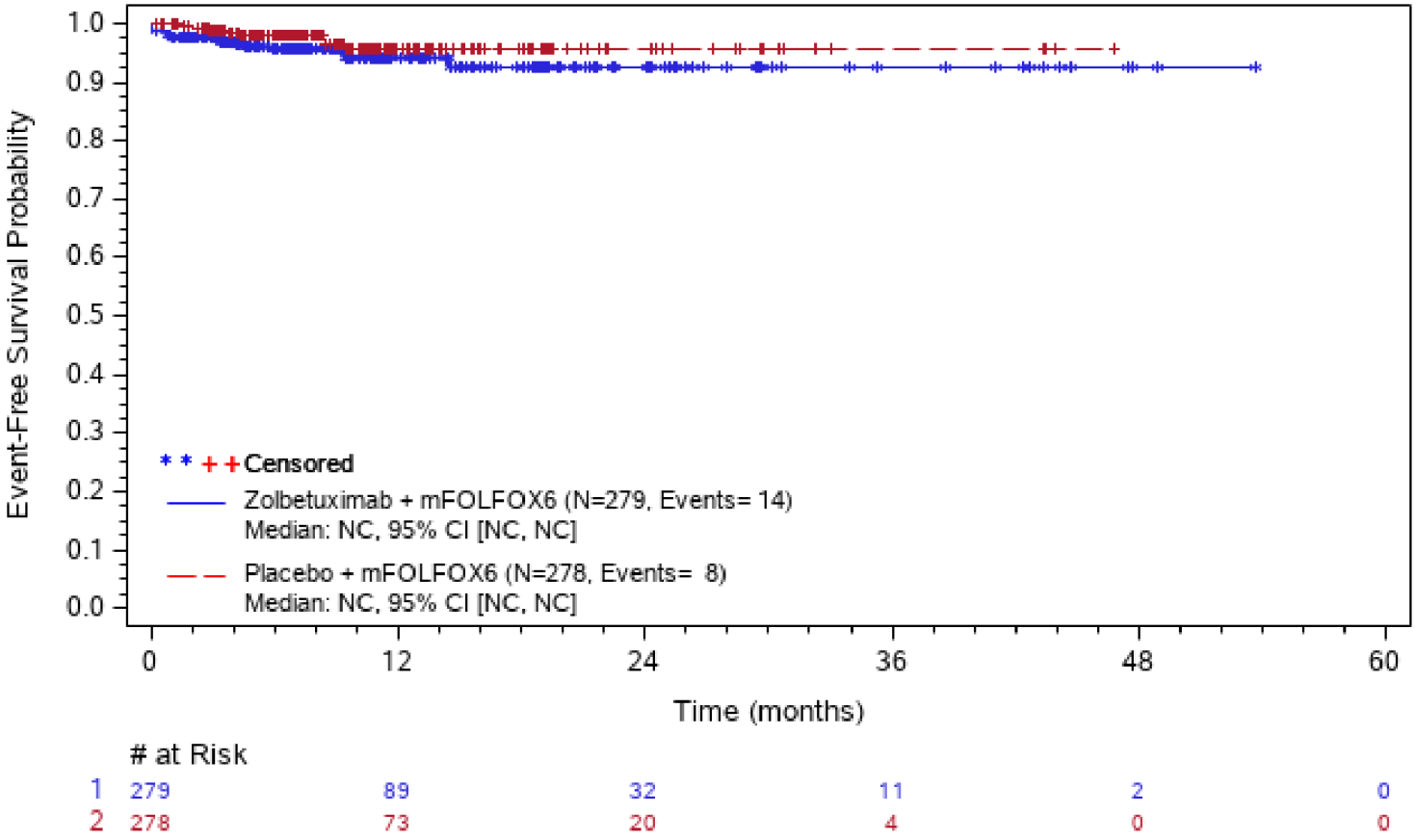


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.121: Kaplan-Meier Plot of Time to first TEAE - Anxiety (PT) - Safety Analysis Set

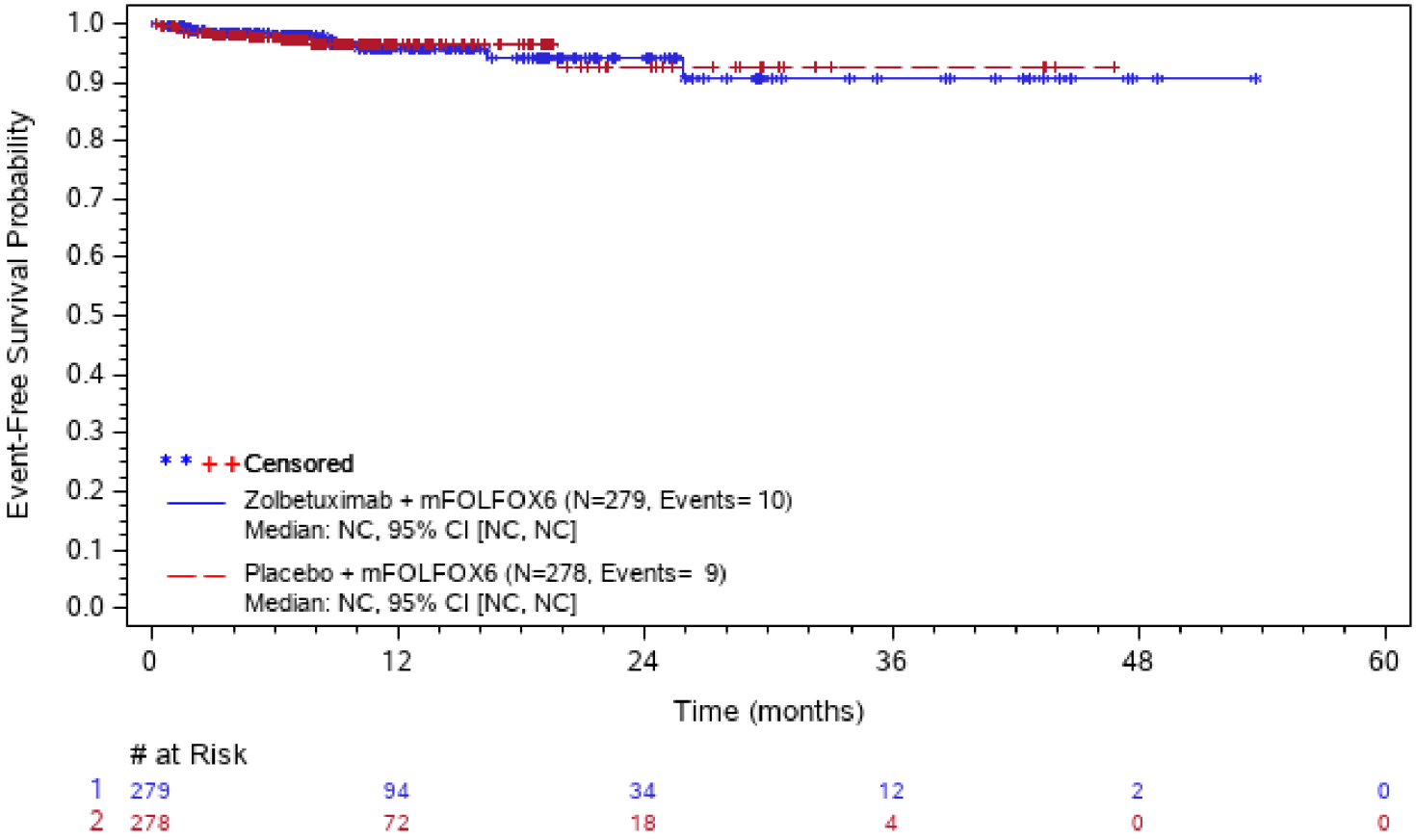


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.122: Kaplan-Meier Plot of Time to first TEAE - Depression (PT) - Safety Analysis Set

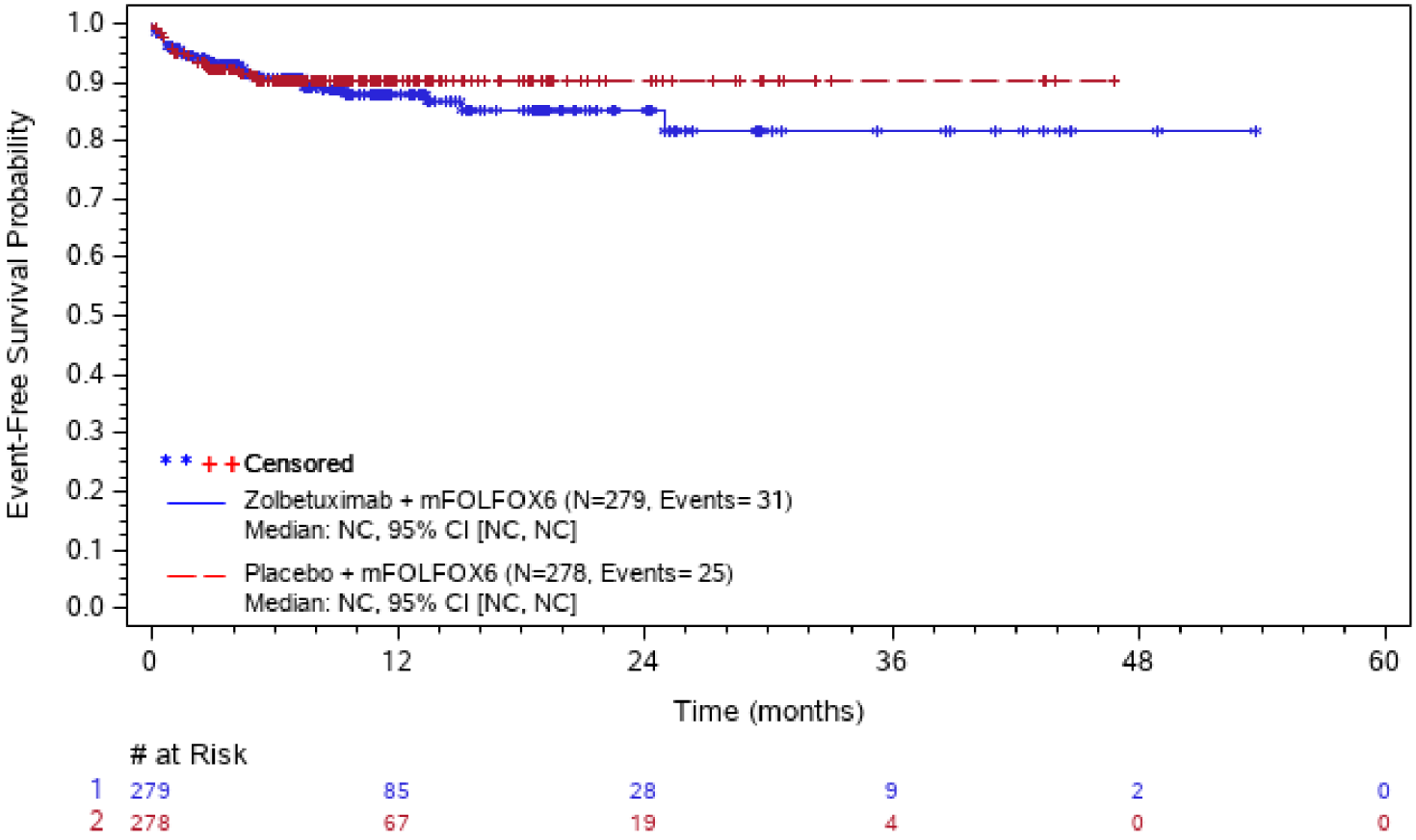


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.123: Kaplan-Meier Plot of Time to first TEAE - Insomnia (PT) - Safety Analysis Set

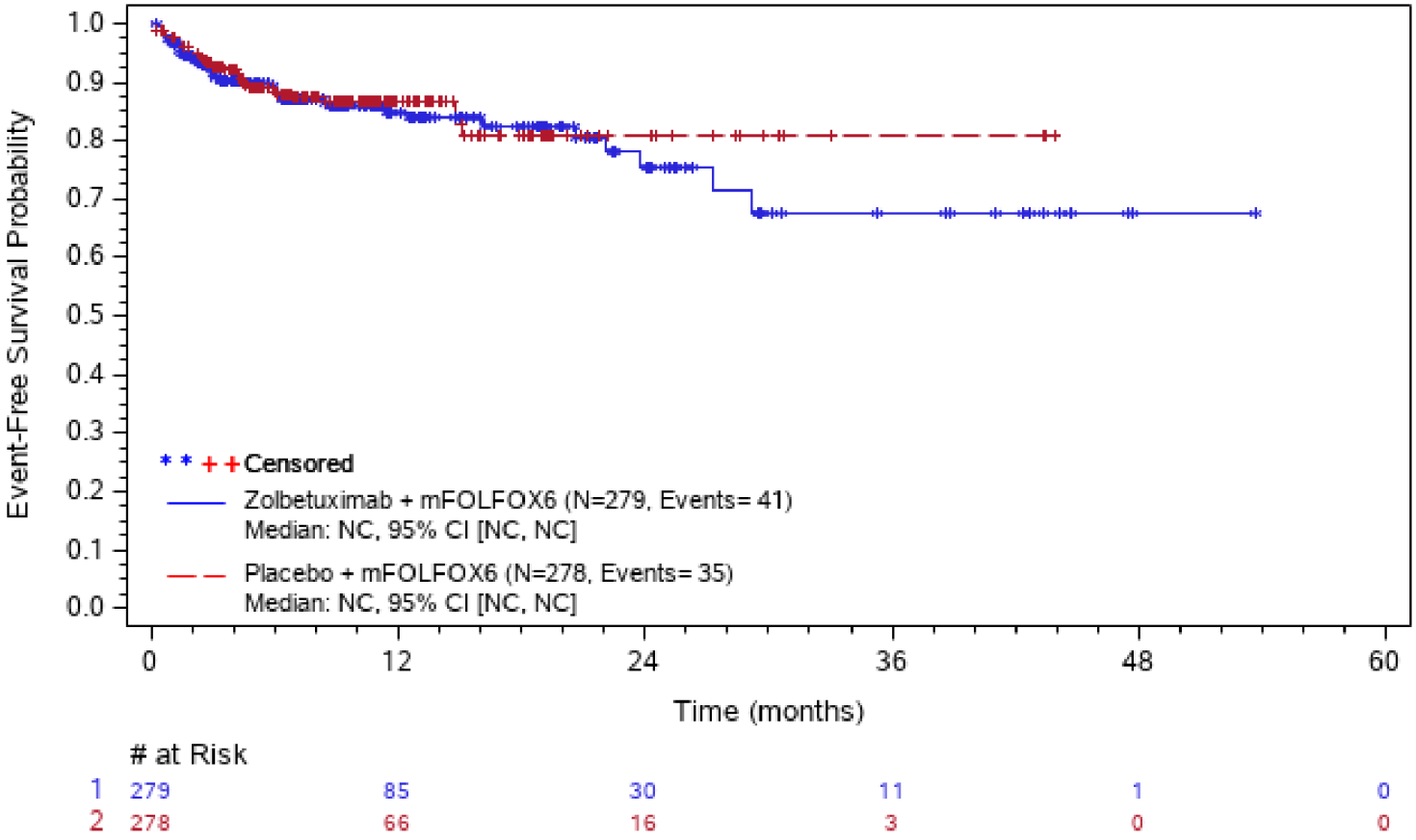


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.124: Kaplan-Meier Plot of Time to first TEAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set

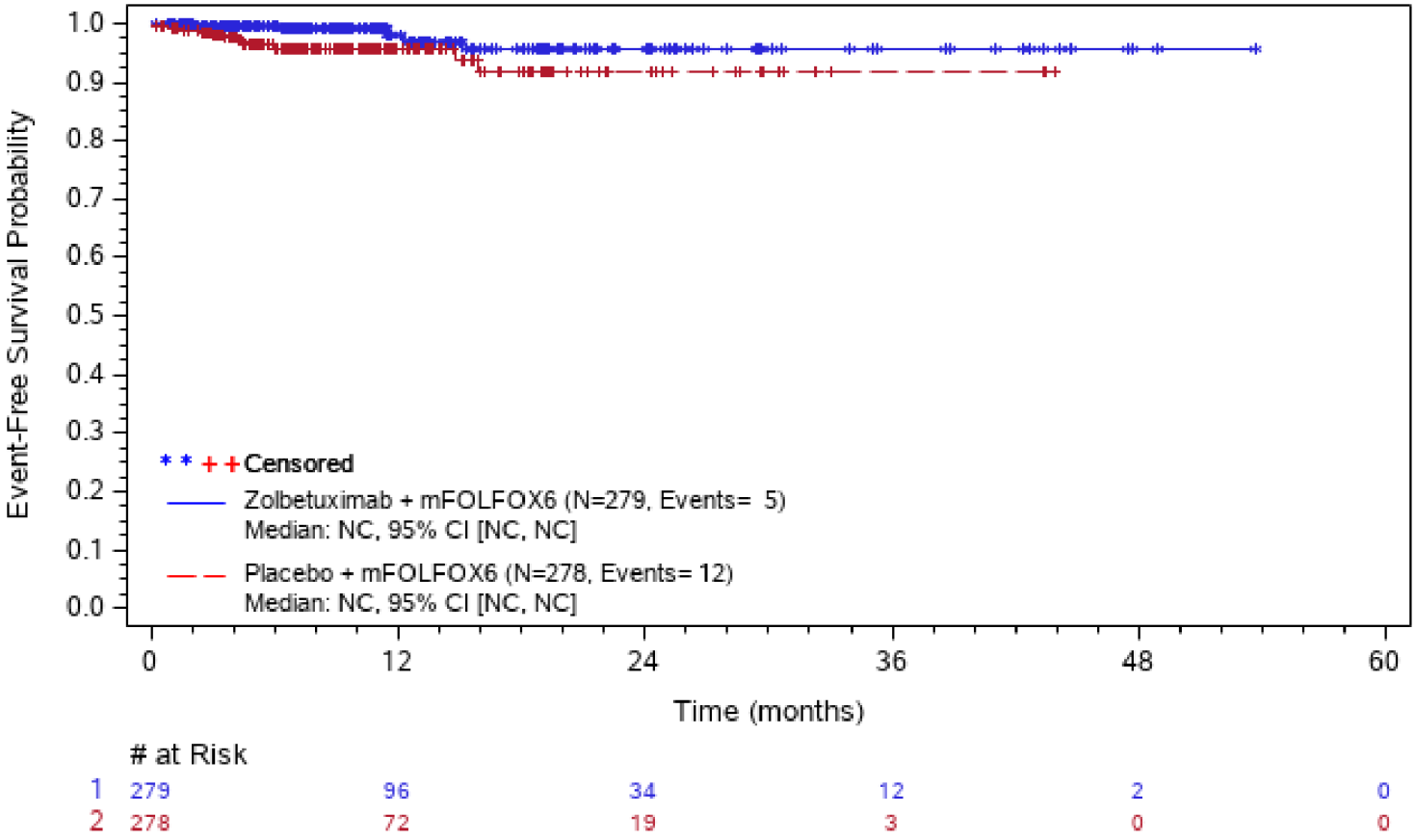


# at Risk						
1	279	85	30	11	1	0
2	278	66	16	3	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.125: Kaplan-Meier Plot of Time to first TEAE - Dysuria (PT) - Safety Analysis Set

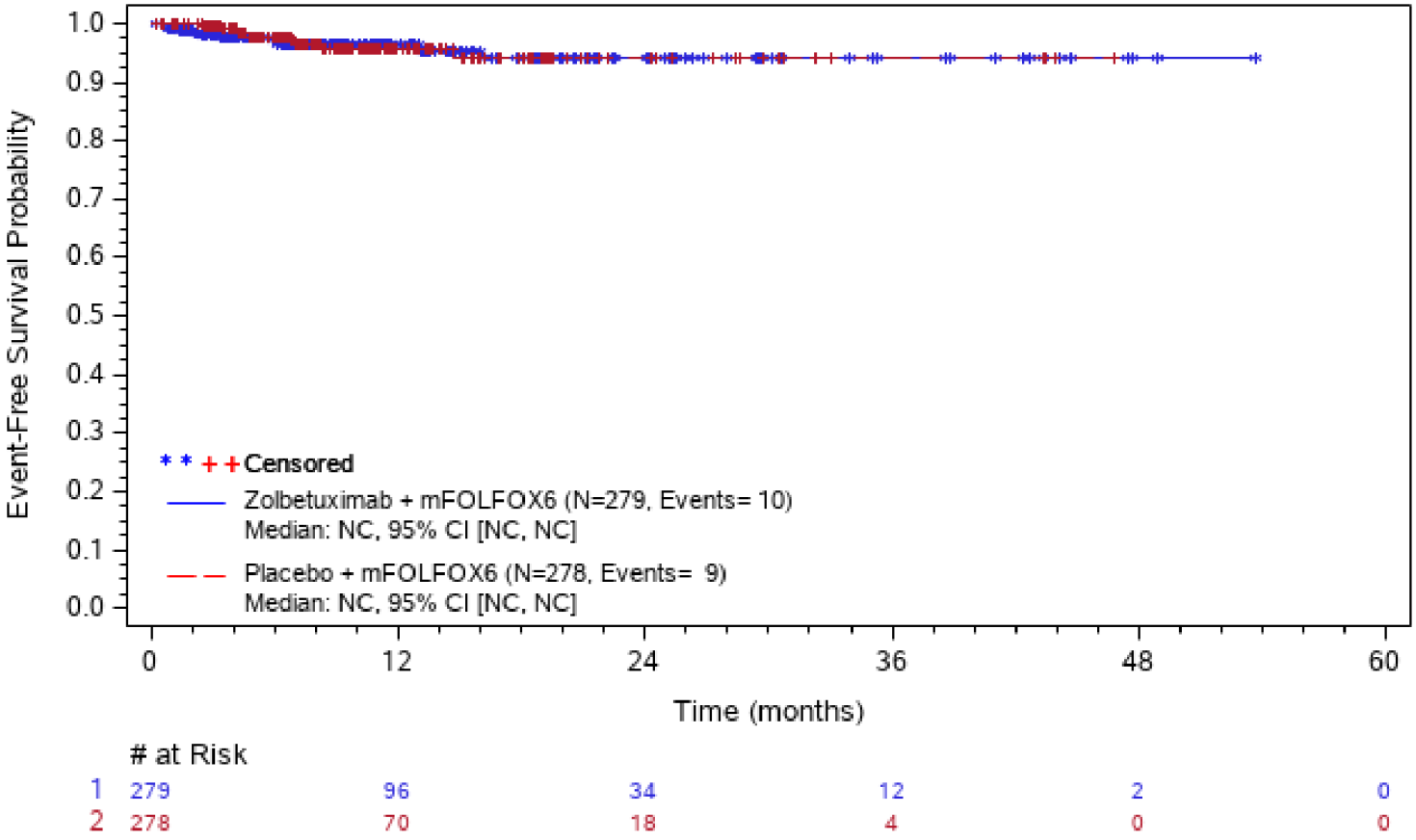


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.126: Kaplan-Meier Plot of Time to first TEAE - Haematuria (PT) - Safety Analysis Set

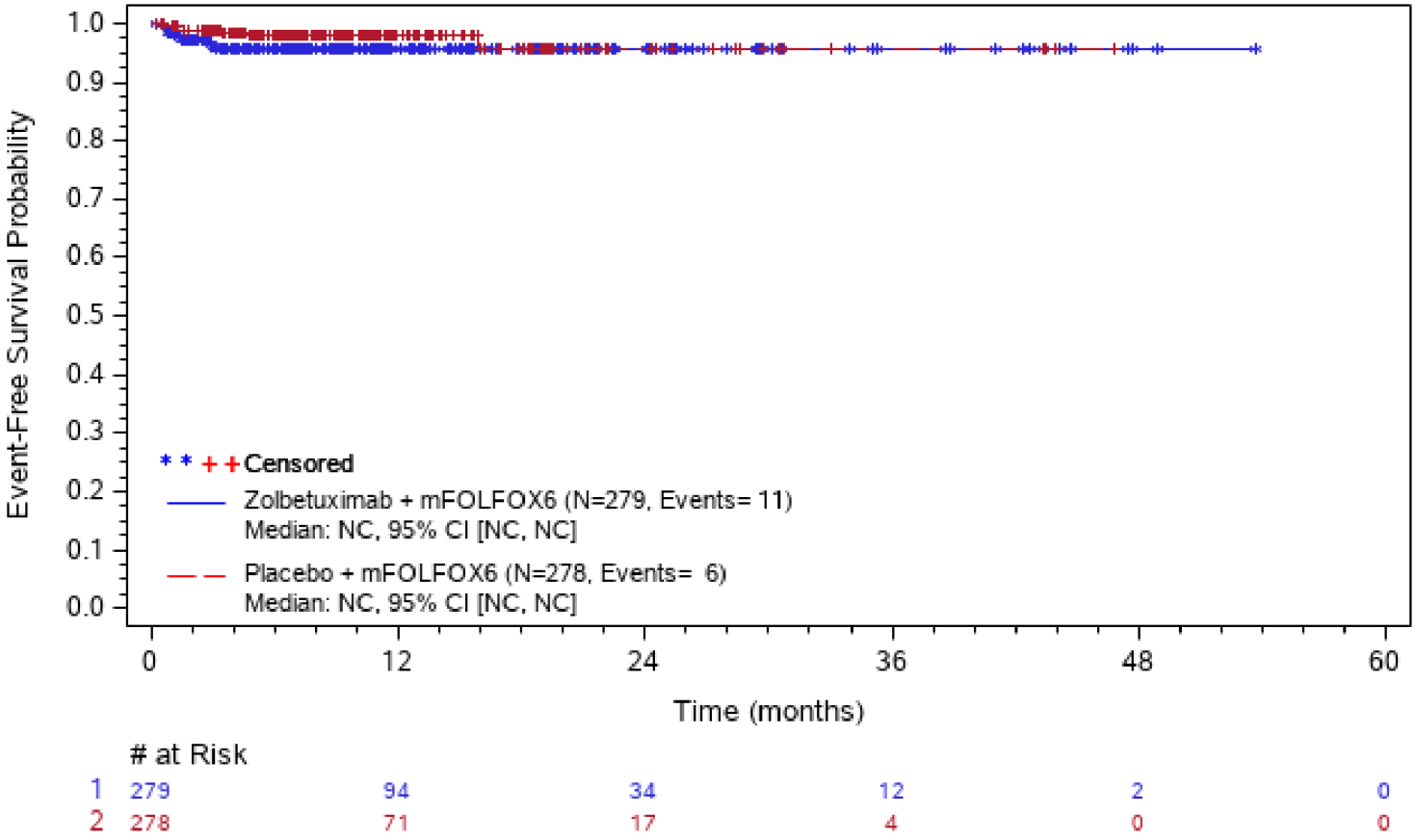


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.127: Kaplan-Meier Plot of Time to first TEAE - Proteinuria (PT) - Safety Analysis Set

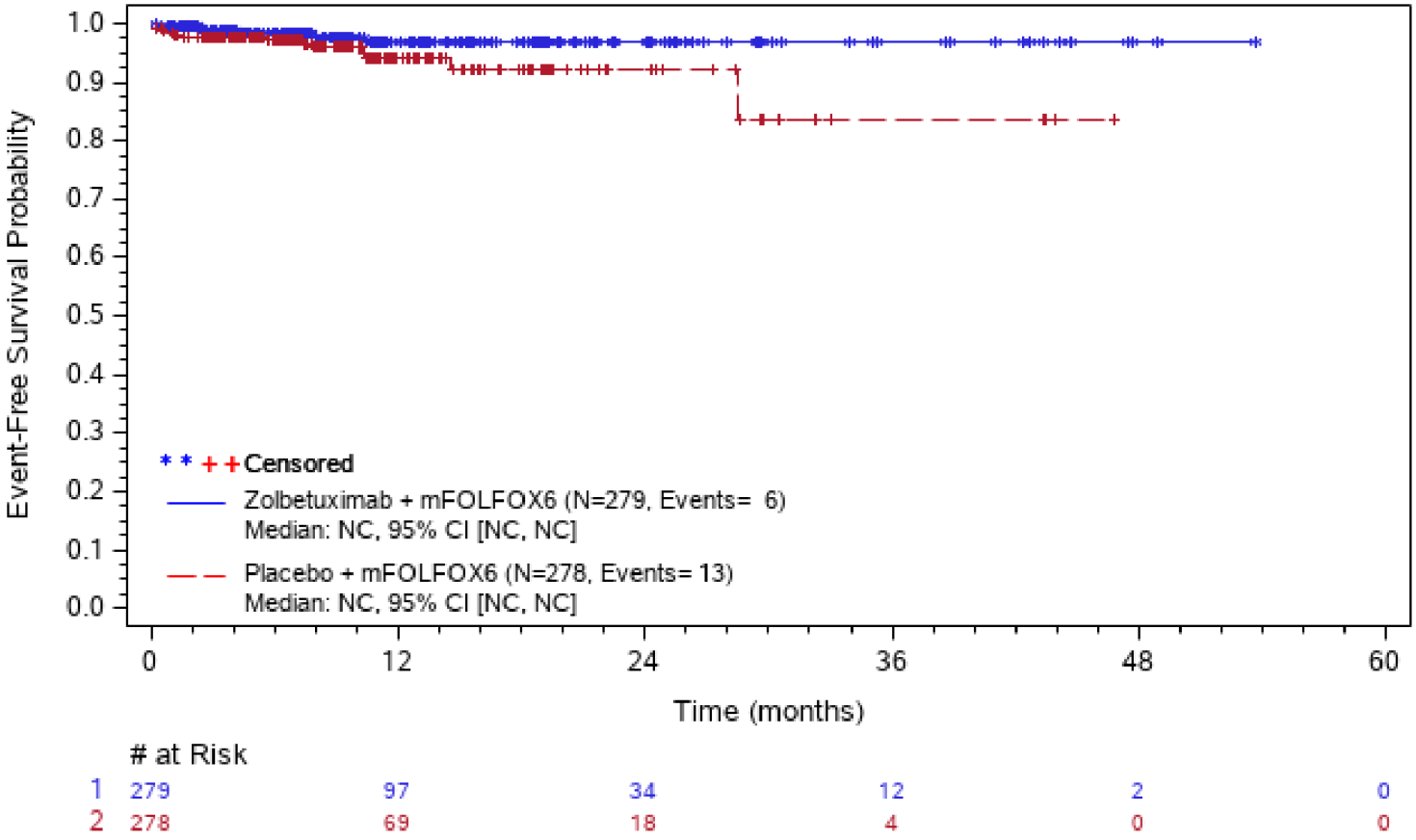


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.128: Kaplan-Meier Plot of Time to first TEAE - Reproductive System And Breast Disorders (SOC) - Safety Analysis Set

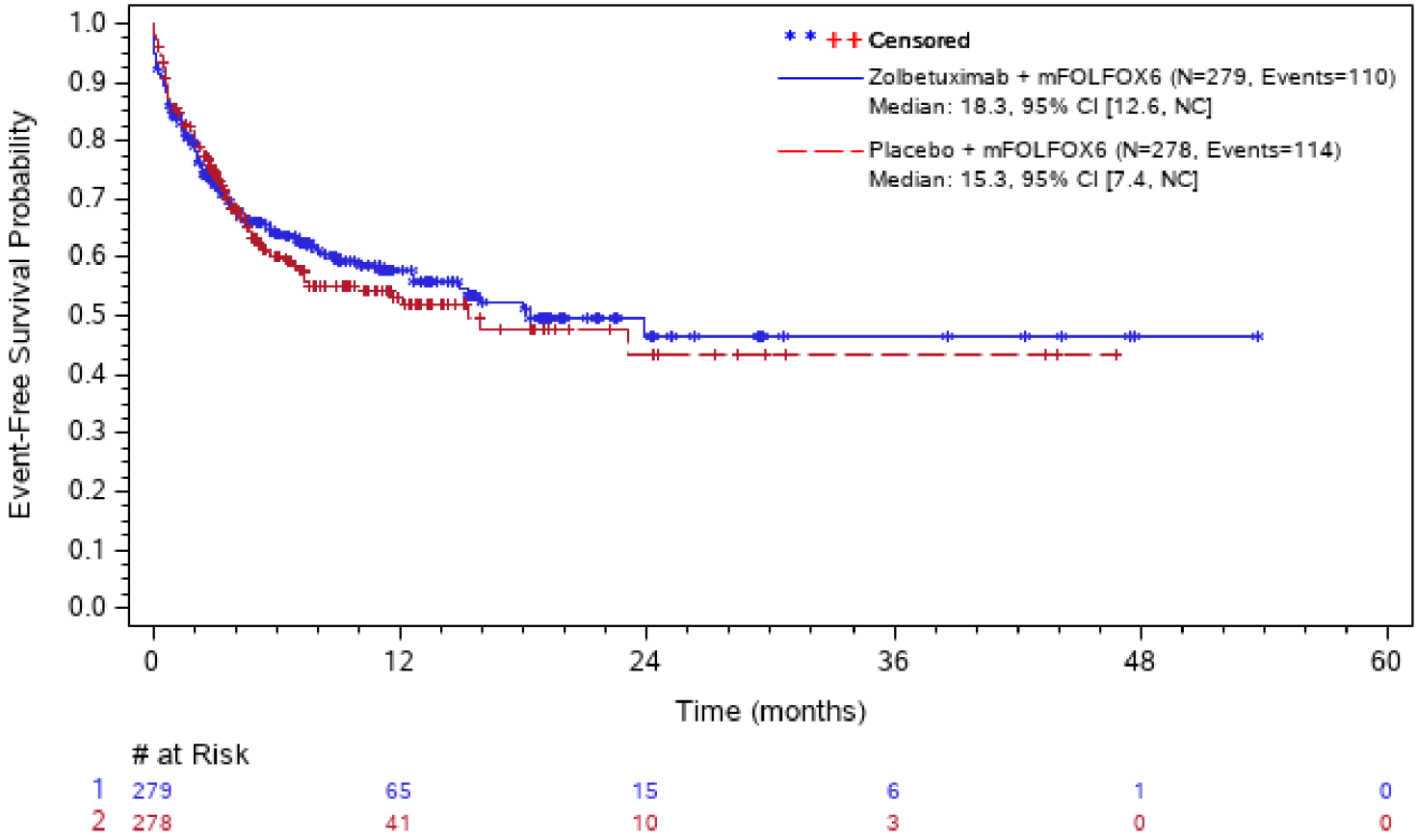


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.129: Kaplan-Meier Plot of Time to first TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

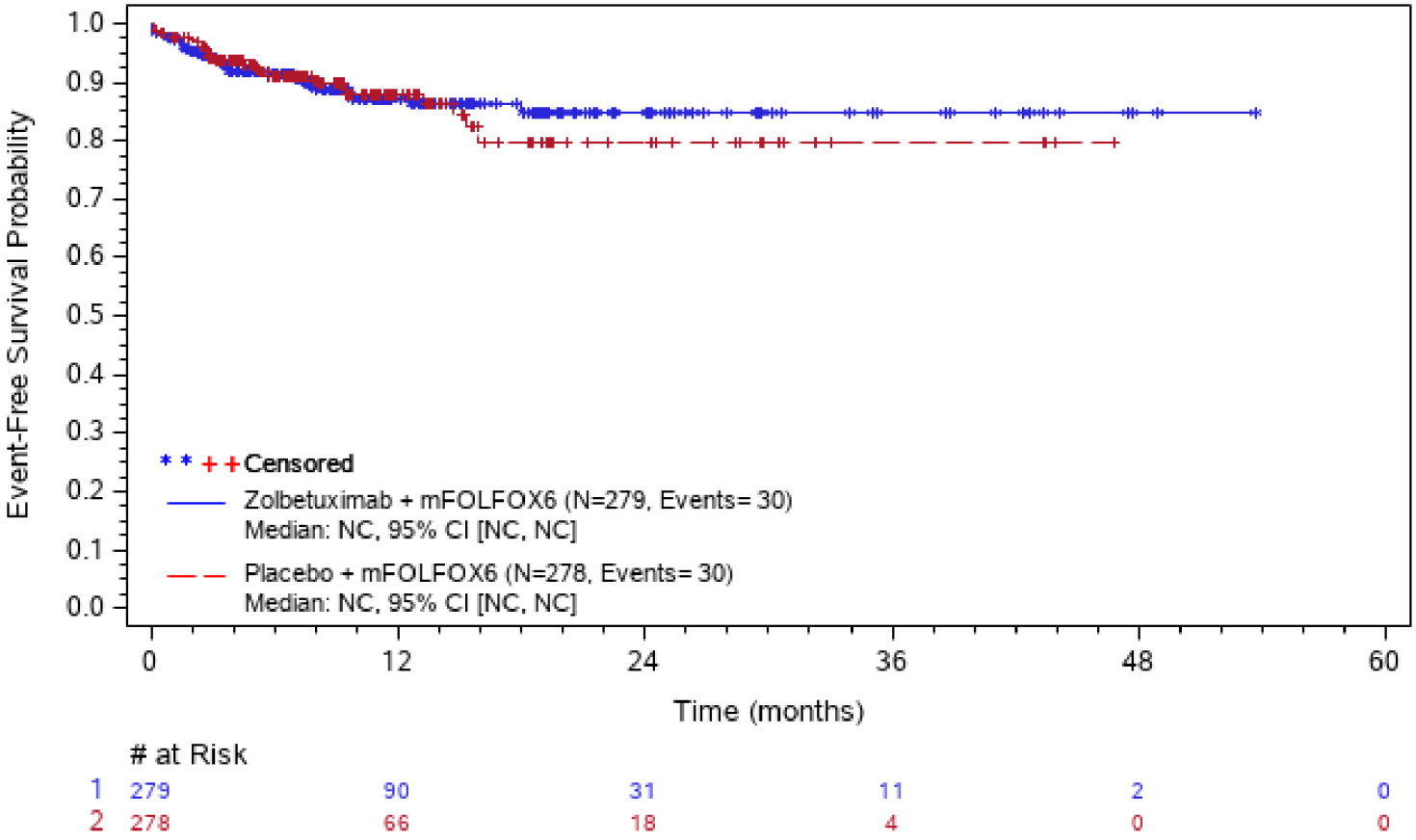


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.130: Kaplan-Meier Plot of Time to first TEAE - Cough (PT) - Safety Analysis Set

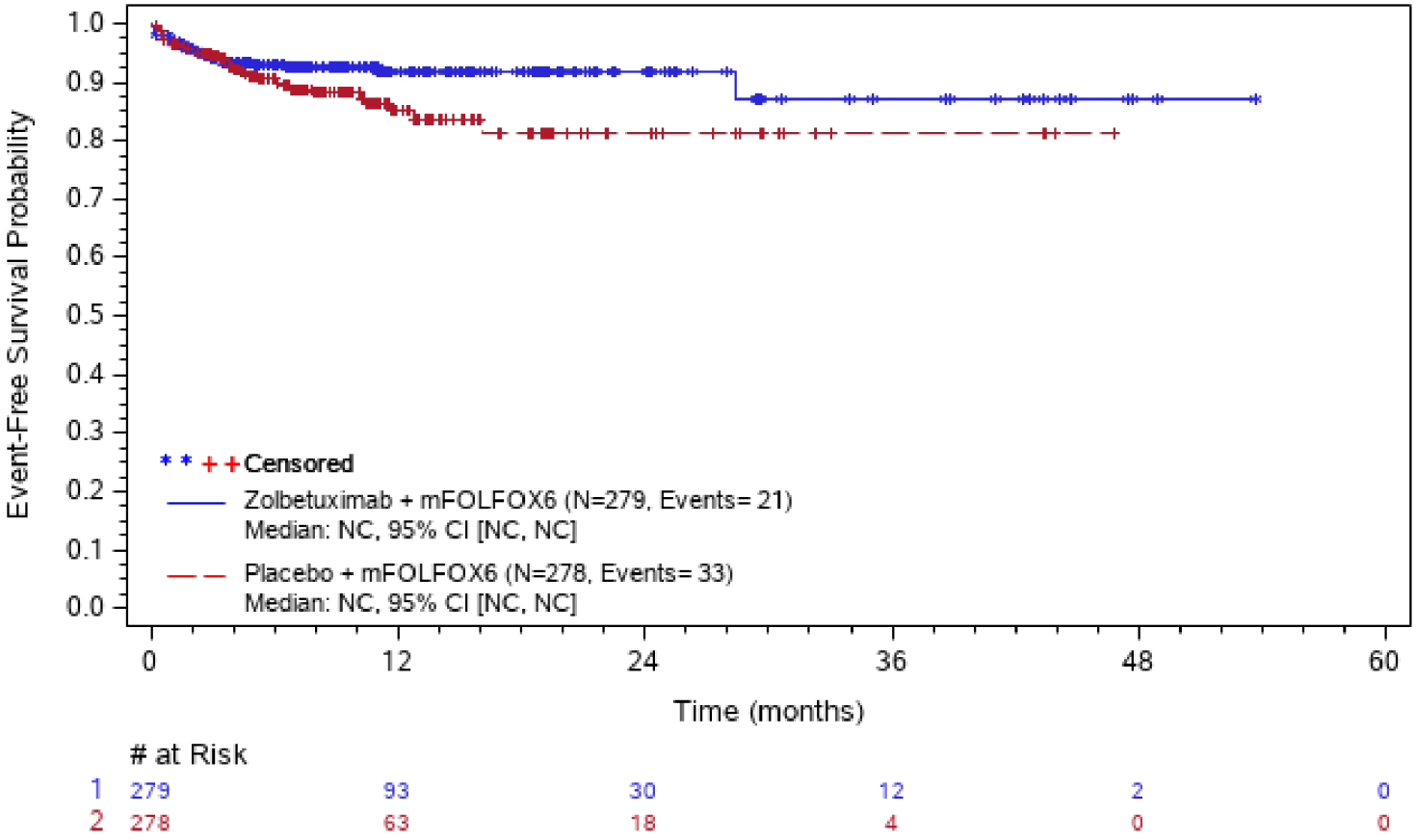


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.131: Kaplan-Meier Plot of Time to first TEAE - Dyspnoea (PT) - Safety Analysis Set

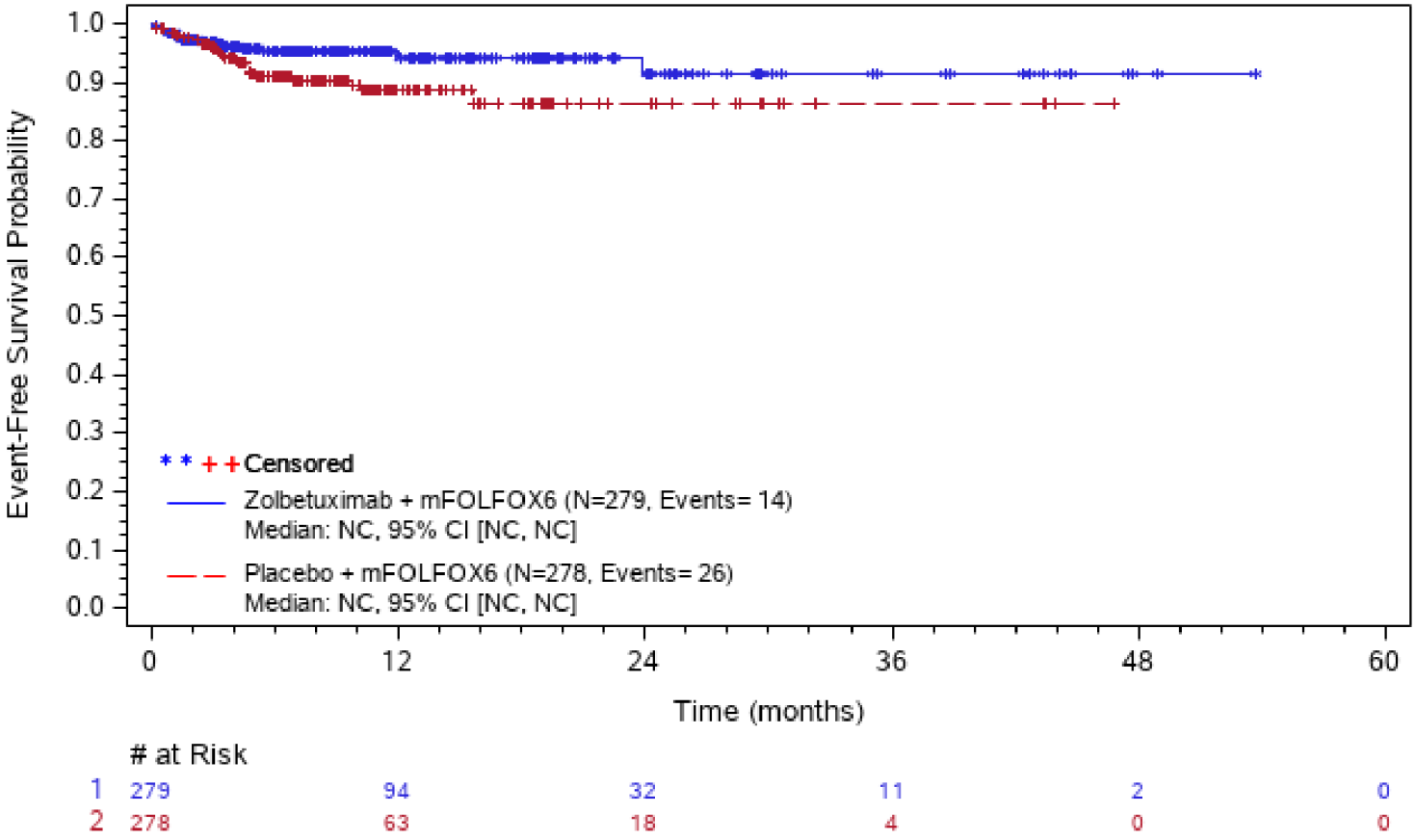


# at Risk						
1	279	93	30	12	2	0
2	278	63	18	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.132: Kaplan-Meier Plot of Time to first TEAE - Epistaxis (PT) - Safety Analysis Set

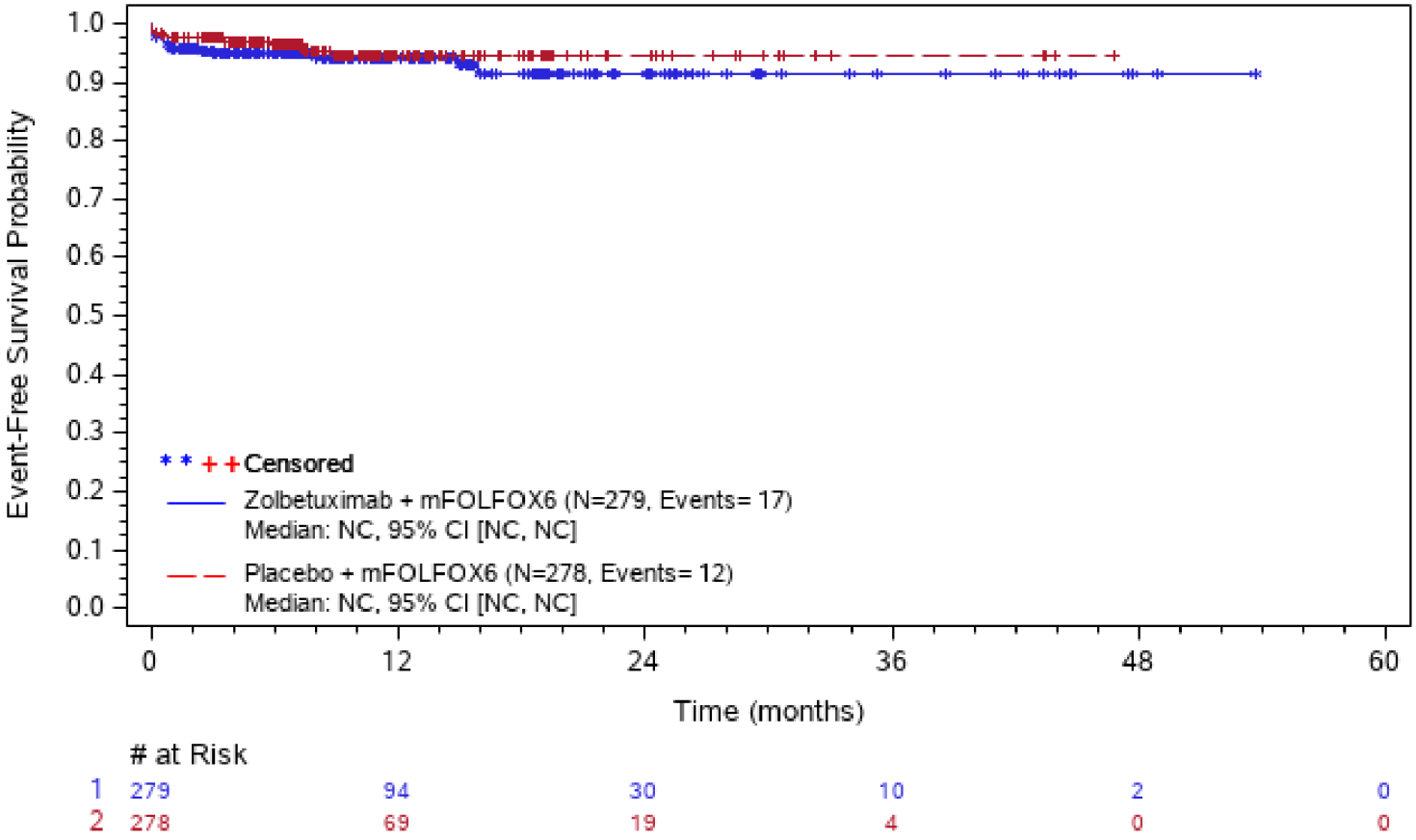


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.133: Kaplan-Meier Plot of Time to first TEAE - Hiccups (PT) - Safety Analysis Set

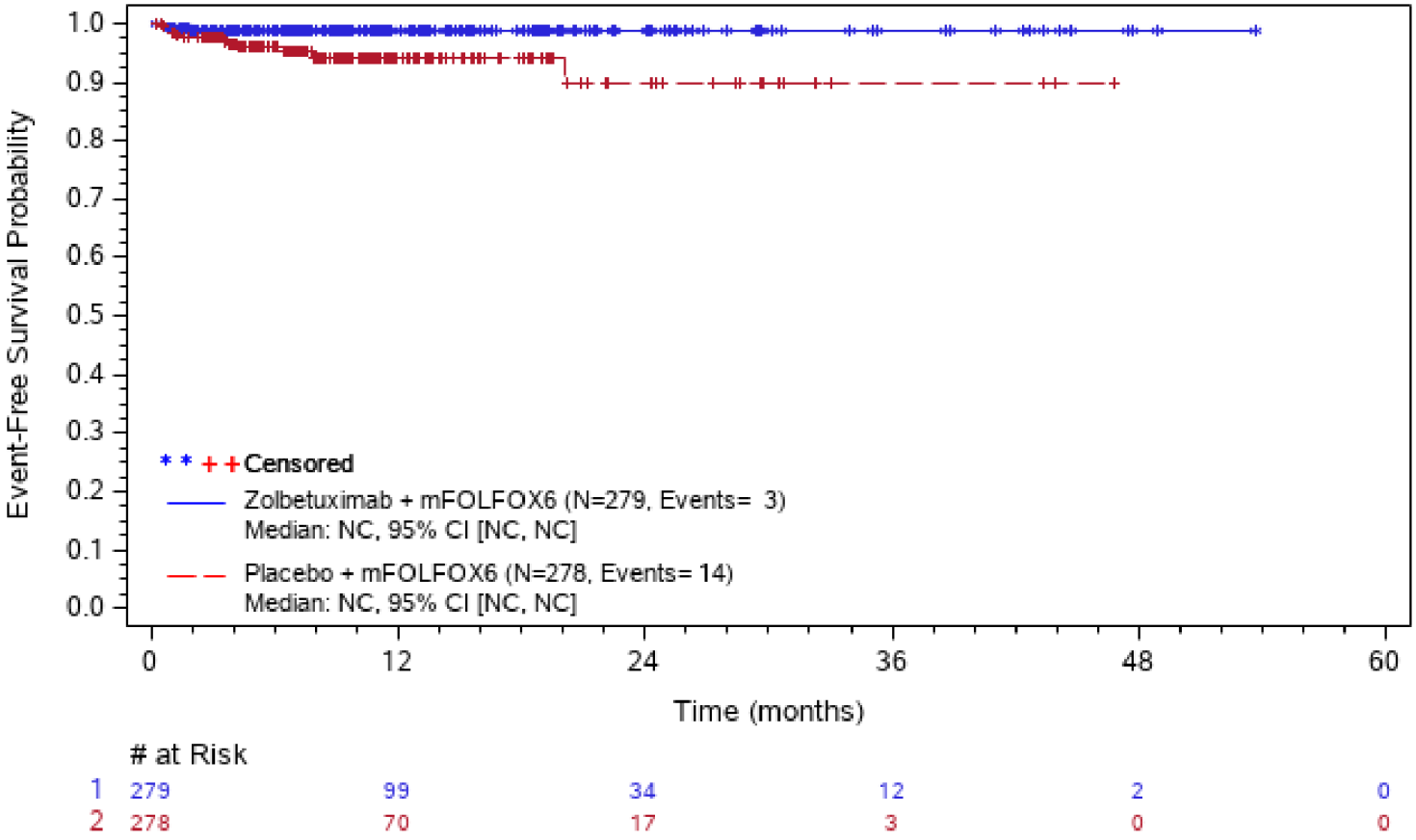


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.134: Kaplan-Meier Plot of Time to first TEAE - Oropharyngeal Pain (PT) - Safety Analysis Set

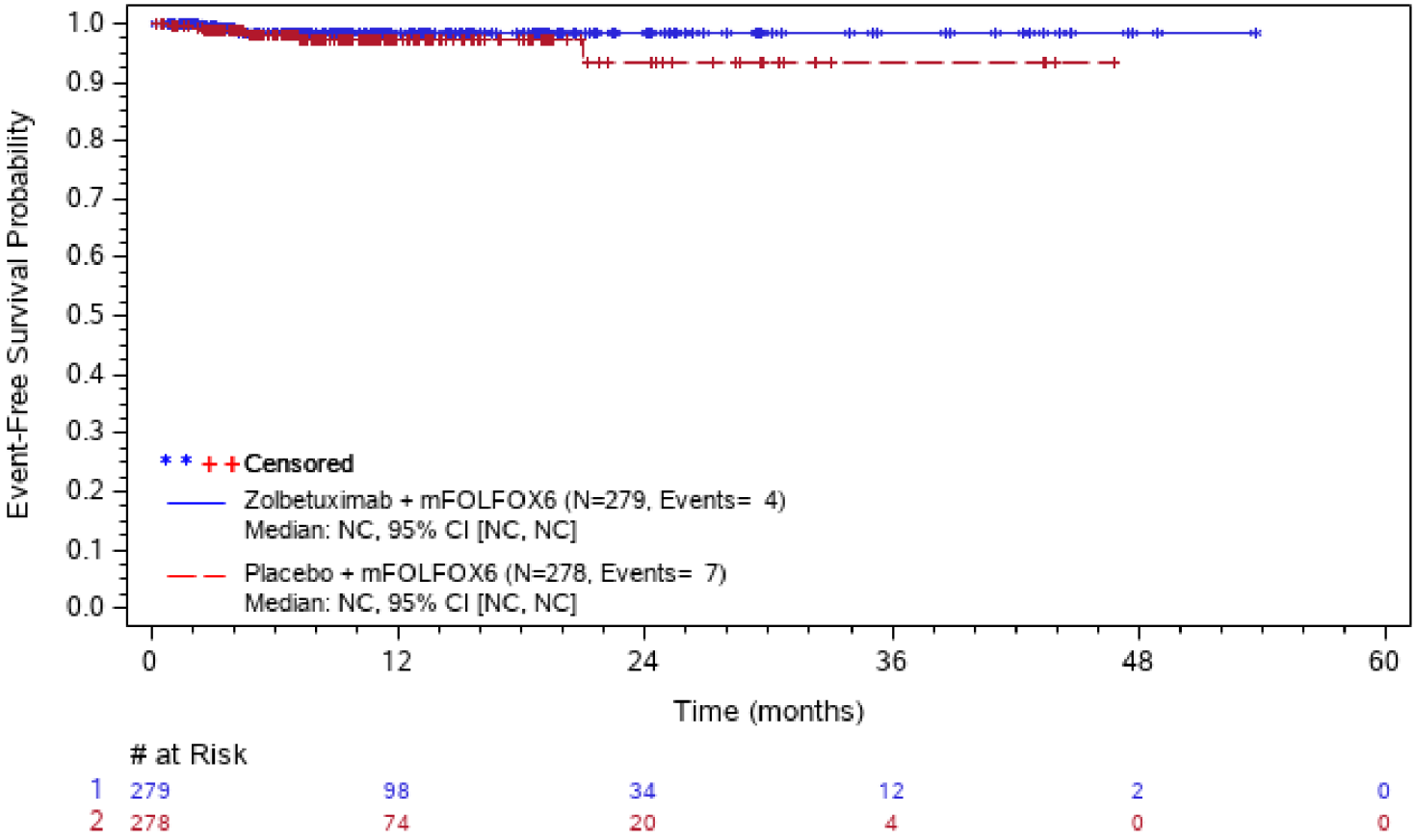


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.135: Kaplan-Meier Plot of Time to first TEAE - Pleural Effusion (PT) - Safety Analysis Set

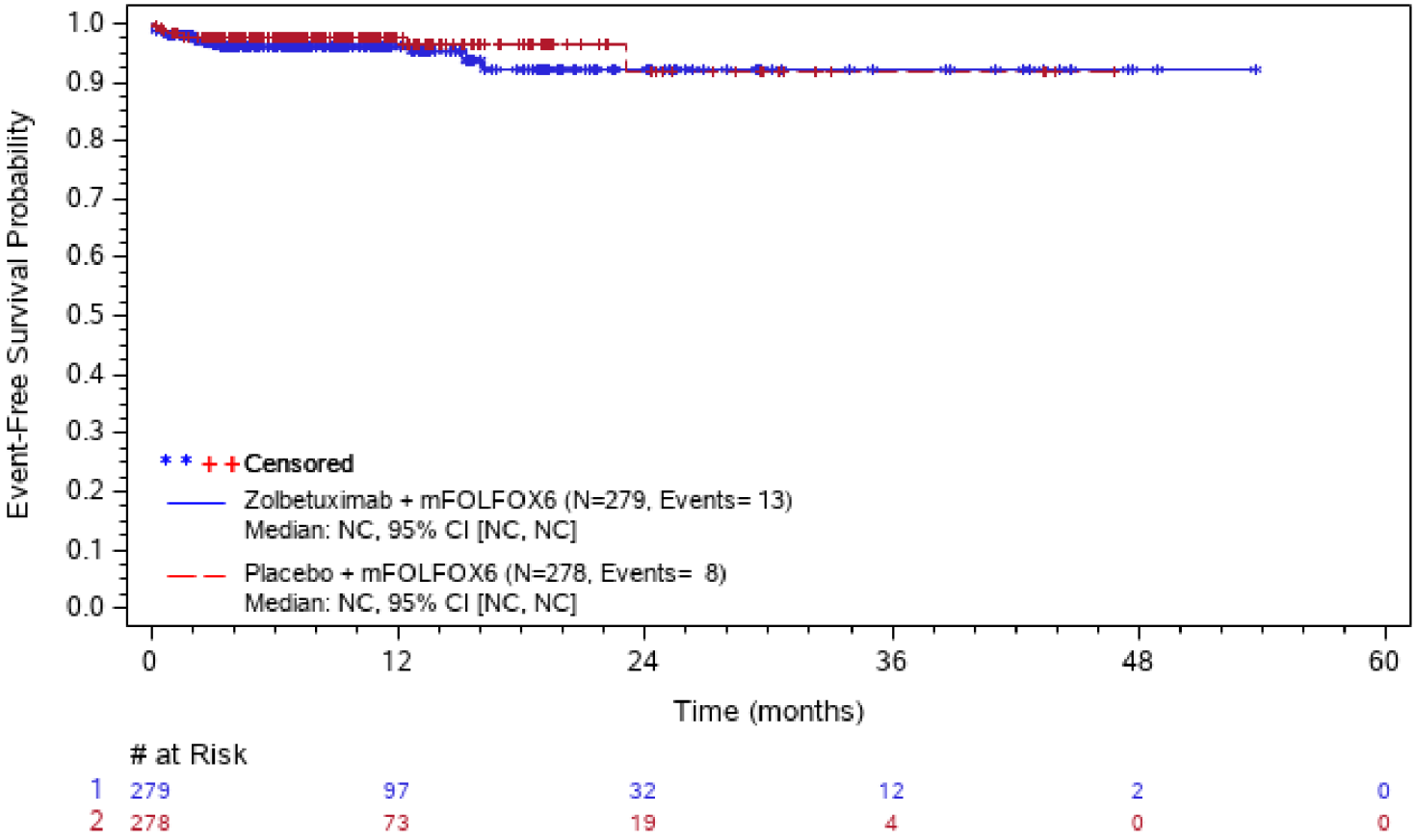


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.136: Kaplan-Meier Plot of Time to first TEAE - Productive Cough (PT) - Safety Analysis Set

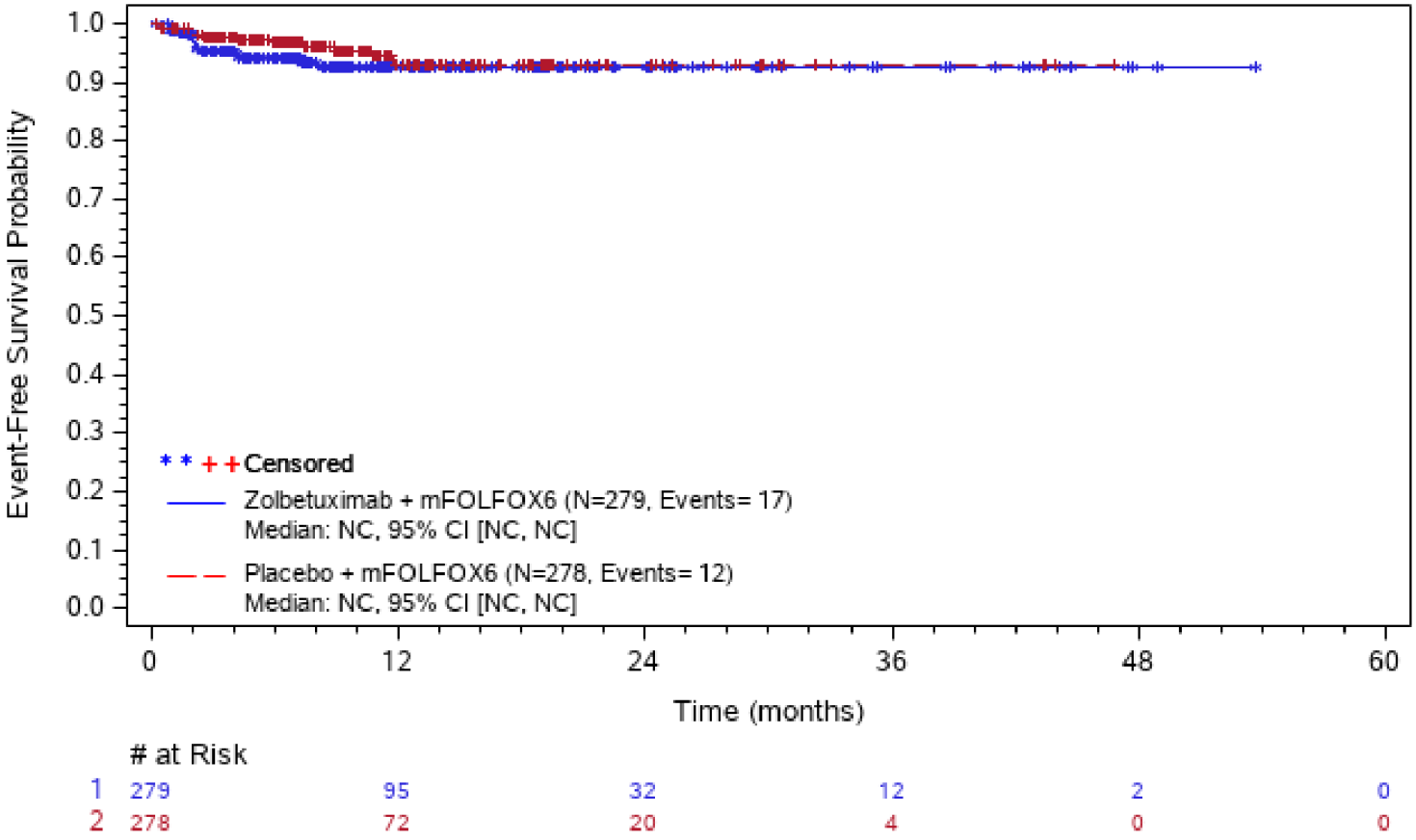


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.137: Kaplan-Meier Plot of Time to first TEAE - Pulmonary Embolism (PT) - Safety Analysis Set

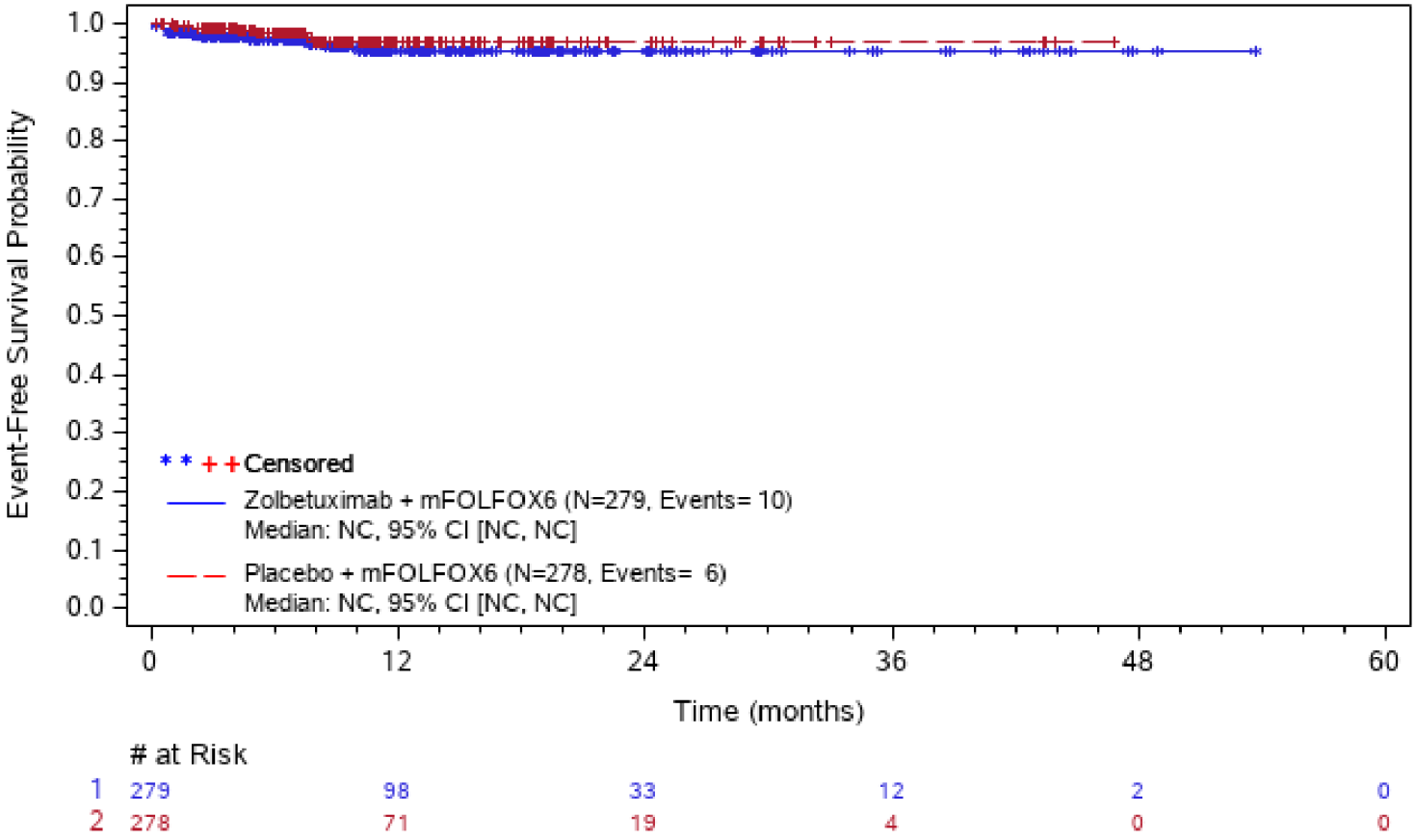


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.138: Kaplan-Meier Plot of Time to first TEAE - Rhinorrhoea (PT) - Safety Analysis Set

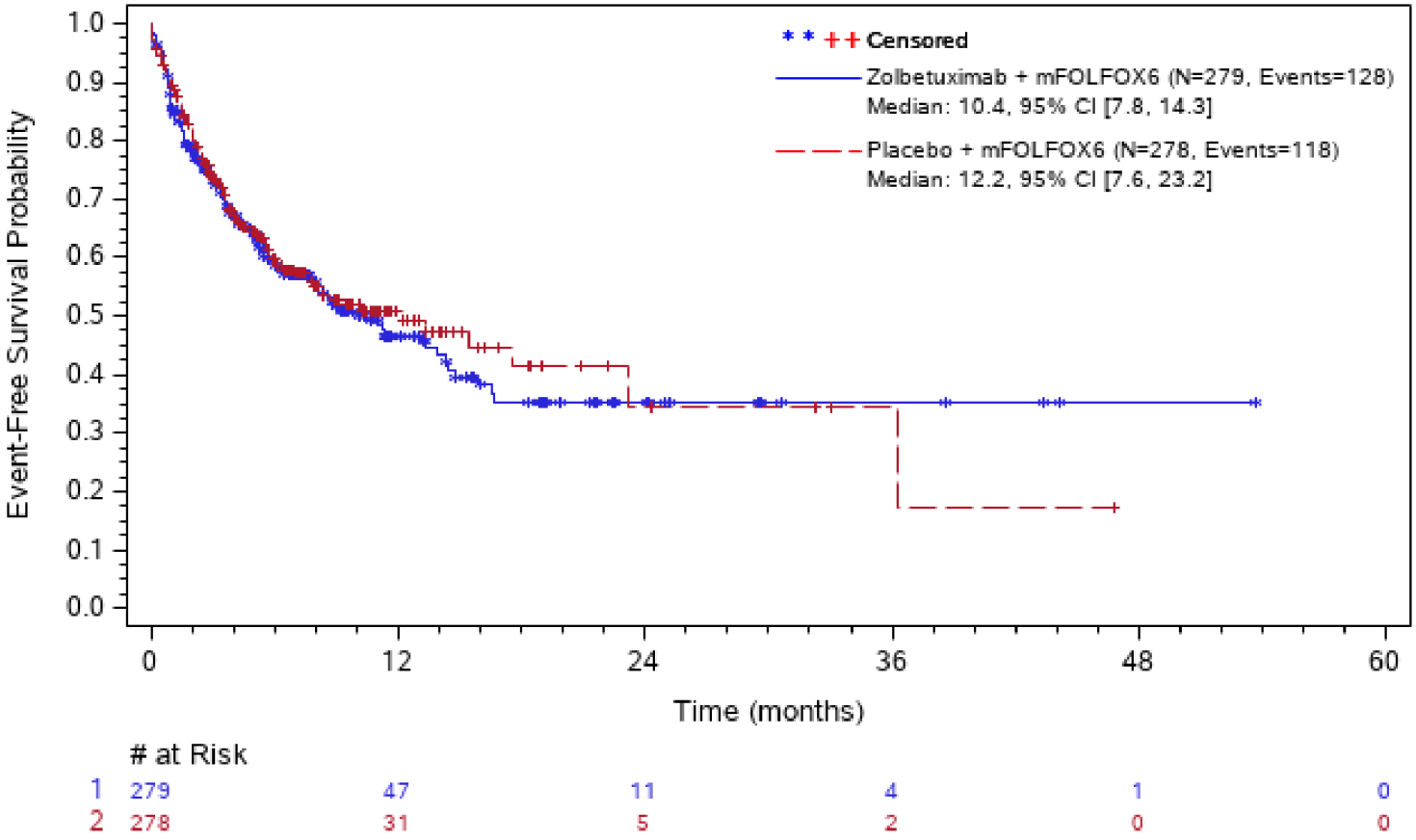


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.139: Kaplan-Meier Plot of Time to first TEAE - Skin And Subcutaneous Tissue Disorders (SOC) - Safety Analysis Set

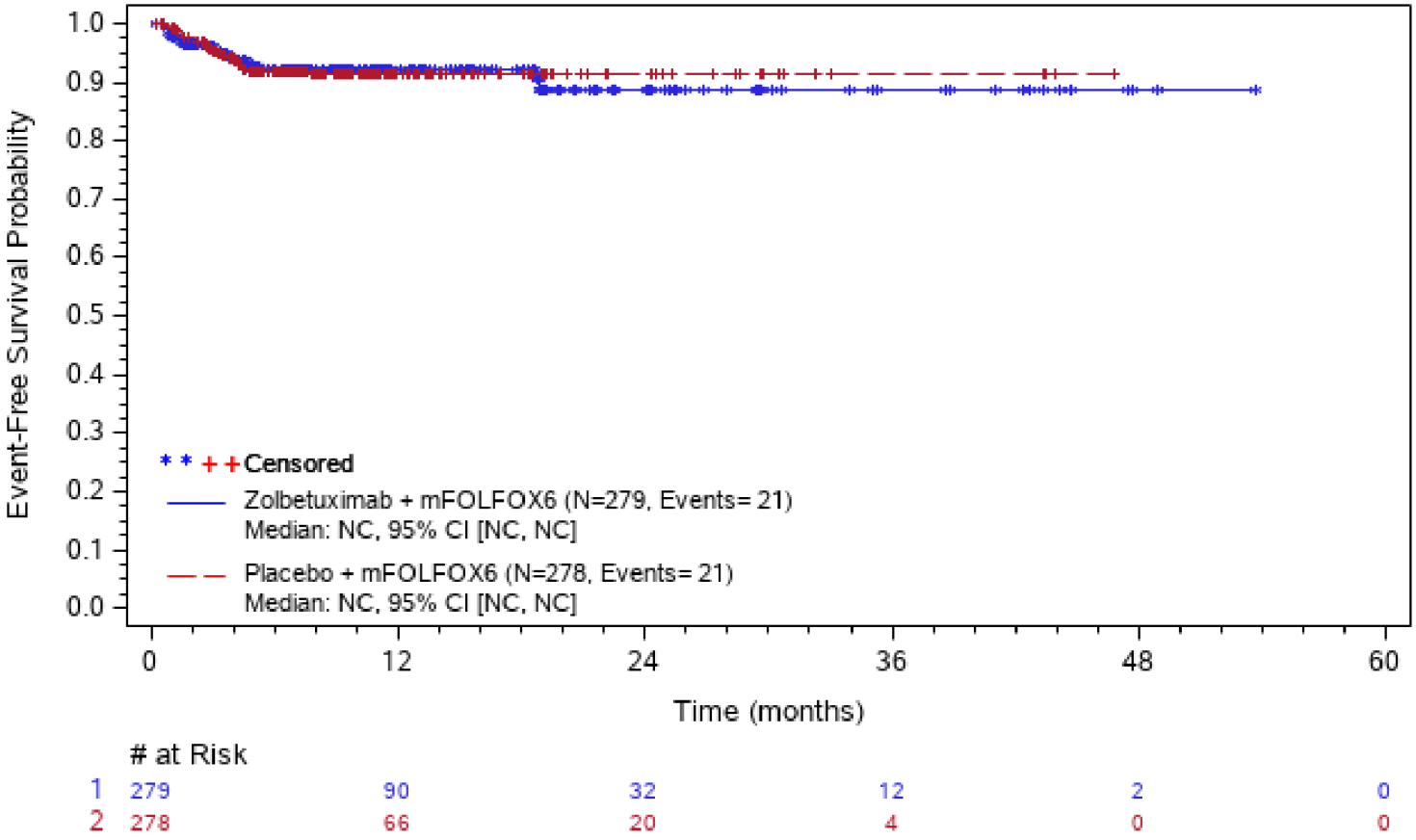


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.140: Kaplan-Meier Plot of Time to first TEAE - Alopecia (PT) - Safety Analysis Set

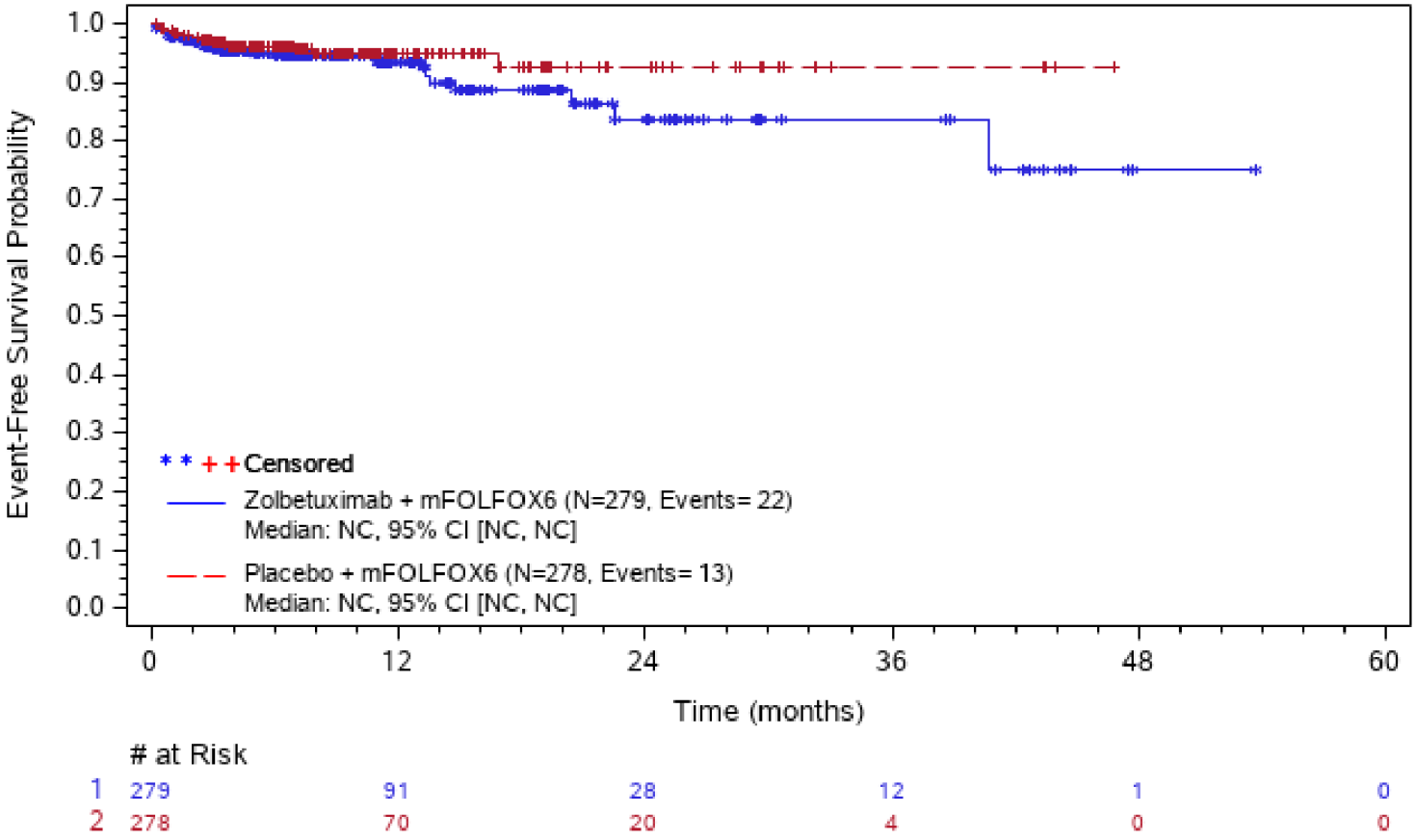


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.141: Kaplan-Meier Plot of Time to first TEAE - Dry Skin (PT) - Safety Analysis Set

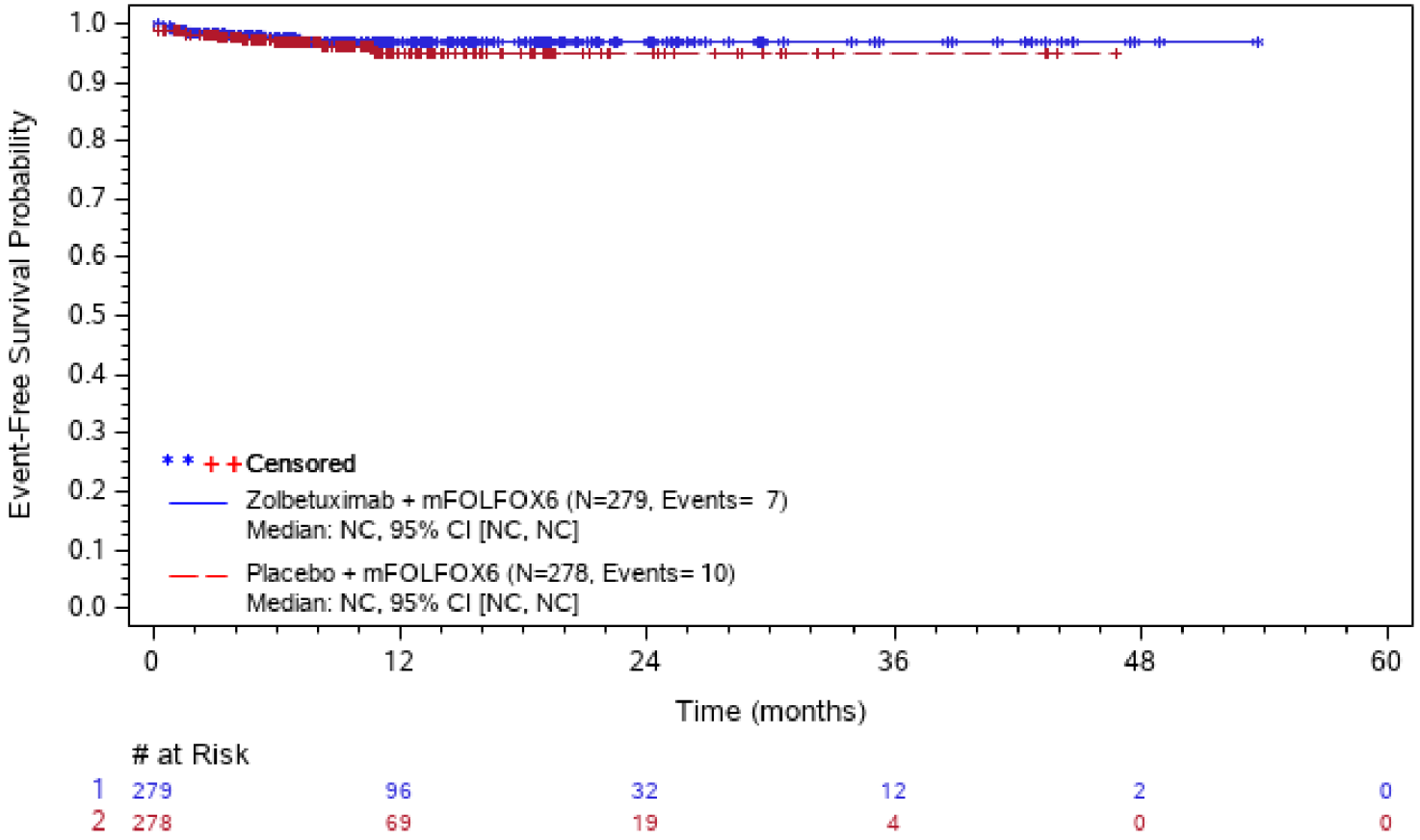


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.142: Kaplan-Meier Plot of Time to first TEAE - Erythema (PT) - Safety Analysis Set

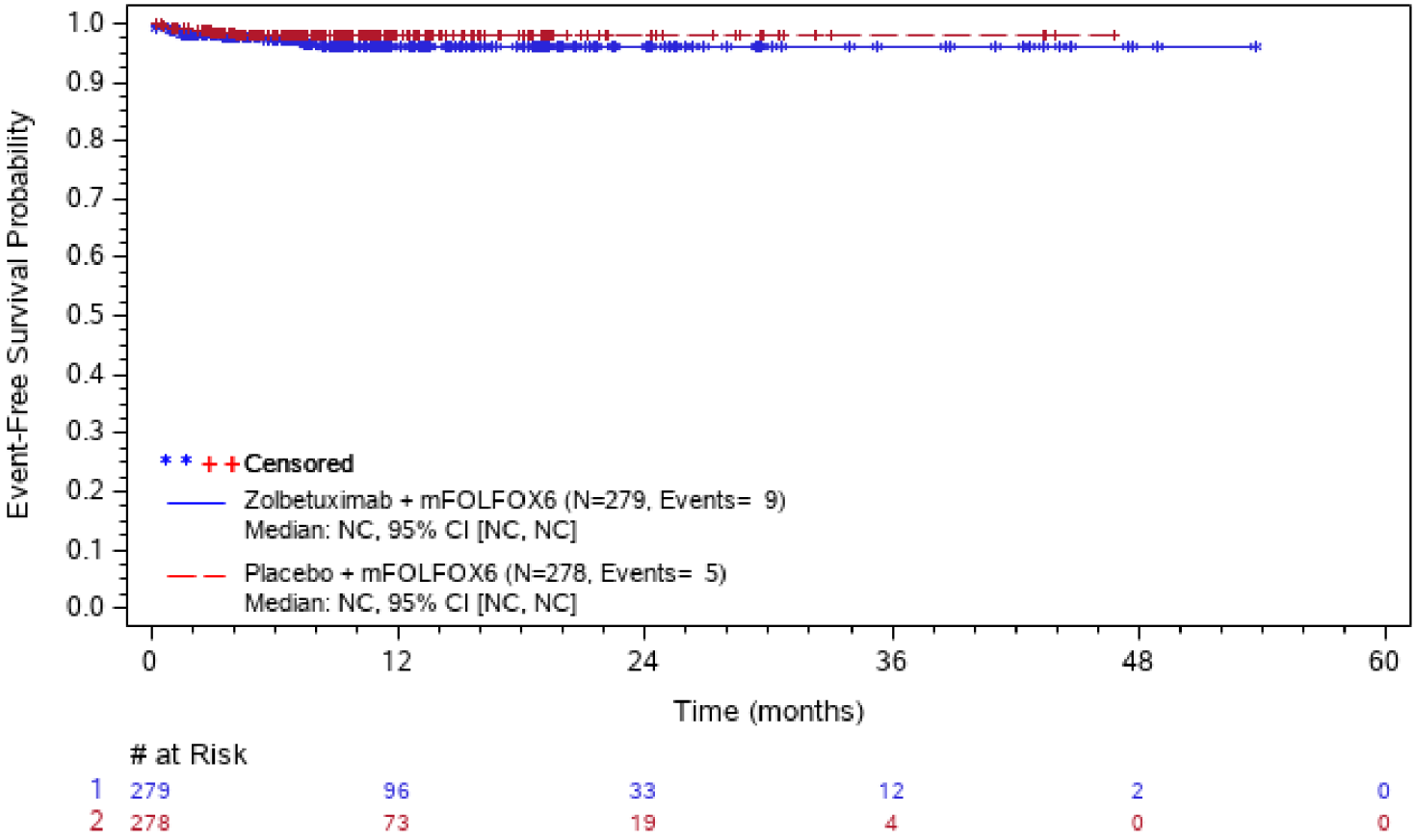


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.143: Kaplan-Meier Plot of Time to first TEAE - Hyperhidrosis (PT) - Safety Analysis Set

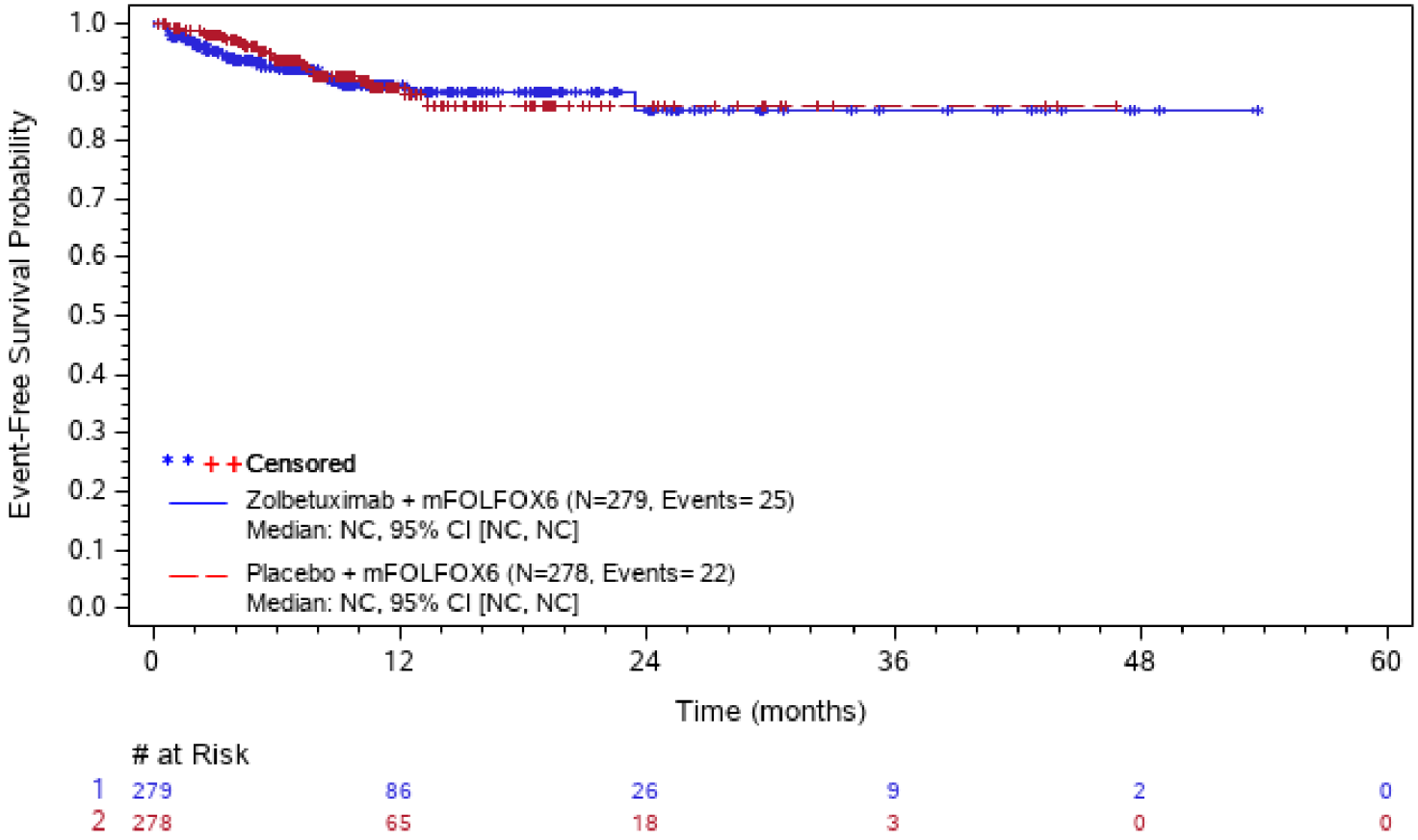


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.144: Kaplan-Meier Plot of Time to first TEAE - Palmar-Plantar Erythrodysaesthesia Syndrome (PT) - Safety Analysis Set

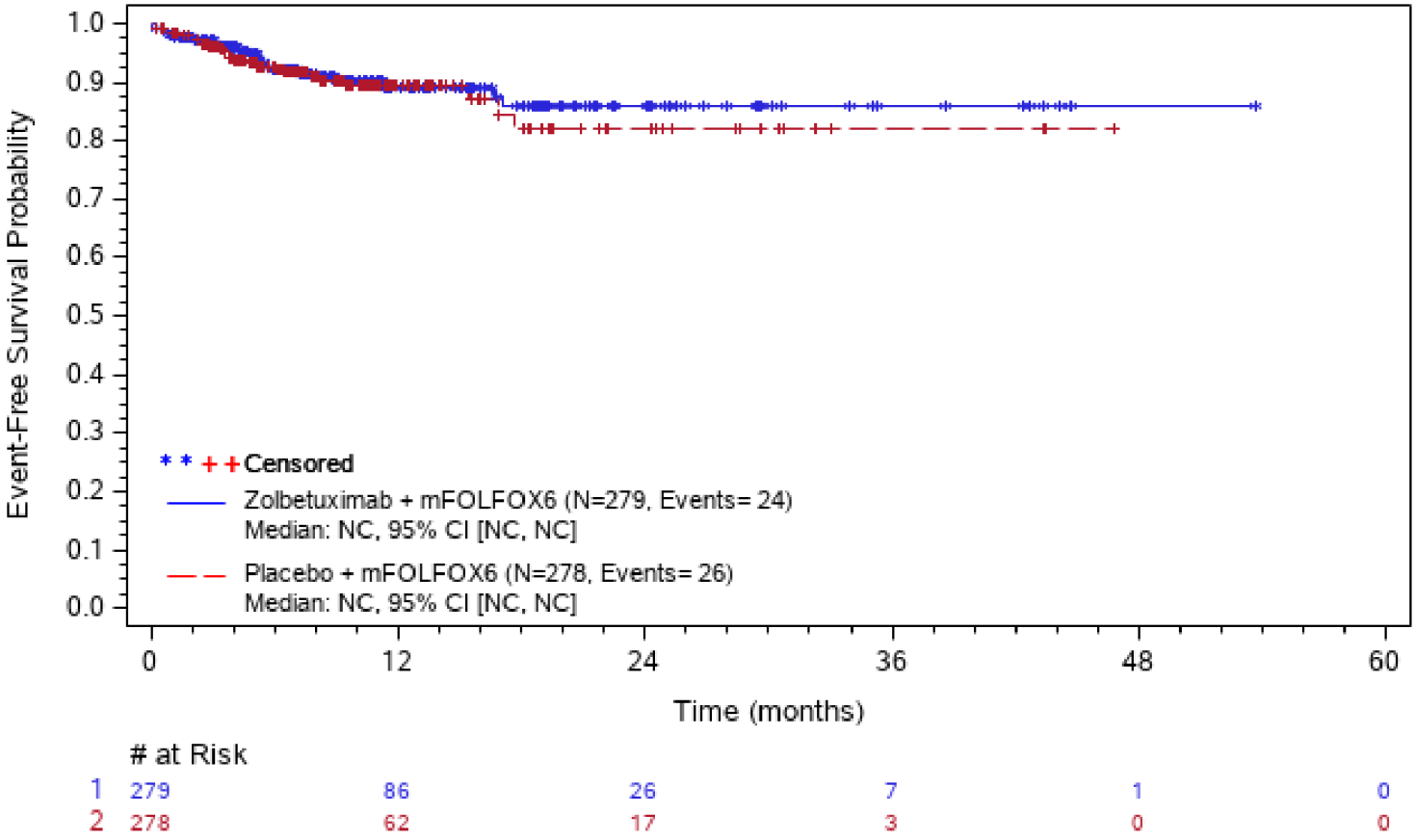


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.145: Kaplan-Meier Plot of Time to first TEAE - Pruritus (PT) - Safety Analysis Set



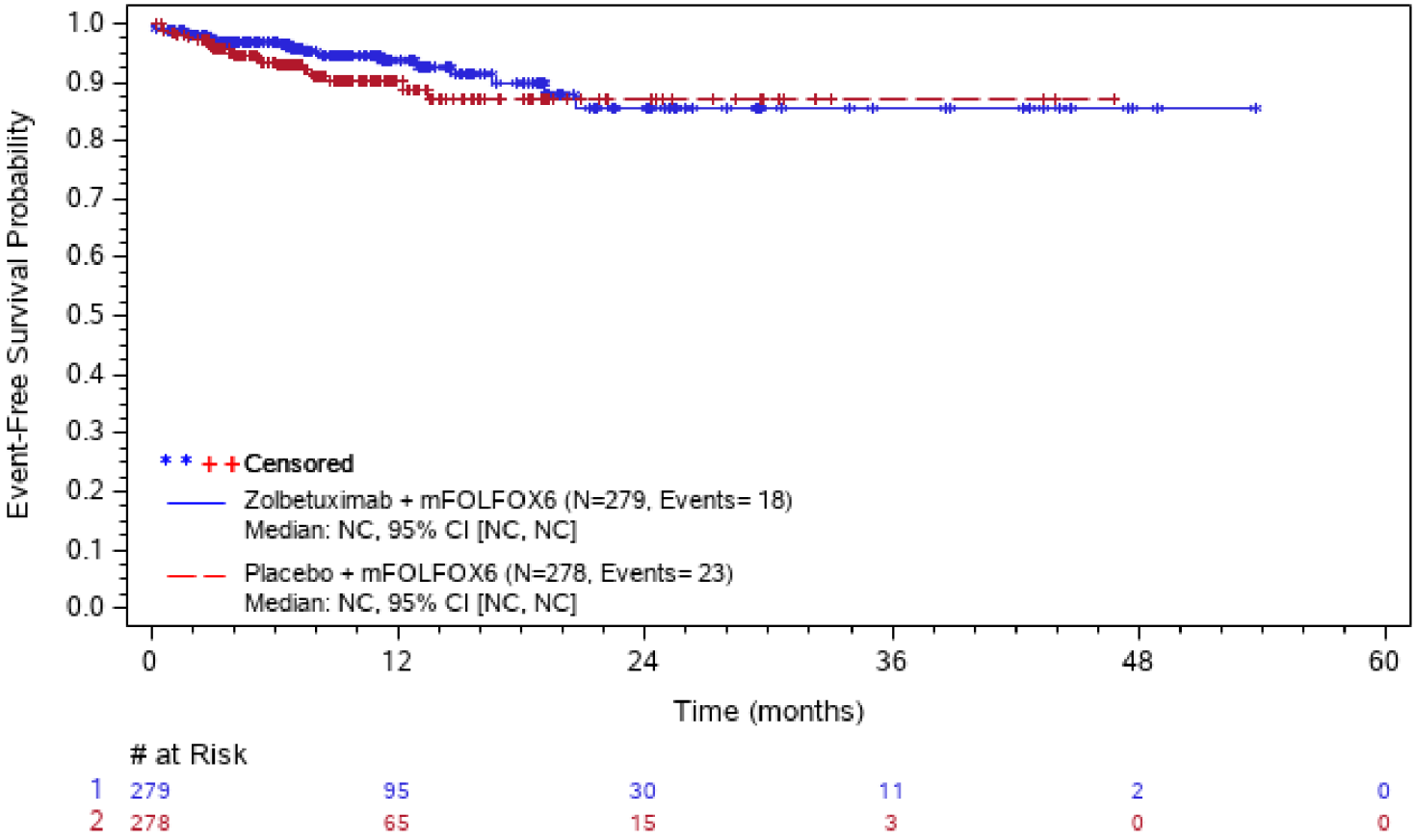
# at Risk						
1	279	86	26	7	1	0
2	278	62	17	3	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.146: Kaplan-Meier Plot of Time to first TEAE - Rash (PT) - Safety Analysis Set

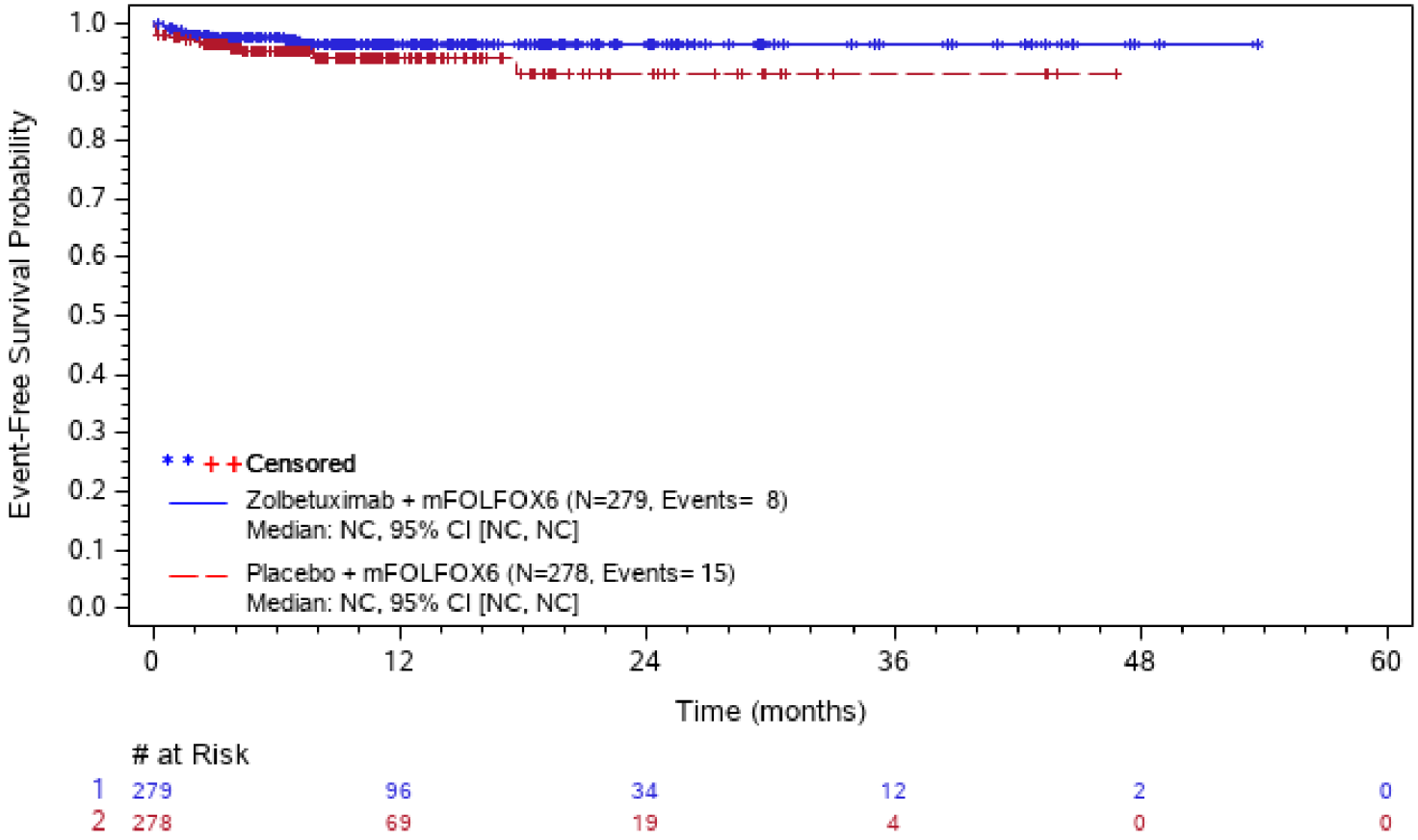


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.147: Kaplan-Meier Plot of Time to first TEAE - Rash Maculo-Papular (PT) - Safety Analysis Set

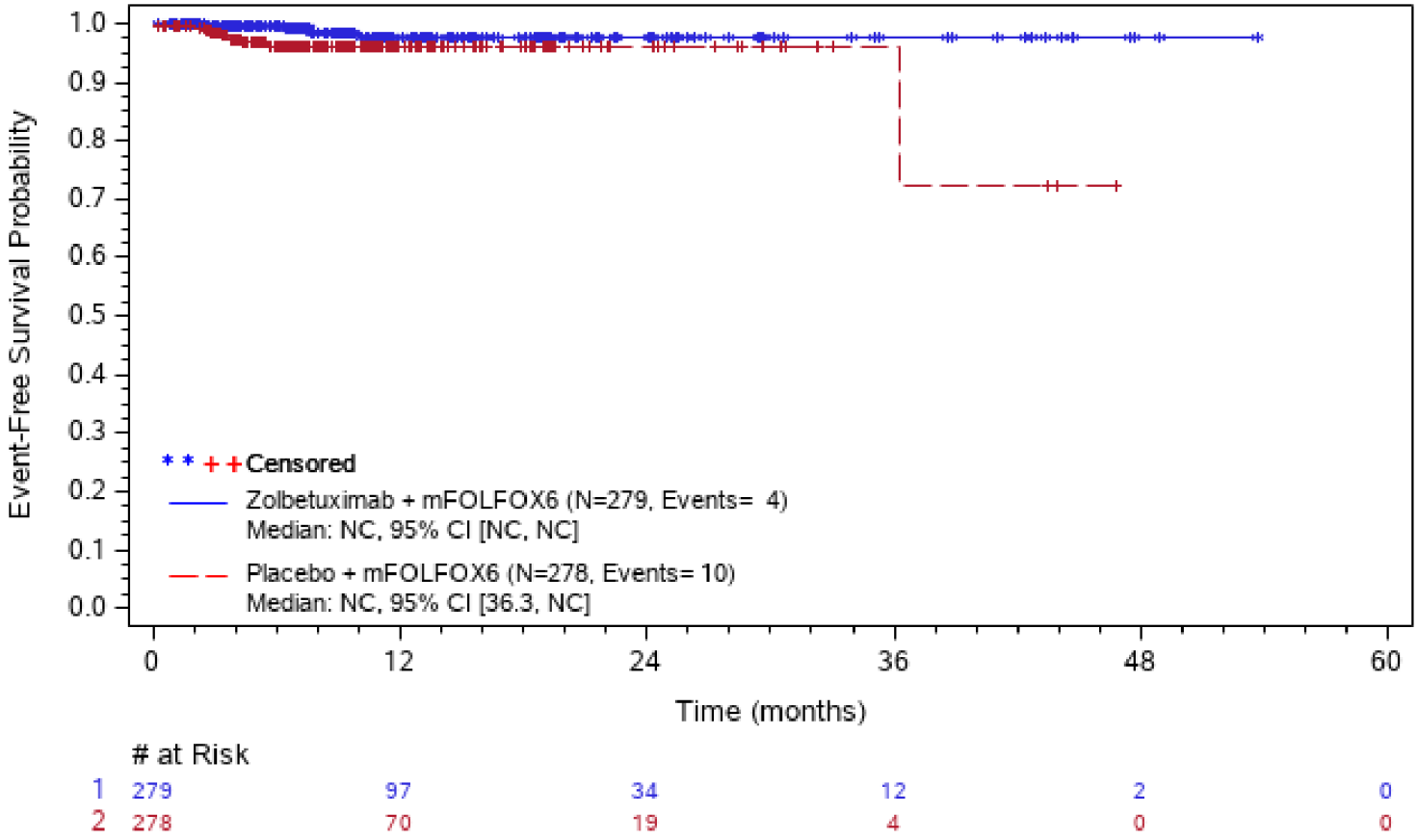


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.148: Kaplan-Meier Plot of Time to first TEAE - Urticaria (PT) - Safety Analysis Set

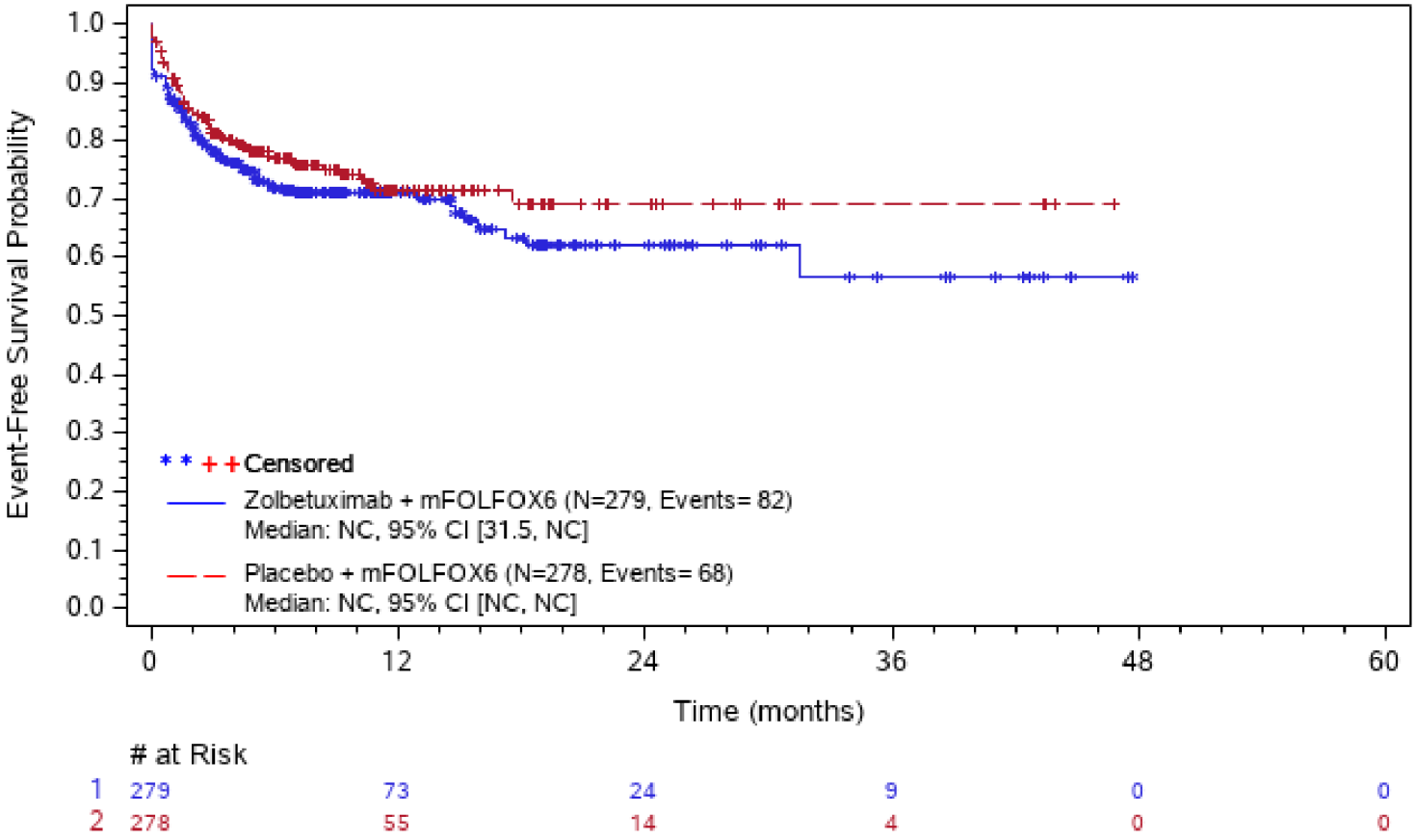


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.149: Kaplan-Meier Plot of Time to first TEAE - Vascular Disorders (SOC) - Safety Analysis Set

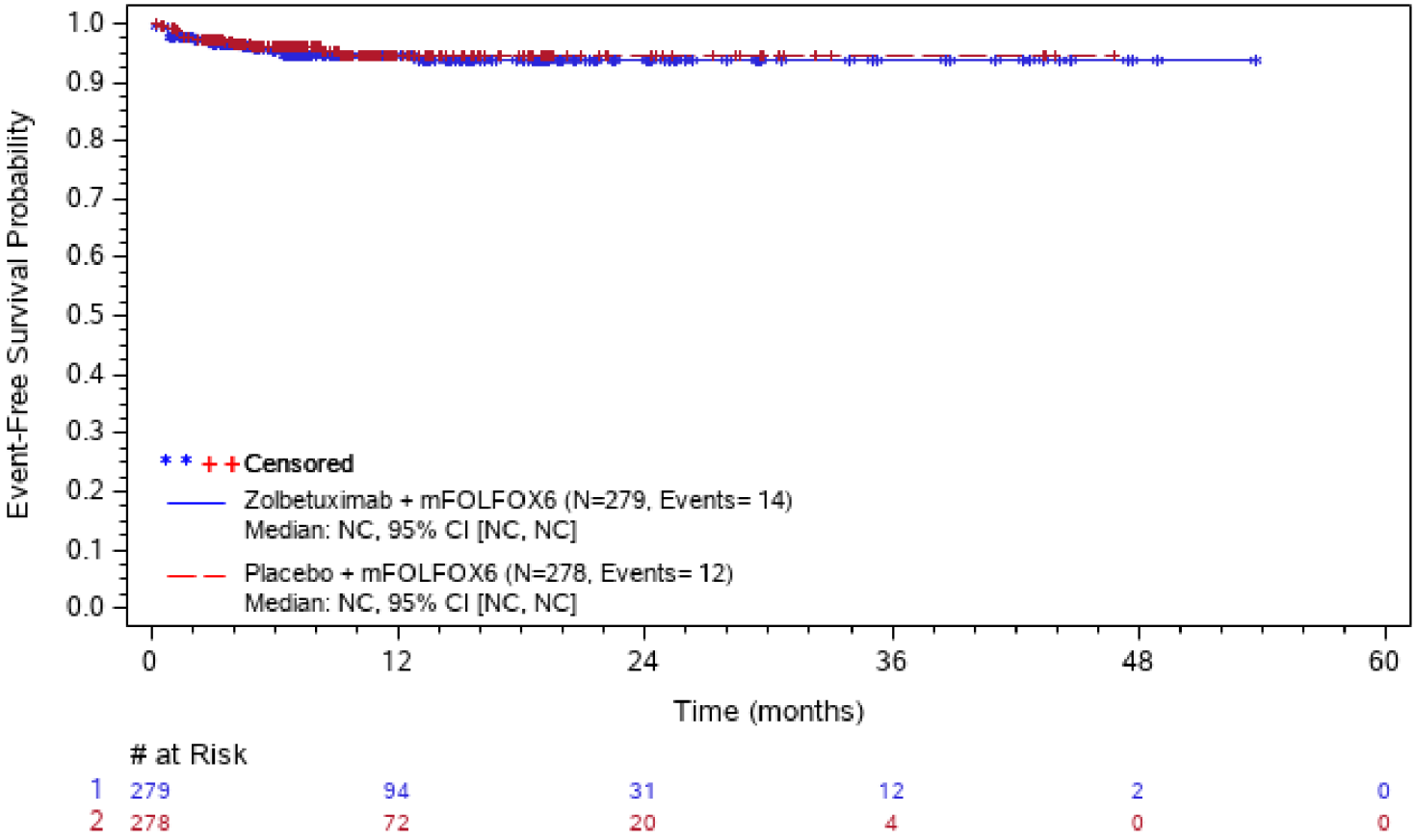


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.150: Kaplan-Meier Plot of Time to first TEAE - Deep Vein Thrombosis (PT) - Safety Analysis Set

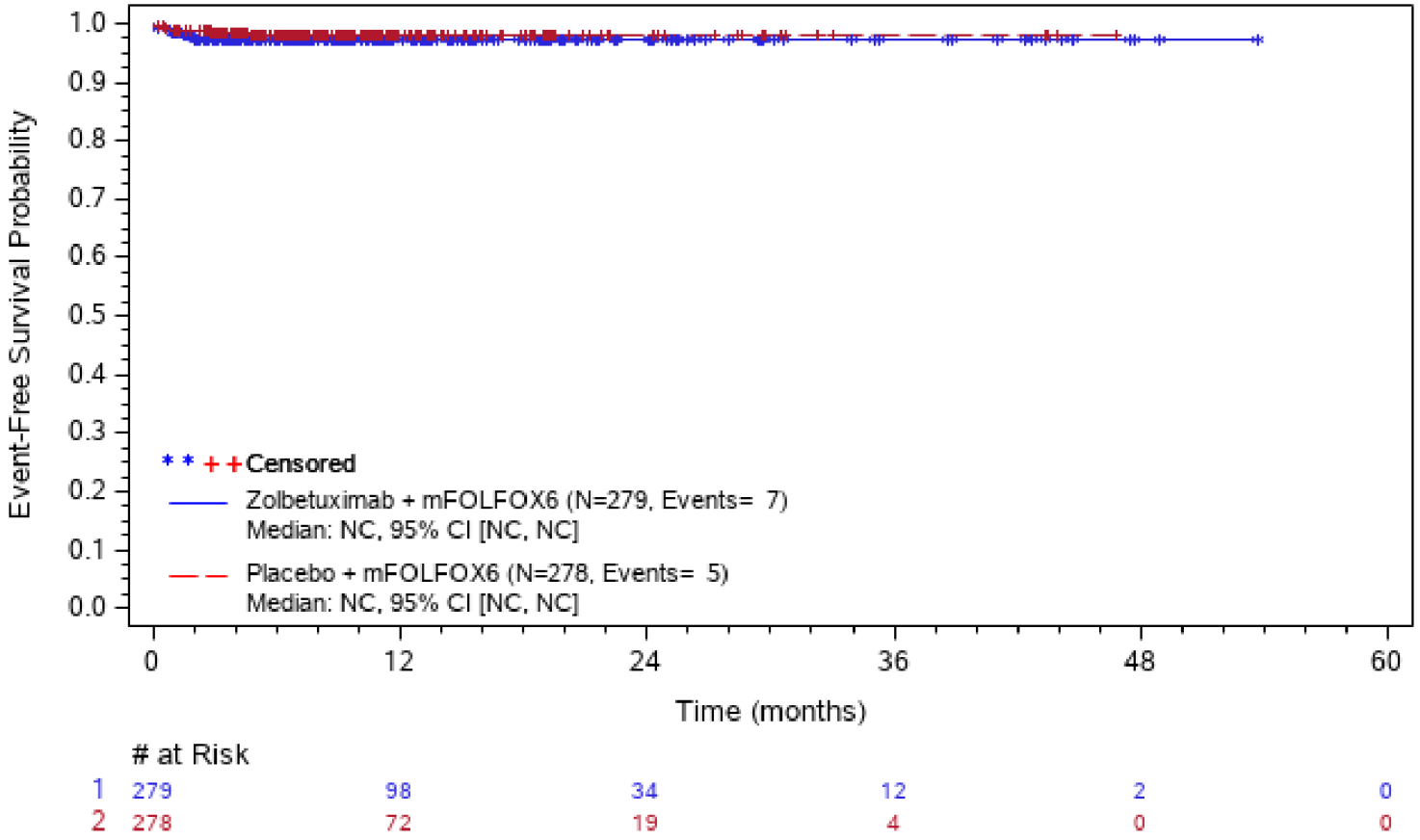


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.151: Kaplan-Meier Plot of Time to first TEAE - Flushing (PT) - Safety Analysis Set

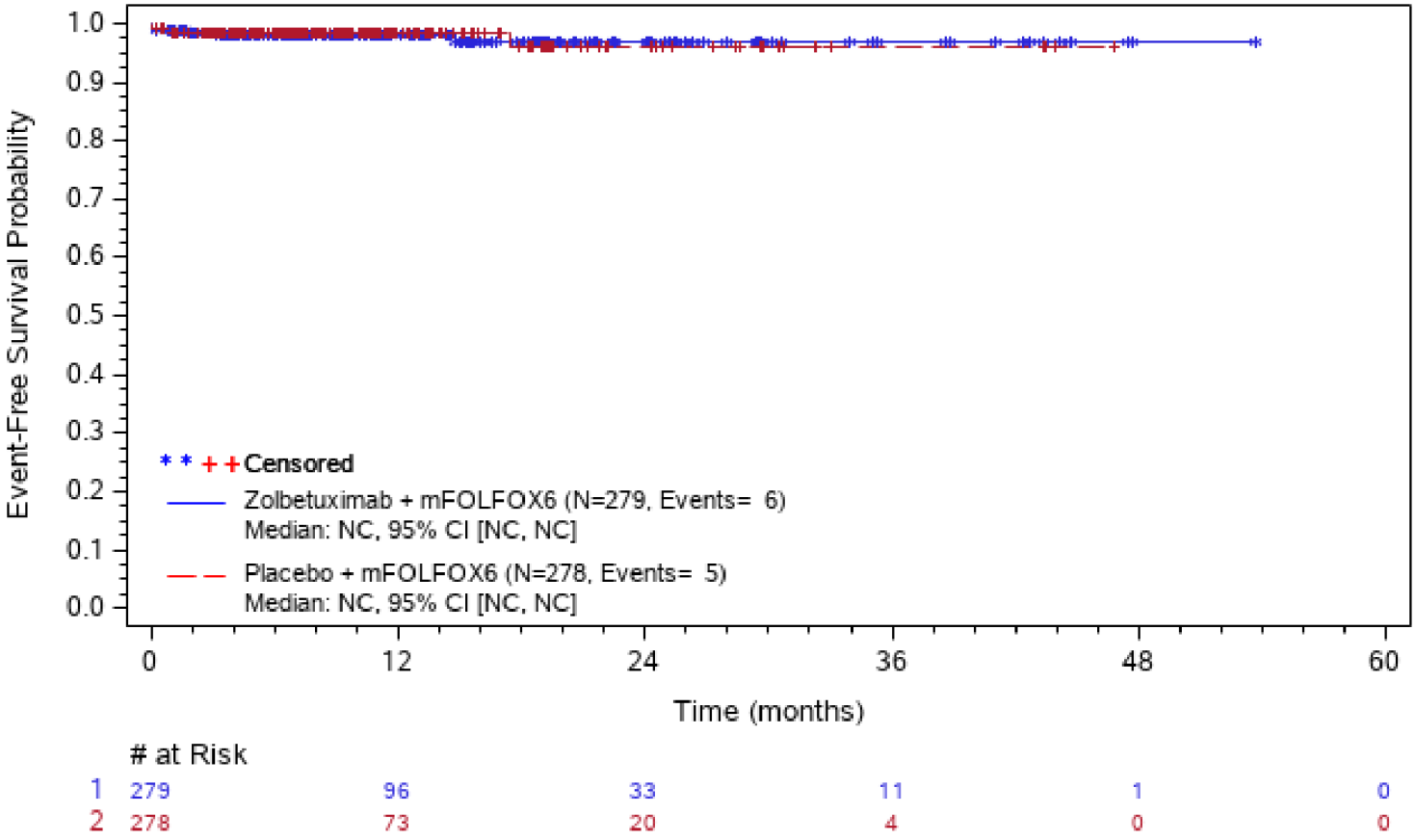


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.152: Kaplan-Meier Plot of Time to first TEAE - Hot Flush (PT) - Safety Analysis Set

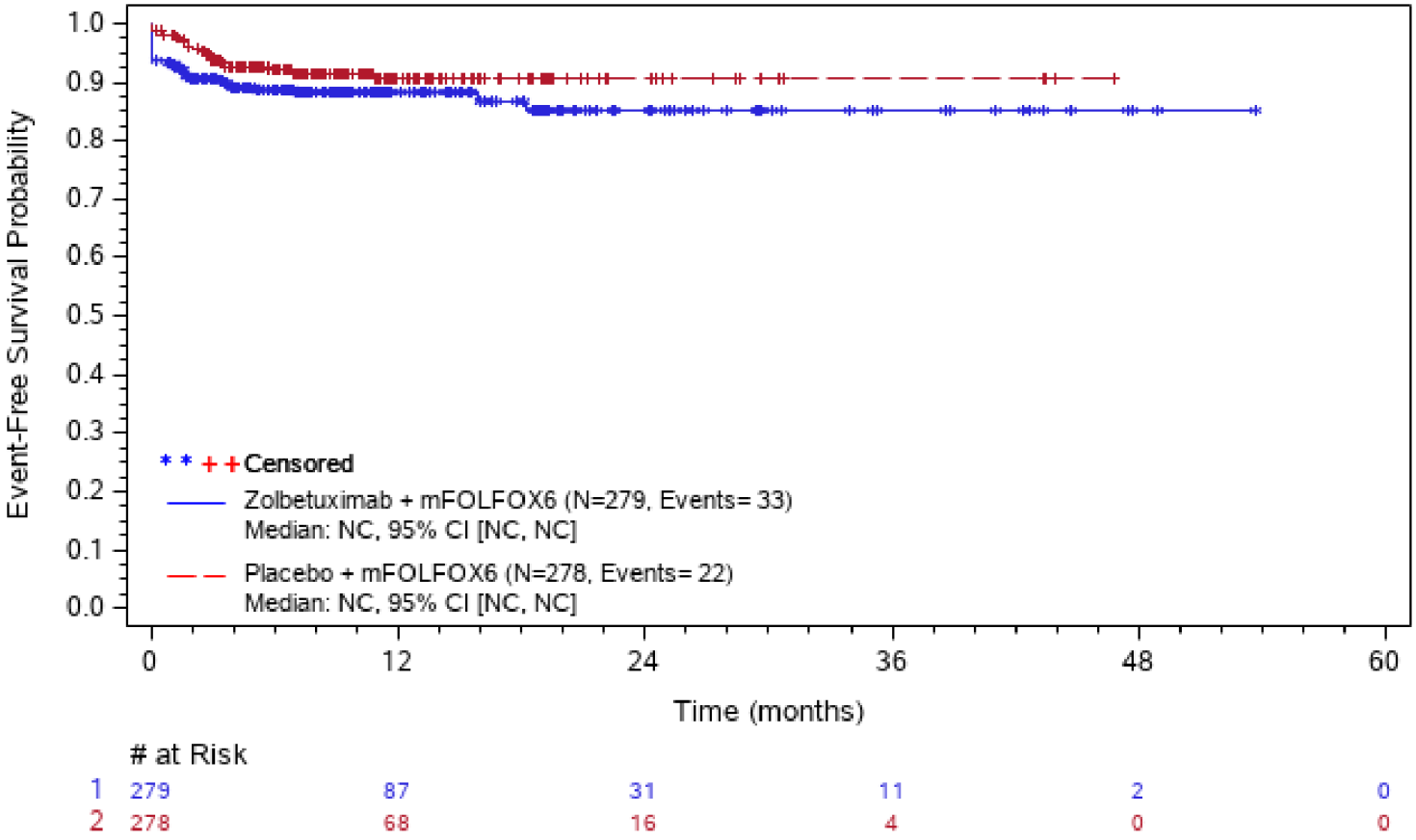


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.153: Kaplan-Meier Plot of Time to first TEAE - Hypertension (PT) - Safety Analysis Set

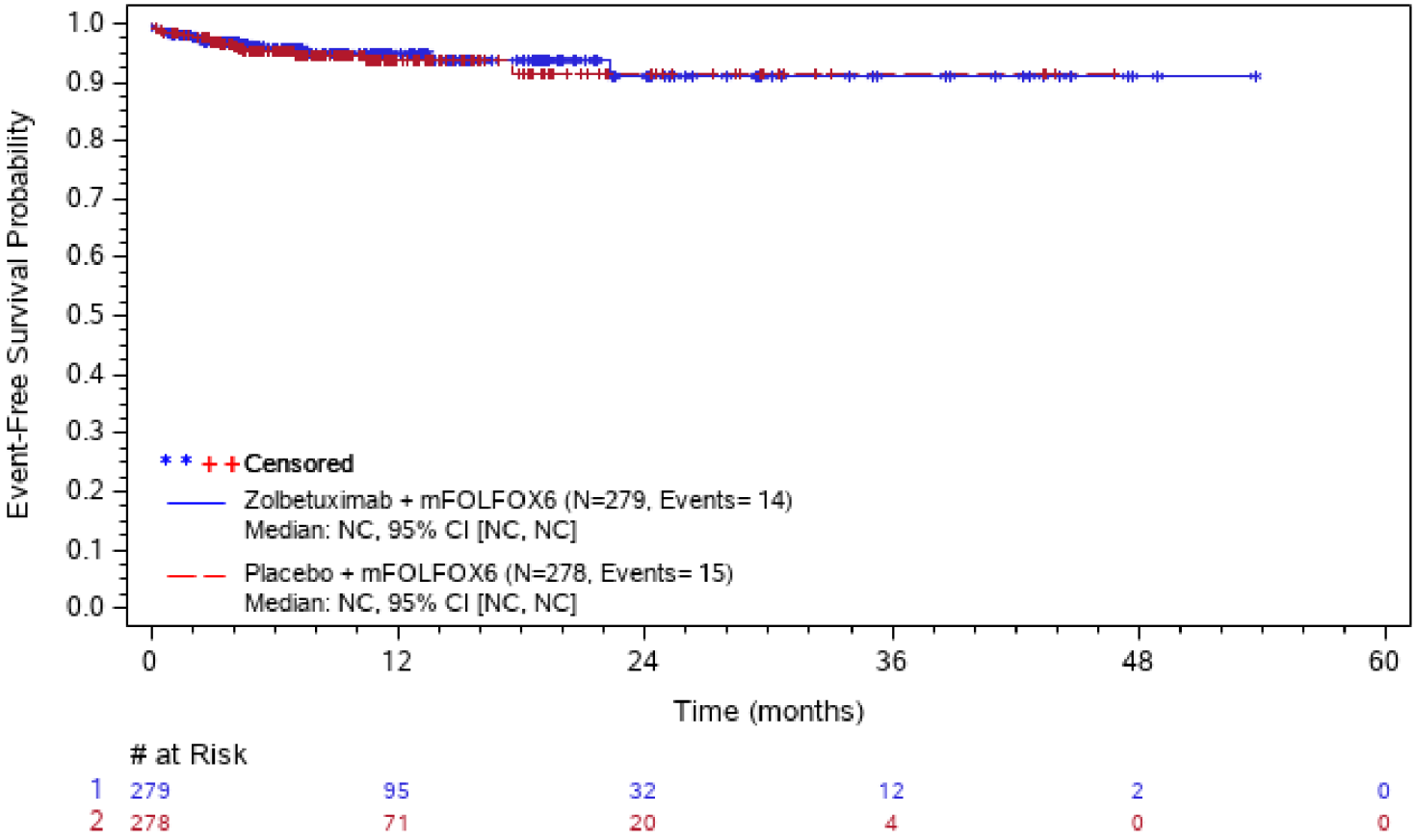


# at Risk						
1	279	87	31	11	2	0
2	278	68	16	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.154: Kaplan-Meier Plot of Time to first TEAE - Hypotension (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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.3.2001.178.1: Summary and Results of Severe TEAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	100 (35.8%)	90 (32.4%)	
Number of patients censored	179 (64.2%)	188 (67.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [21.4, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.167 [0.877, 1.552]
Log-rank test			
Two-sided stratified log-rank p-value			0.2855

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.179.1: Summary and Results of Severe TEAEs - Anaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	26 (9.4%)	
Number of patients censored	255 (91.4%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.909 [0.521, 1.586]
Log-rank test			
Two-sided stratified log-rank p-value			0.7367

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.180.1: Summary and Results of Severe TEAEs - Leukopenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	3 (1.1%)	
Number of patients censored	271 (97.1%)	275 (98.9%)	
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			2.791 [0.739, 10.548]
Log-rank test			
Two-sided stratified log-rank p-value			0.1142

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.181.1: Summary and Results of Severe TEAEs - Neutropenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	79 (28.3%)	65 (23.4%)	
Number of patients censored	200 (71.7%)	213 (76.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.286 [0.926, 1.787]
Log-rank test			
Two-sided stratified log-rank p-value			0.1284

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.182.1: Summary and Results of Severe TEAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	102 (36.6%)	56 (20.1%)	
Number of patients censored	177 (63.4%)	222 (79.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [20.0, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.066 [1.488, 2.867]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.182.2: Summary and Results of Severe TEAEs by Subgroups - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	69 (38.8)	NC [17.8, NC]	177	41 (23.2)	NC [NC, NC]	1.858 [1.261, 2.737]	0.0017	0.4916
>65 years	101	33 (32.7)	NC [20.0, NC]	101	15 (14.9)	NC [NC, NC]	2.385 [1.294, 4.395]	0.0042	
Sex									
Male	174	56 (32.2)	NC [19.1, NC]	173	34 (19.7)	NC [NC, NC]	1.758 [1.147, 2.693]	0.0095	0.3540
Female	105	46 (43.8)	28.9 [5.1, NC]	105	22 (21.0)	NC [NC, NC]	2.400 [1.443, 3.994]	0.0006	
Region									
Asia	87	18 (20.7)	NC [NC, NC]	88	14 (15.9)	NC [NC, NC]	1.194 [0.590, 2.418]	0.6315	0.1070
Non-Asia	192	84 (43.8)	28.9 [7.7, NC]	190	42 (22.1)	NC [NC, NC]	2.357 [1.627, 3.416]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	77 (35.6)	NC [20.0, NC]	216	42 (19.4)	NC [NC, NC]	2.011 [1.380, 2.931]	0.0003	0.8952
>=3	63	25 (39.7)	NC [4.1, NC]	62	14 (22.6)	NC [NC, NC]	1.942 [1.008, 3.739]	0.0432	

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 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: 08SEP23

Table 301.3.2001.183.1: Summary and Results of Severe TEAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	7 (2.5%)	
Number of patients censored	265 (95.0%)	271 (97.5%)	
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			2.194 [0.884, 5.447]
Log-rank test			
Two-sided stratified log-rank p-value			0.0824

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.184.1: Summary and Results of Severe TEAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	10 (3.6%)	
Number of patients censored	267 (95.7%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.174 [0.506, 2.723]
Log-rank test			
Two-sided stratified log-rank p-value			0.7081

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.185.1: Summary and Results of Severe TEAEs - Dysphagia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	8 (2.9%)	
Number of patients censored	274 (98.2%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.602 [0.195, 1.852]
Log-rank test			
Two-sided stratified log-rank p-value			0.3707

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.186.1: Summary and Results of Severe TEAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.553 [0.506, 4.763]
Log-rank test			
Two-sided stratified log-rank p-value			0.4381

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.187.1: Summary and Results of Severe TEAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	19 (6.8%)	
Number of patients censored	234 (83.9%)	259 (93.2%)	
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			2.514 [1.469, 4.304]
Log-rank test			
Two-sided stratified log-rank p-value			0.0005

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.187.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	29 (16.3)	NC [NC, NC]	177	15 (8.5)	NC [NC, NC]	2.080 [1.115, 3.880]	0.0200	0.2807
>65 years	101	16 (15.8)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.159 [1.389, 12.456]	0.0057	
Sex									
Male	174	23 (13.2)	NC [NC, NC]	173	10 (5.8)	NC [NC, NC]	2.422 [1.153, 5.089]	0.0166	0.8748
Female	105	22 (21.0)	NC [NC, NC]	105	9 (8.6)	NC [NC, NC]	2.628 [1.209, 5.712]	0.0117	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	6 (6.8)	NC [NC, NC]	1.430 [0.505, 4.051]	0.5066	0.2576
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	3.047 [1.615, 5.746]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	34 (15.7)	NC [NC, NC]	216	12 (5.6)	NC [NC, NC]	3.009 [1.557, 5.813]	0.0006	0.2934
>=3	63	11 (17.5)	NC [NC, NC]	62	7 (11.3)	NC [NC, NC]	1.650 [0.639, 4.261]	0.2978	

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 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: 08SEP23

Table 301.3.2001.188.1: Summary and Results of Severe TEAEs - Stomatitis (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	3 (1.1%)	
Number of patients censored	272 (97.5%)	275 (98.9%)	
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			2.085 [0.521, 8.344]
Log-rank test			
Two-sided stratified log-rank p-value			0.2884

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.189.1: Summary and Results of Severe TEAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	17 (6.1%)	
Number of patients censored	234 (83.9%)	261 (93.9%)	
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			2.851 [1.629, 4.988]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.189.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	30 (16.9)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	2.277 [1.207, 4.295]	0.0103	0.2439
>65 years	101	15 (14.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	5.289 [1.531, 18.271]	0.0032	
Sex									
Male	174	21 (12.1)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	2.397 [1.097, 5.235]	0.0251	0.6072
Female	105	24 (22.9)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	3.303 [1.484, 7.353]	0.0020	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	4 (4.5)	NC [NC, NC]	2.125 [0.649, 6.954]	0.2081	0.6727
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	3.037 [1.610, 5.728]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	35 (16.2)	NC [NC, NC]	216	11 (5.1)	NC [NC, NC]	3.380 [1.716, 6.658]	0.0002	0.2735
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.757 [0.638, 4.837]	0.2728	

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 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: 08SEP23

Table 301.3.2001.190.1: Summary and Results of Severe TEAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	48 (17.2%)	33 (11.9%)	
Number of patients censored	231 (82.8%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [31.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.366 [0.872, 2.140]
Log-rank test			
Two-sided stratified log-rank p-value			0.1720

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.191.1: Summary and Results of Severe TEAEs - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	21 (7.5%)	7 (2.5%)	
Number of patients censored	258 (92.5%)	271 (97.5%)	
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			2.598 [1.091, 6.187]
Log-rank test			
Two-sided stratified log-rank p-value			0.0255

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.191.2: Summary and Results of Severe TEAEs by Subgroups - Asthenia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [31.3, NC]	177	6 (3.4)	NC [26.5, NC]	1.988 [0.753, 5.248]	0.1573	0.2848
>65 years	101	8 (7.9)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	7.698 [0.962, 61.632]	0.0231	
Sex									
Male	174	16 (9.2)	NC [31.3, NC]	173	3 (1.7)	NC [NC, NC]	4.965 [1.442, 17.093]	0.0049	0.1046
Female	105	5 (4.8)	NC [27.3, NC]	105	4 (3.8)	NC [26.5, NC]	1.040 [0.275, 3.931]	0.9536	
Region									
Asia	87	6 (6.9)	NC [27.3, NC]	88	3 (3.4)	NC [26.5, NC]	1.059 [0.254, 4.403]	0.9376	0.2786
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	4 (2.1)	NC [NC, NC]	4.013 [1.331, 12.095]	0.0076	
Number of Organs with Metastatic Sites									
0-2	216	17 (7.9)	NC [31.3, NC]	216	6 (2.8)	NC [NC, NC]	2.492 [0.977, 6.356]	0.0480	0.6779
>=3	63	4 (6.3)	NC [NC, NC]	62	1 (1.6)	NC [NC, NC]	4.161 [0.463, 37.402]	0.1672	

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 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: 08SEP23

Table 301.3.2001.192.1: Summary and Results of Severe TEAEs - Fatigue (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	15 (5.4%)	
Number of patients censored	261 (93.5%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.143 [0.573, 2.278]
Log-rank test			
Two-sided stratified log-rank p-value			0.7025

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.193.1: Summary and Results of Severe TEAEs - Hepatobiliary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	10 (3.6%)	
Number of patients censored	270 (96.8%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.857 [0.346, 2.125]
Log-rank test			
Two-sided stratified log-rank p-value			0.7388

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.194.1: Summary and Results of Severe TEAEs - Infections And Infestations (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	29 (10.4%)	26 (9.4%)	
Number of patients censored	250 (89.6%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.050 [0.616, 1.789]
Log-rank test			
Two-sided stratified log-rank p-value			0.8588

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.195.1: Summary and Results of Severe TEAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	9 (3.2%)	
Number of patients censored	272 (97.5%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.671 [0.247, 1.821]
Log-rank test			
Two-sided stratified log-rank p-value			0.4305

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.196.1: Summary and Results of Severe TEAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	14 (5.0%)	8 (2.9%)	
Number of patients censored	265 (95.0%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.663 [0.694, 3.985]
Log-rank test			
Two-sided stratified log-rank p-value			0.2492

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.197.1: Summary and Results of Severe TEAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	94 (33.7%)	87 (31.3%)	
Number of patients censored	185 (66.3%)	191 (68.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [23.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.089 [0.813, 1.460]
Log-rank test			
Two-sided stratified log-rank p-value			0.5568

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.198.1: Summary and Results of Severe TEAEs - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	2 (0.7%)	10 (3.6%)	
Number of patients censored	277 (99.3%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.185 [0.040, 0.852]
Log-rank test			
Two-sided stratified log-rank p-value			0.0156

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.198.2: Summary and Results of Severe TEAEs by Subgroups - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	8 (4.5)				
>65 years	101	1 (1.0)		101	2 (2.0)				
Sex									
Male	174	2 (1.1)		173	6 (3.5)				
Female	105	0 (0.0)		105	4 (3.8)				
Region									
Asia	87	2 (2.3)		88	1 (1.1)				
Non-Asia	192	0 (0.0)		190	9 (4.7)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)	NC [NC, NC]	216	8 (3.7)	NC [NC, NC]	0.221 [0.047, 1.043]	0.0366	0.9939
>=3	63	0 (0.0)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.000 [0.000, NC]	0.1743	

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 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: 08SEP23

Table 301.3.2001.199.1: Summary and Results of Severe TEAEs - Aspartate Aminotransferase Increased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	9 (3.2%)	
Number of patients censored	275 (98.6%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.418 [0.128, 1.369]
Log-rank test			
Two-sided stratified log-rank p-value			0.1373

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.200.1: Summary and Results of Severe TEAEs - Neutrophil Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	69 (24.7%)	69 (24.8%)	
Number of patients censored	210 (75.3%)	209 (75.2%)	
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			1.001 [0.716, 1.399]
Log-rank test			
Two-sided stratified log-rank p-value			0.9845

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.201.1: Summary and Results of Severe TEAEs - White Blood Cell Count Decreased (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	16 (5.8%)	
Number of patients censored	271 (97.1%)	262 (94.2%)	
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			0.490 [0.209, 1.146]
Log-rank test			
Two-sided stratified log-rank p-value			0.0929

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.202.1: Summary and Results of Severe TEAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	66 (23.7%)	35 (12.6%)	
Number of patients censored	213 (76.3%)	243 (87.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.898 [1.256, 2.869]
Log-rank test			
Two-sided stratified log-rank p-value			0.0020

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.202.2: Summary and Results of Severe TEAEs by Subgroups - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	38 (21.3)	NC [29.1, NC]	177	19 (10.7)	NC [NC, NC]	2.079 [1.198, 3.608]	0.0078	0.7171
>65 years	101	28 (27.7)	NC [21.8, NC]	101	16 (15.8)	NC [NC, NC]	1.749 [0.945, 3.237]	0.0712	
Sex									
Male	174	42 (24.1)	NC [NC, NC]	173	24 (13.9)	NC [NC, NC]	1.811 [1.096, 2.993]	0.0186	0.6349
Female	105	24 (22.9)	NC [29.1, NC]	105	11 (10.5)	NC [NC, NC]	2.196 [1.074, 4.491]	0.0269	
Region									
Asia	87	15 (17.2)	NC [29.1, NC]	88	14 (15.9)	NC [17.4, NC]	0.839 [0.399, 1.764]	0.6432	0.0201
Non-Asia	192	51 (26.6)	NC [21.9, NC]	190	21 (11.1)	NC [NC, NC]	2.687 [1.616, 4.468]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	51 (23.6)	NC [29.1, NC]	216	26 (12.0)	NC [NC, NC]	1.993 [1.241, 3.199]	0.0036	0.7198
>=3	63	15 (23.8)	NC [NC, NC]	62	9 (14.5)	NC [NC, NC]	1.710 [0.748, 3.910]	0.1974	

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 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: 08SEP23

Table 301.3.2001.203.1: Summary and Results of Severe TEAEs - Decreased Appetite (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	9 (3.2%)	
Number of patients censored	262 (93.9%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.843 [0.819, 4.150]
Log-rank test			
Two-sided stratified log-rank p-value			0.1337

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.204.1: Summary and Results of Severe TEAEs - Hypoalbuminaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	2 (0.7%)	
Number of patients censored	267 (95.7%)	276 (99.3%)	
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			6.443 [1.441, 28.801]
Log-rank test			
Two-sided stratified log-rank p-value			0.0050

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.204.2: Summary and Results of Severe TEAEs by Subgroups - Hypoalbuminaemia (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	8 (4.5)	NC [NC, NC]	177	2 (1.1)	NC [NC, NC]	4.285 [0.910, 20.180]	0.0447	0.9912
>65 years	101	4 (4.0)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	2.71E7 [0.000, NC]	0.0581	
Sex									
Male	174	6 (3.4)		173	2 (1.2)				
Female	105	6 (5.7)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	NC [NC, NC]	NC	0.9994
Non-Asia	192	12 (6.3)	NC [NC, NC]	190	2 (1.1)	NC [NC, NC]	6.411 [1.434, 28.658]	0.0052	
Number of Organs with Metastatic Sites									
0-2	216	9 (4.2)	NC [NC, NC]	216	2 (0.9)	NC [NC, NC]	4.542 [0.979, 21.071]	0.0339	0.9932
>=3	63	3 (4.8)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.22E7 [0.000, NC]	0.0712	

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 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: 08SEP23

Table 301.3.2001.205.1: Summary and Results of Severe TEAEs - Hypokalaemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	10 (3.6%)	
Number of patients censored	263 (94.3%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.588 [0.720, 3.502]
Log-rank test			
Two-sided stratified log-rank p-value			0.2477

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.206.1: Summary and Results of Severe TEAEs - Hypophosphataemia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	7 (2.5%)	
Number of patients censored	271 (97.1%)	271 (97.5%)	
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			1.035 [0.369, 2.899]
Log-rank test			
Two-sided stratified log-rank p-value			0.9483

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.207.1: Summary and Results of Severe TEAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	18 (6.5%)	
Number of patients censored	264 (94.6%)	260 (93.5%)	
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			0.834 [0.419, 1.658]
Log-rank test			
Two-sided stratified log-rank p-value			0.6039

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.208.1: Summary and Results of Severe TEAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.876 [0.378, 2.033]
Log-rank test			
Two-sided stratified log-rank p-value			0.7579

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.209.1: Summary and Results of Severe TEAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	37 (13.3%)	33 (11.9%)	
Number of patients censored	242 (86.7%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.134 [0.707, 1.816]
Log-rank test			
Two-sided stratified log-rank p-value			0.6022

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.210.1: Summary and Results of Severe TEAEs - Paraesthesia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.488 [0.419, 5.289]
Log-rank test			
Two-sided stratified log-rank p-value			0.5366

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.211.1: Summary and Results of Severe TEAEs - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	15 (5.4%)	
Number of patients censored	267 (95.7%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.797 [0.370, 1.718]
Log-rank test			
Two-sided stratified log-rank p-value			0.5616

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.212.1: Summary and Results of Severe TEAEs - Syncope (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	5 (1.8%)	
Number of patients censored	274 (98.2%)	273 (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			0.990 [0.284, 3.447]
Log-rank test			
Two-sided stratified log-rank p-value			0.9877

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.213.1: Summary and Results of Severe TEAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	16 (5.8%)	
Number of patients censored	261 (93.5%)	262 (94.2%)	
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			1.155 [0.588, 2.272]
Log-rank test			
Two-sided stratified log-rank p-value			0.6748

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.214.1: Summary and Results of Severe TEAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	9 (3.2%)	6 (2.2%)	
Number of patients censored	270 (96.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.547 [0.549, 4.353]
Log-rank test			
Two-sided stratified log-rank p-value			0.4052

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.215.1: Summary and Results of Severe TEAEs - Vascular Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	13 (4.7%)	
Number of patients censored	255 (91.4%)	265 (95.3%)	
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			1.892 [0.962, 3.722]
Log-rank test			
Two-sided stratified log-rank p-value			0.0605

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.216.1: Summary and Results of Severe TEAEs - Hypertension (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	10 (3.6%)	
Number of patients censored	264 (94.6%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.564 [0.702, 3.482]
Log-rank test			
Two-sided stratified log-rank p-value			0.2717

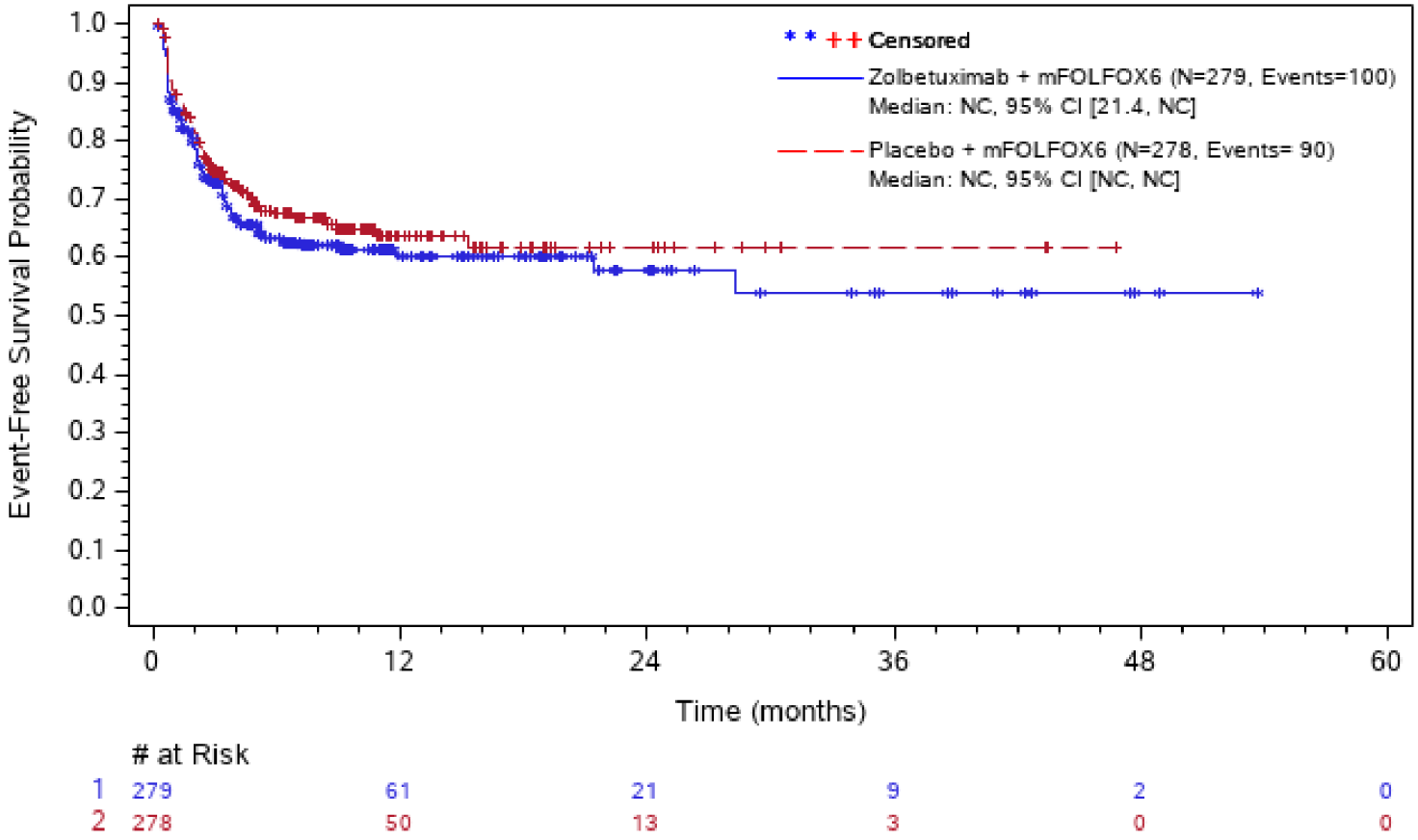
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwere unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.178: Kaplan-Meier Plot of Time to first Severe TEAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

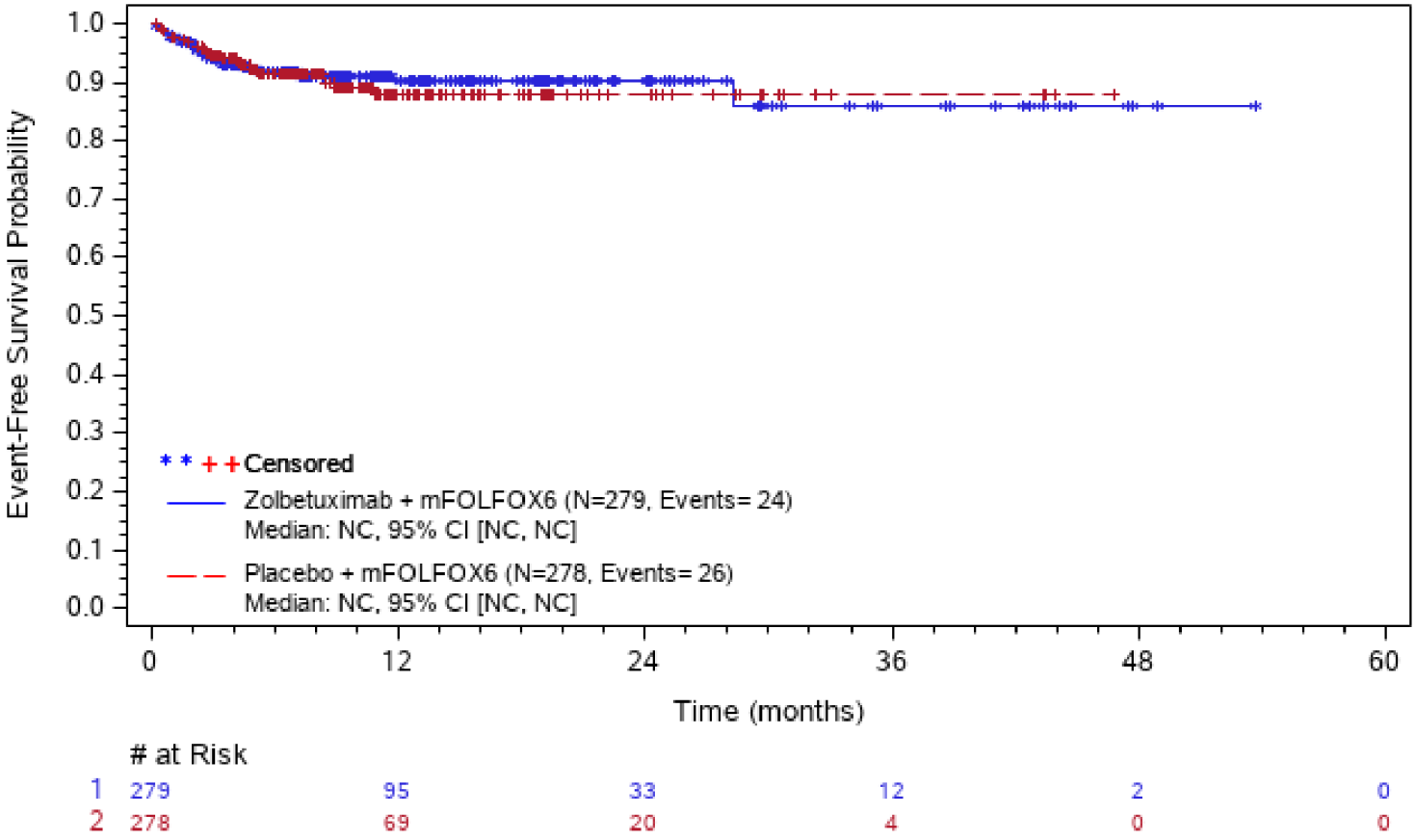


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.179: Kaplan-Meier Plot of Time to first Severe TEAE - Anaemia (PT) - Safety Analysis Set

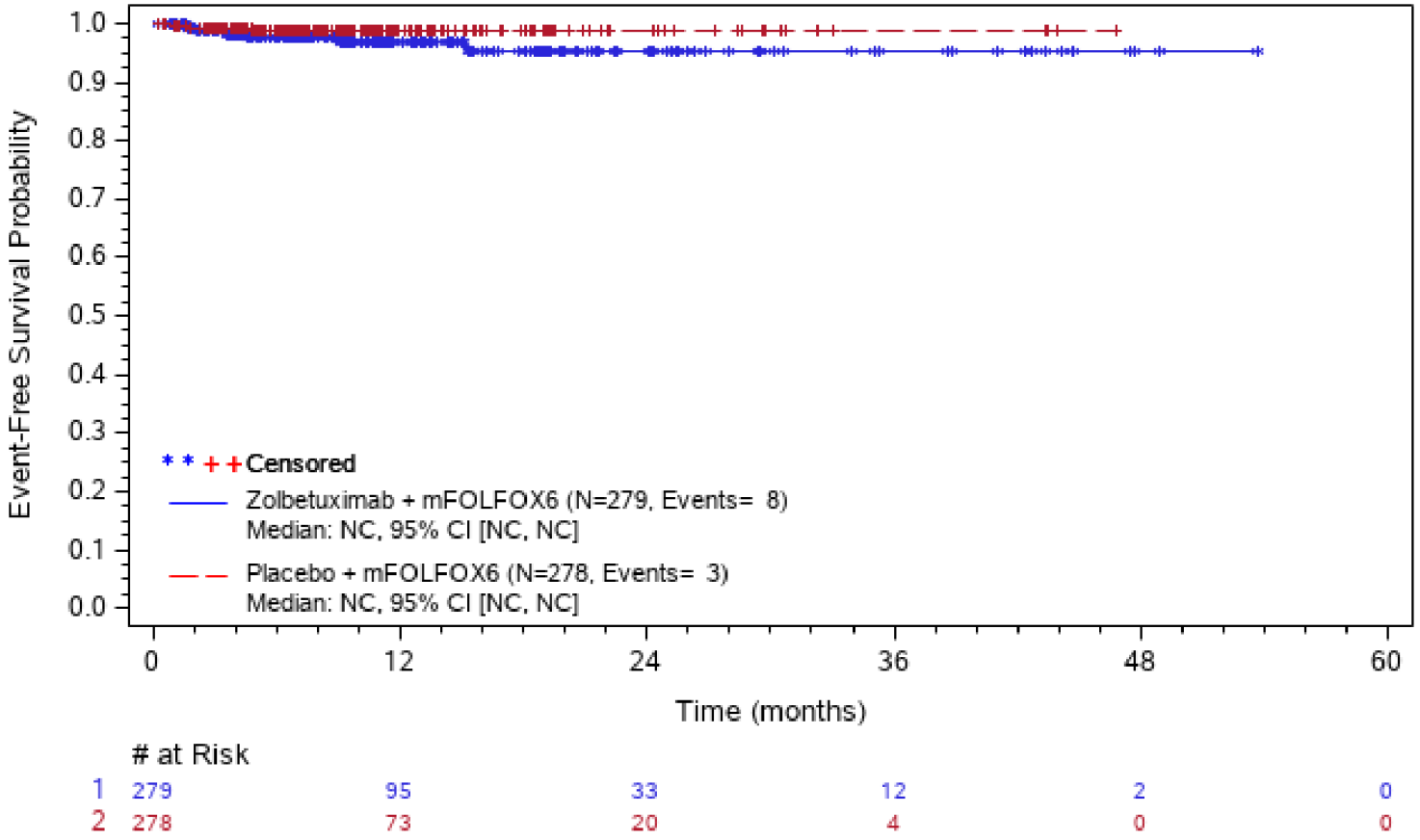


# at Risk						
1	279	95	33	12	2	0
2	278	69	20	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.180: Kaplan-Meier Plot of Time to first Severe TEAE - Leukopenia (PT) - Safety Analysis Set

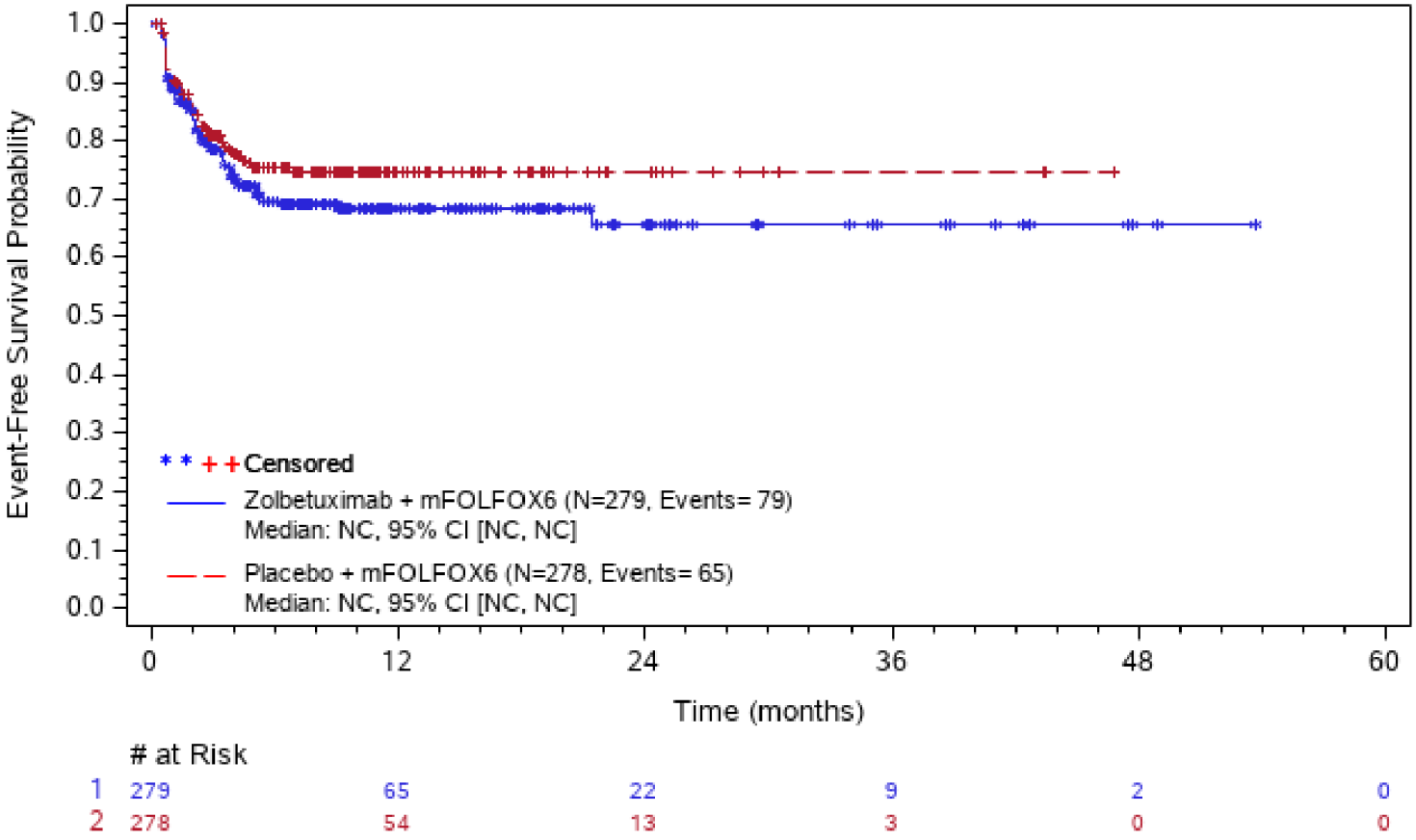


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.181: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (PT) - Safety Analysis Set

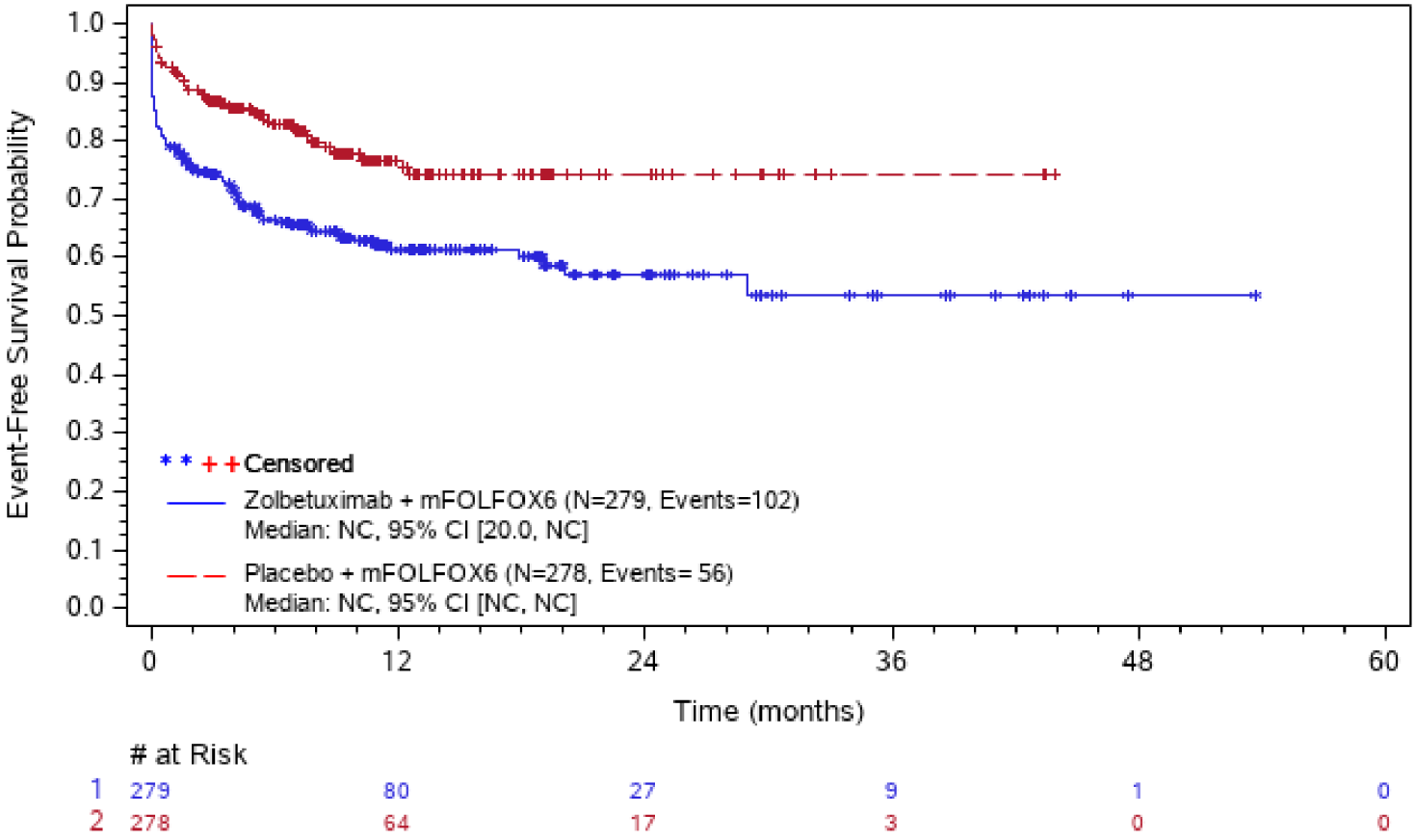


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.182: Kaplan-Meier Plot of Time to first Severe TEAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set

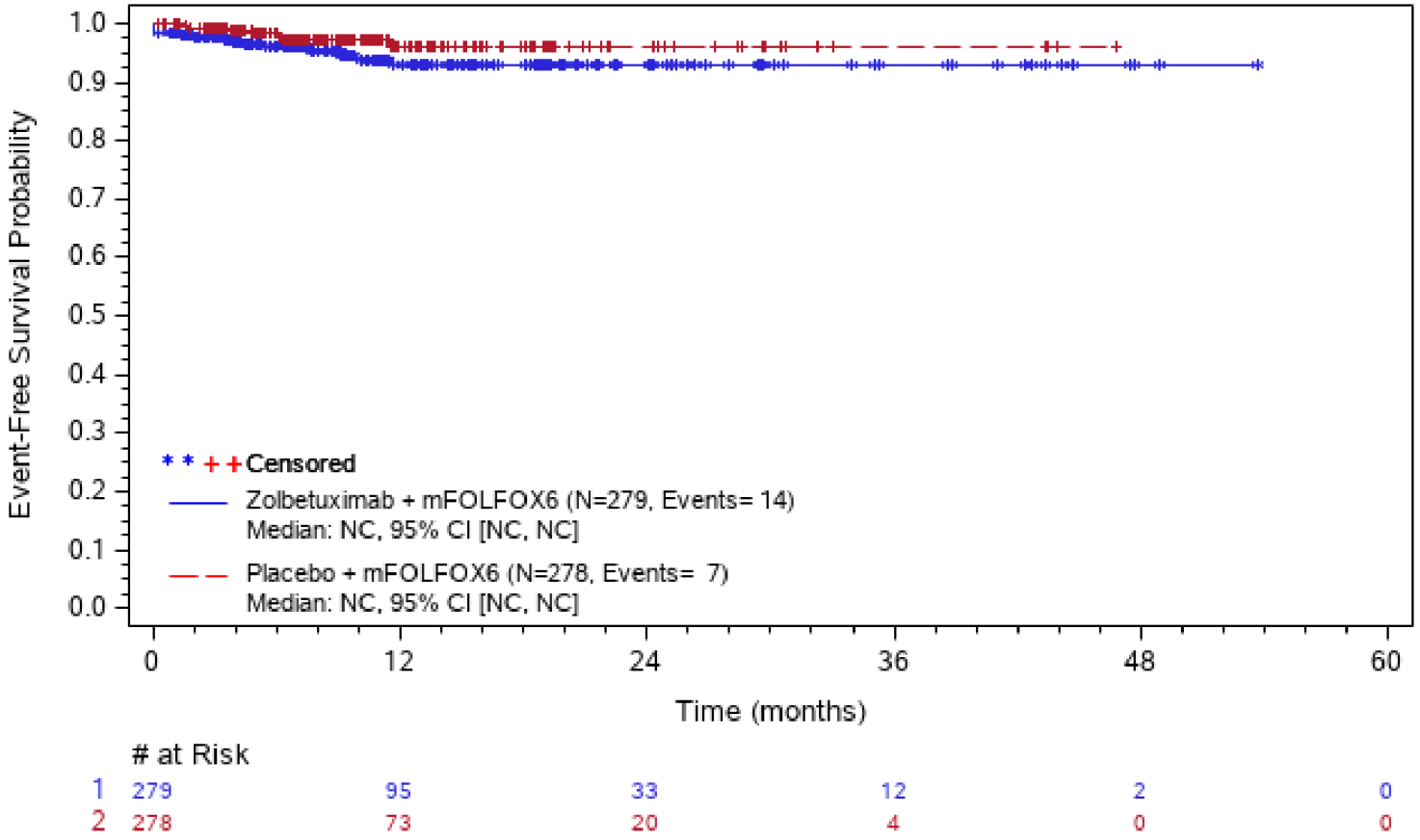


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.183: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (PT) - Safety Analysis Set

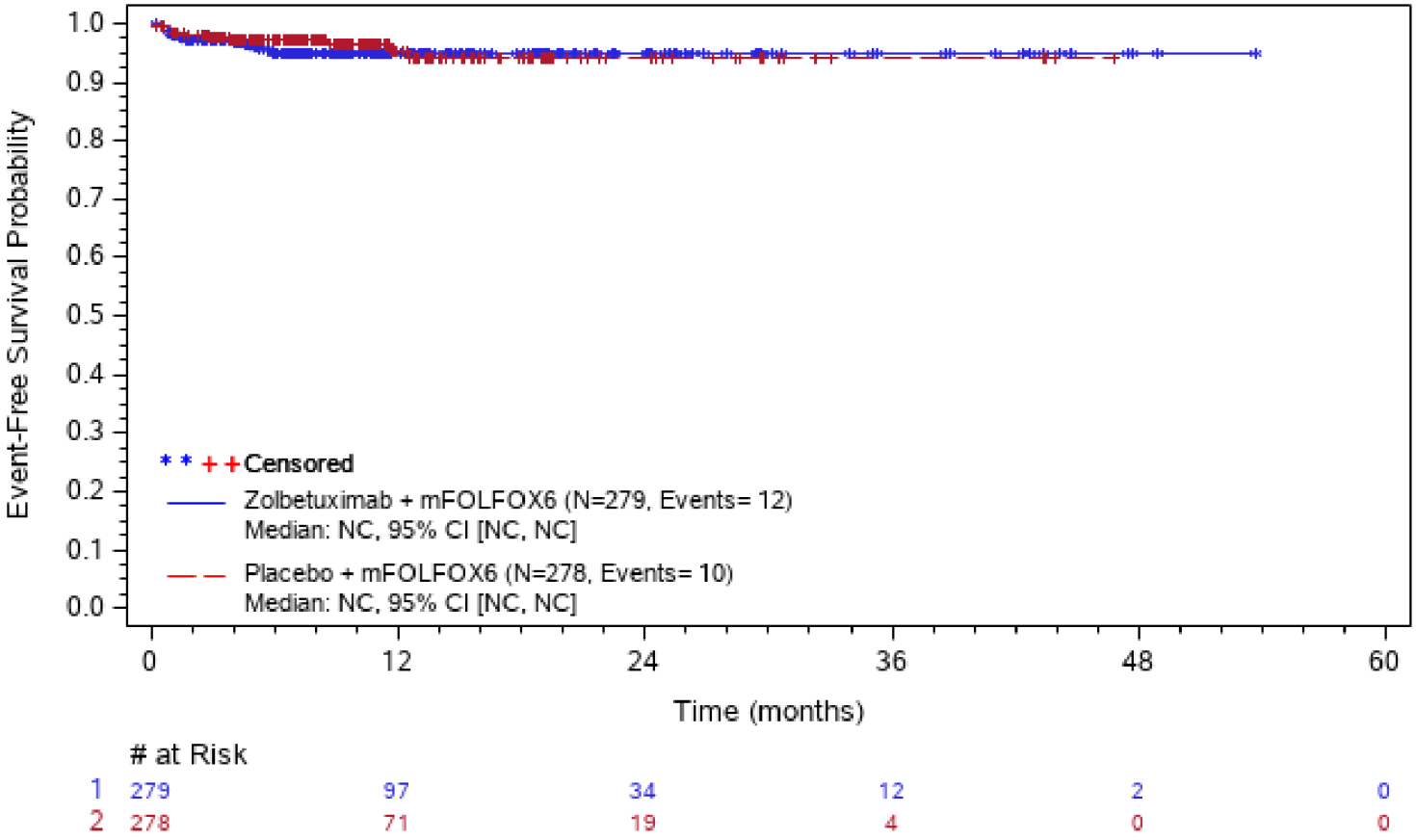


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.184: Kaplan-Meier Plot of Time to first Severe TEAE - Diarrhoea (PT) - Safety Analysis Set

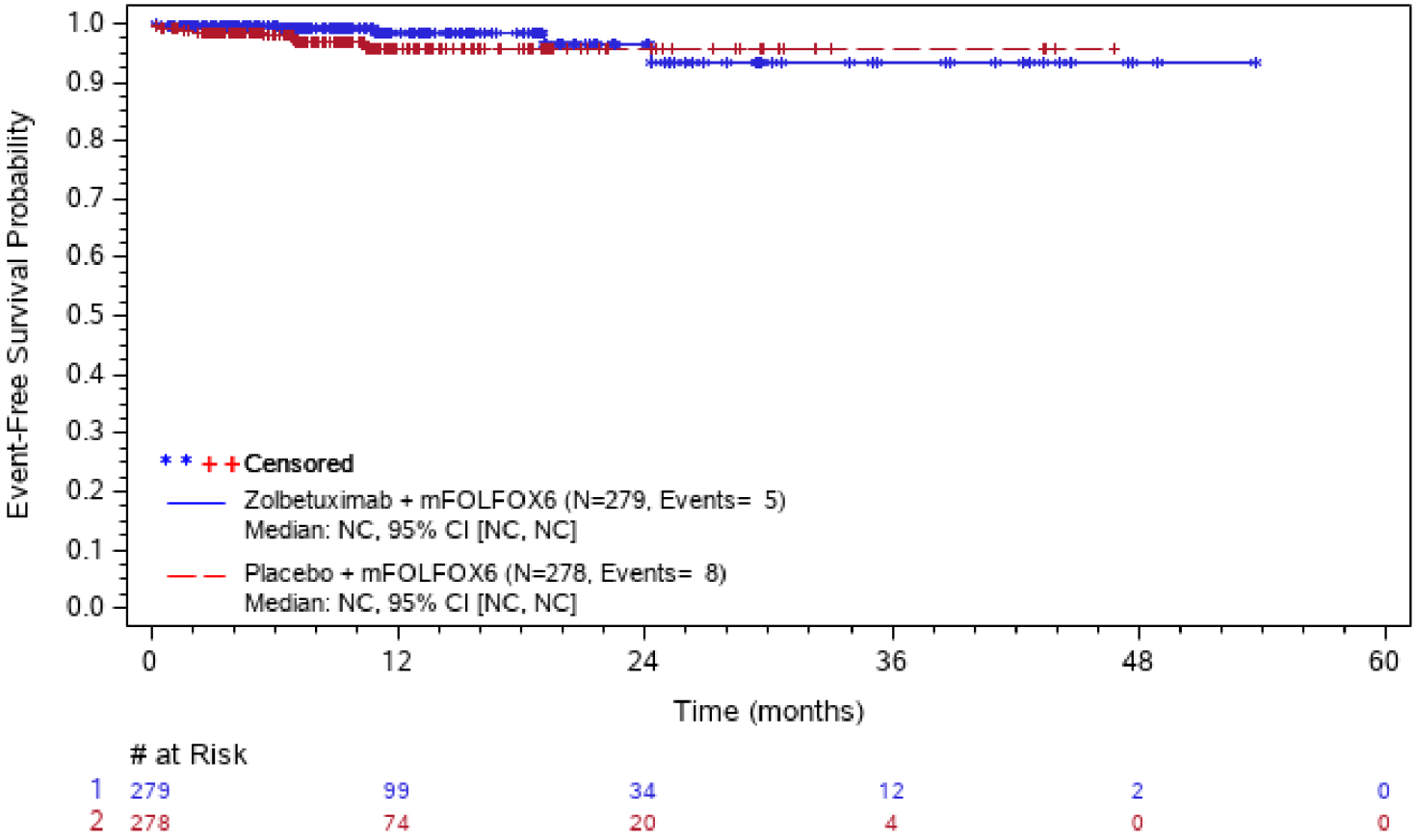


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.185: Kaplan-Meier Plot of Time to first Severe TEAE - Dysphagia (PT) - Safety Analysis Set

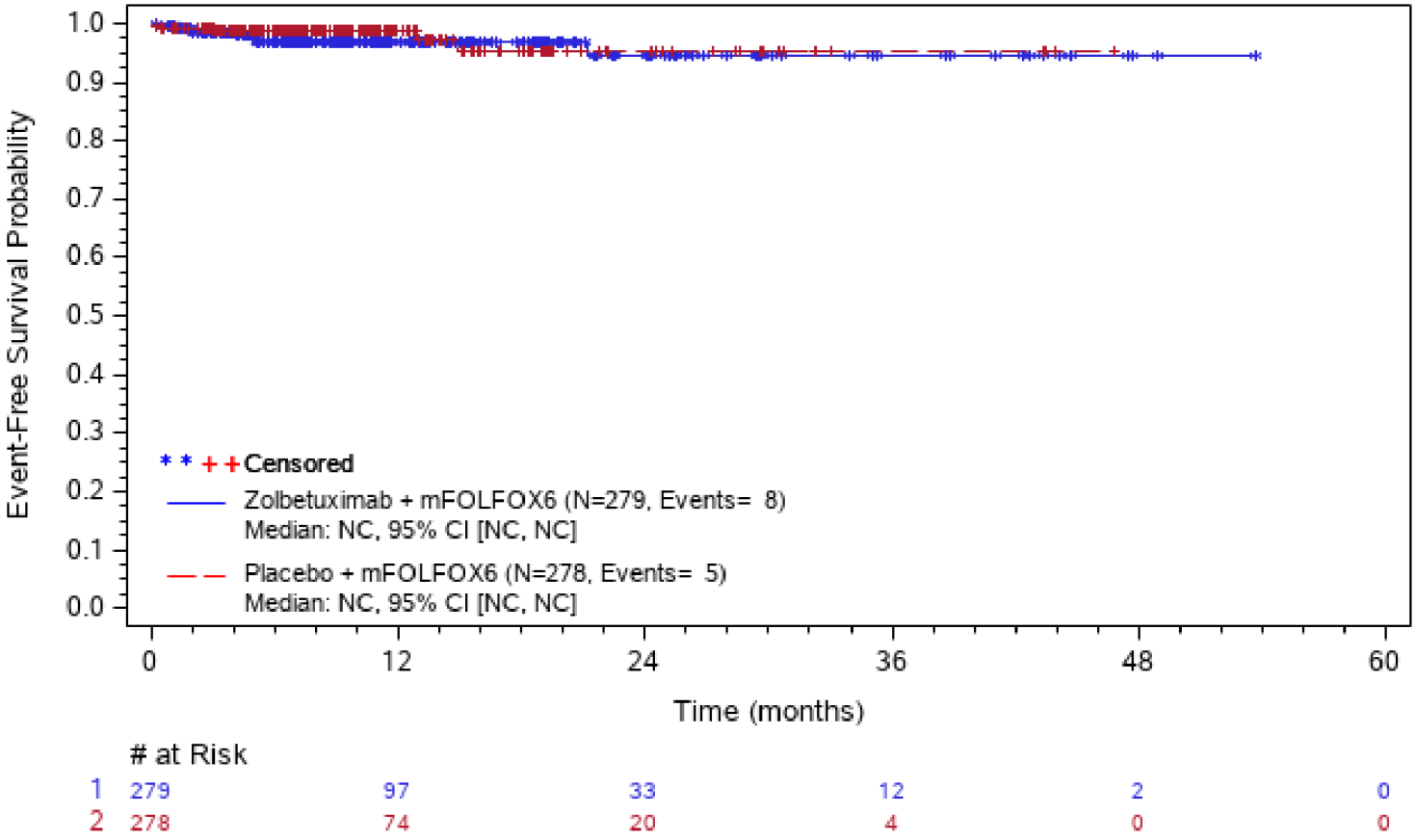


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.186: Kaplan-Meier Plot of Time to first Severe TEAE - Intestinal Obstruction (PT) - Safety Analysis Set

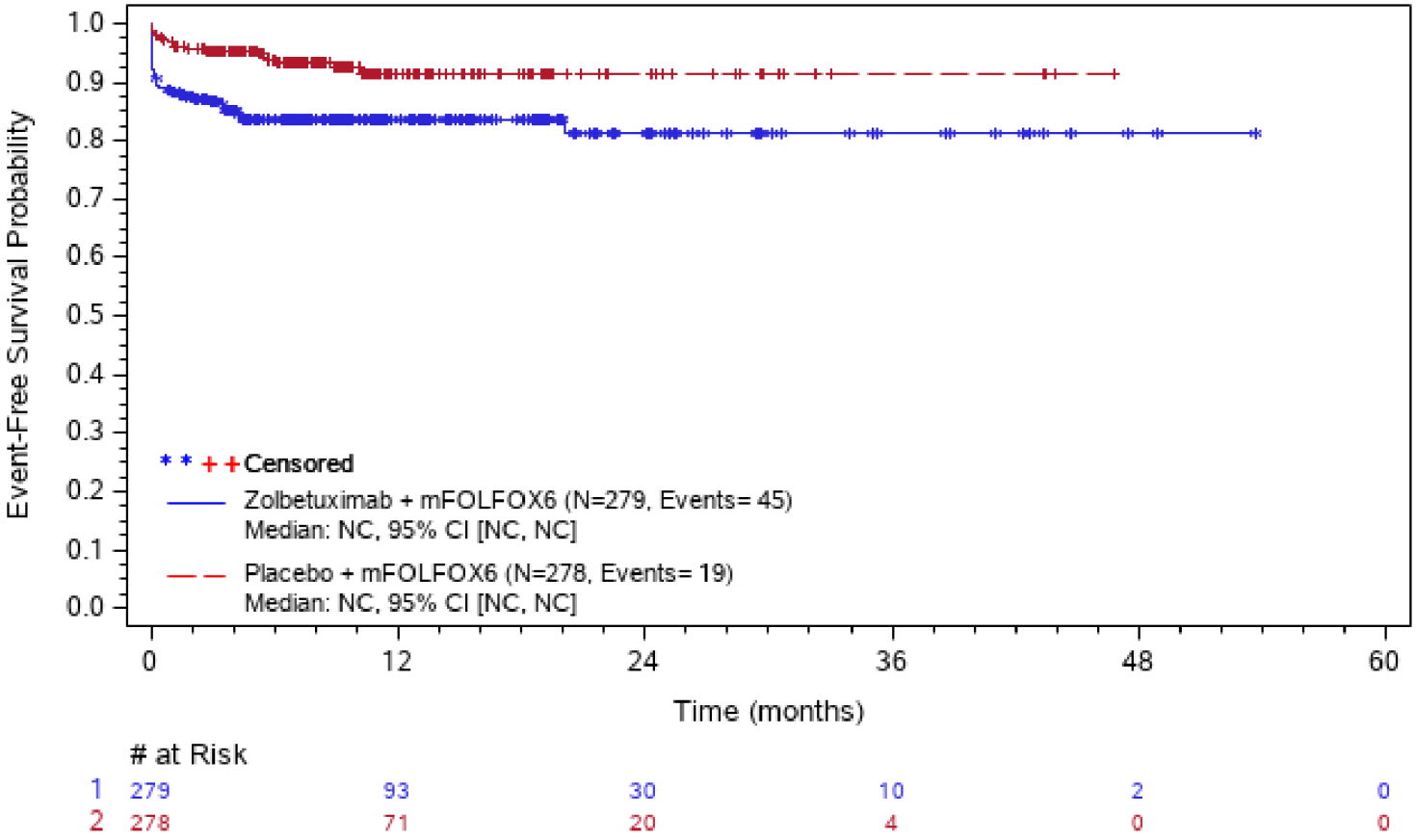


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.187: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (PT) - Safety Analysis Set

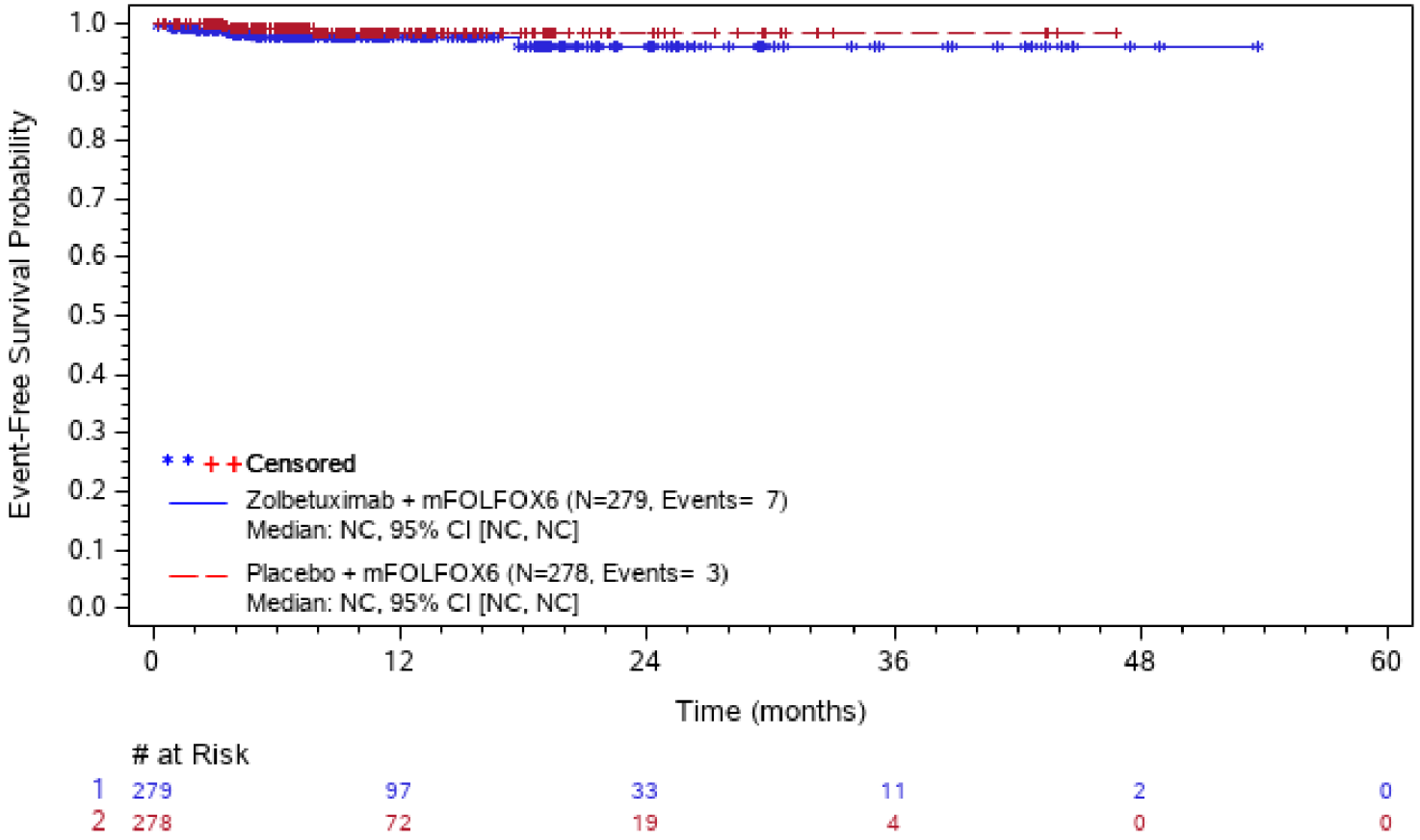


# at Risk						
1	279	93	30	10	2	0
2	278	71	20	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.188: Kaplan-Meier Plot of Time to first Severe TEAE - Stomatitis (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.

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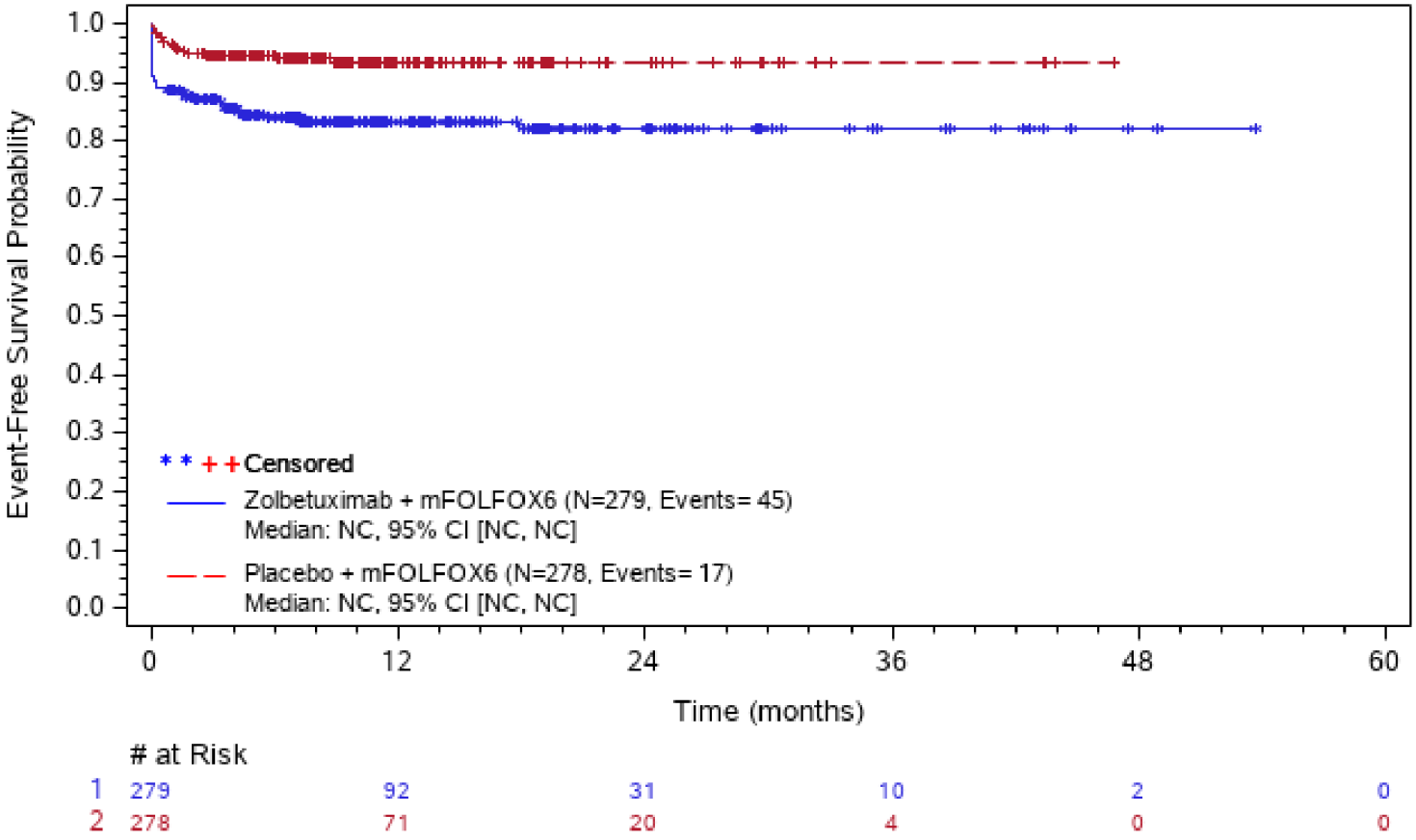
Figure 301.3.2001.189: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (PT) - Safety Analysis Set



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: 08SEP23

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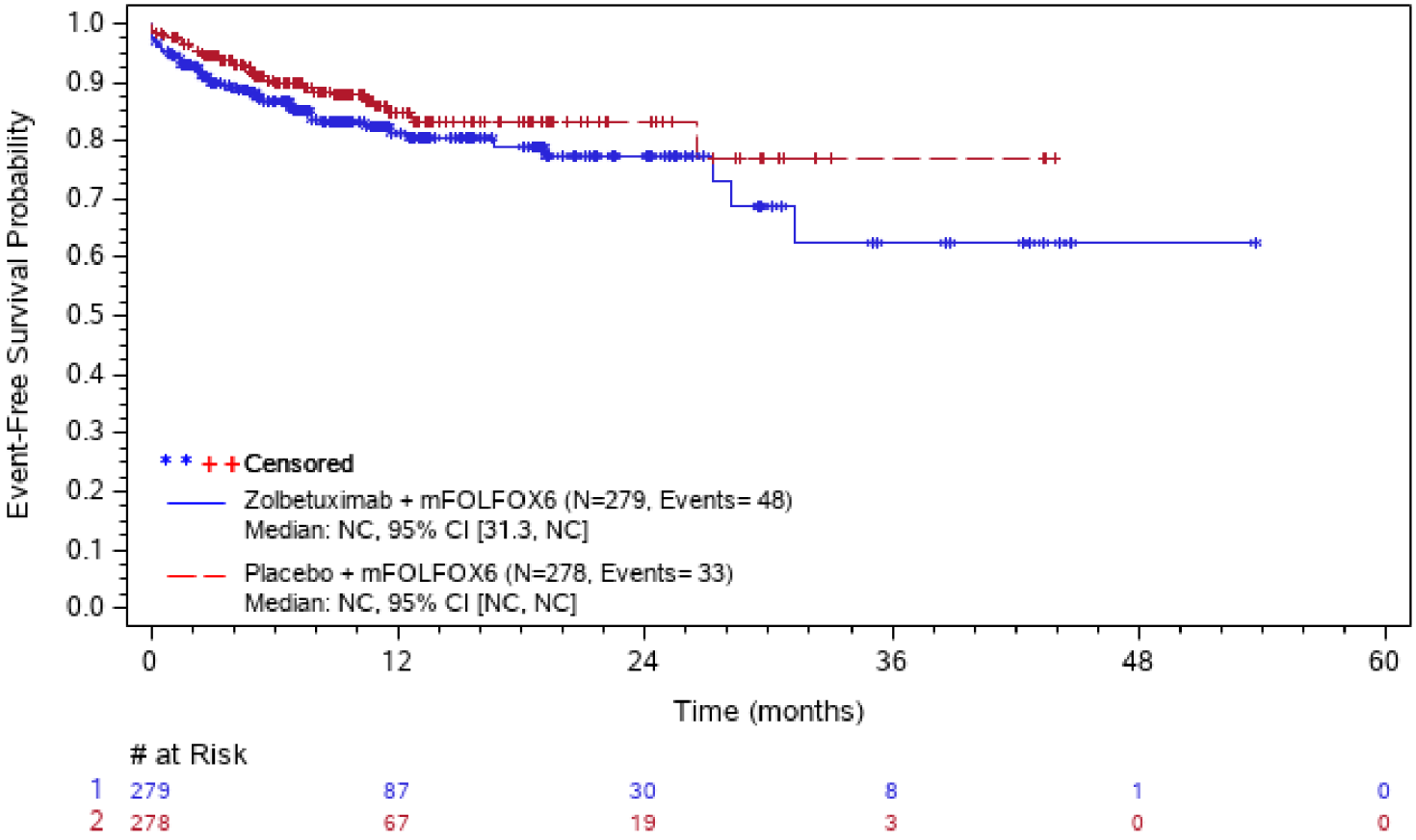
Figure 301.3.2001.190: Kaplan-Meier Plot of Time to first Severe TEAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set



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: 08SEP23

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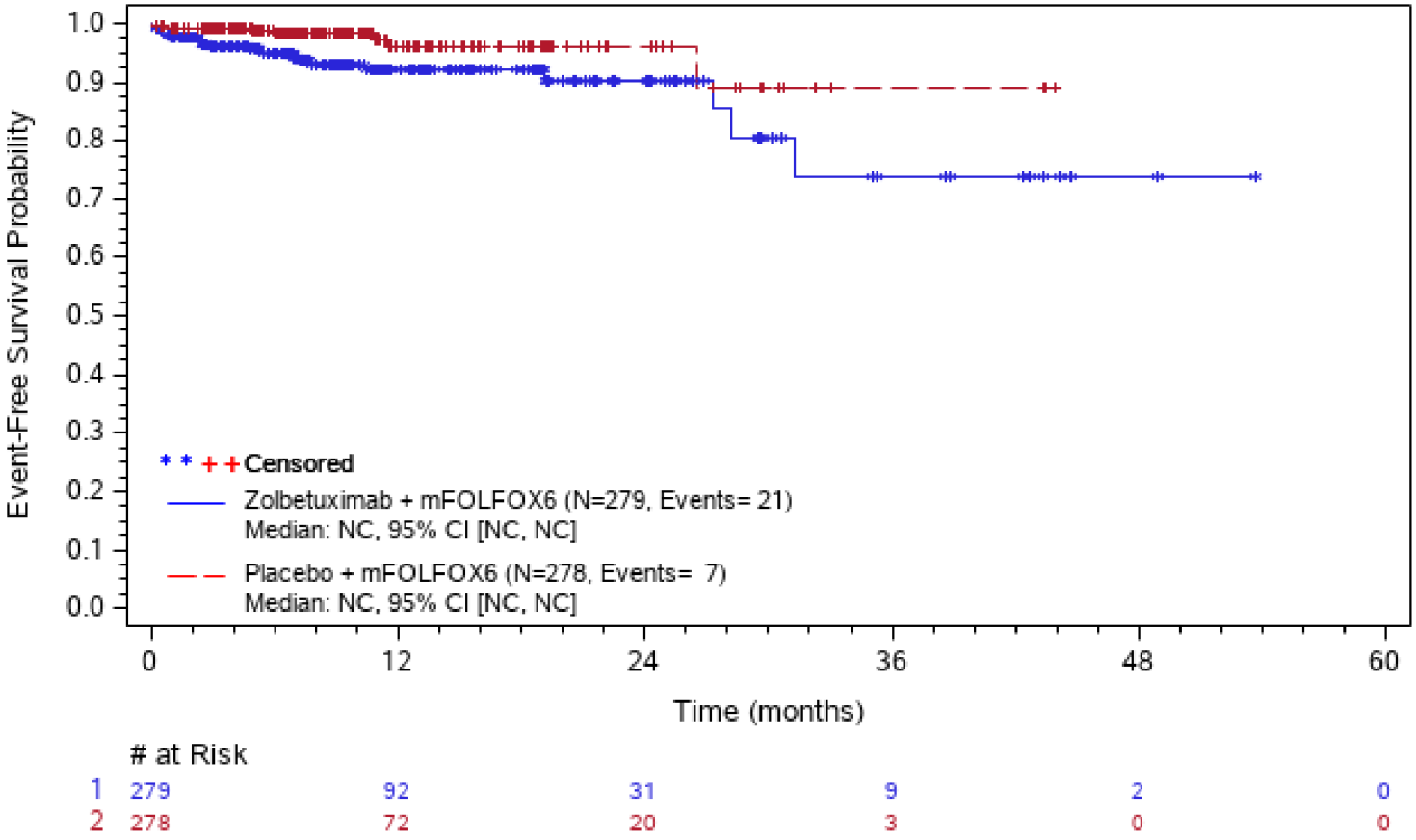
Figure 301.3.2001.191: Kaplan-Meier Plot of Time to first Severe TEAE - Asthenia (PT) - Safety Analysis Set

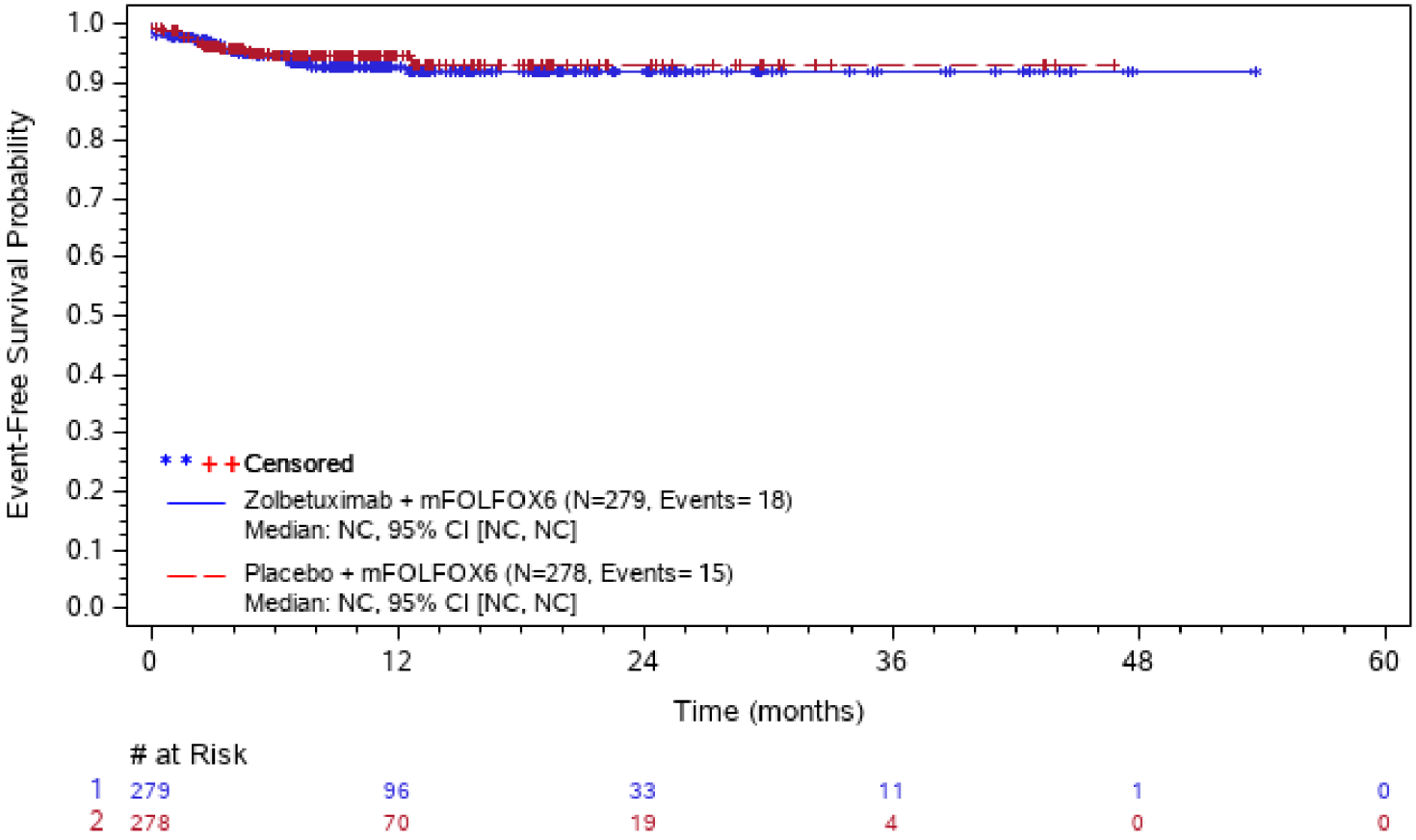


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.192: Kaplan-Meier Plot of Time to first Severe TEAE - Fatigue (PT) - Safety Analysis Set

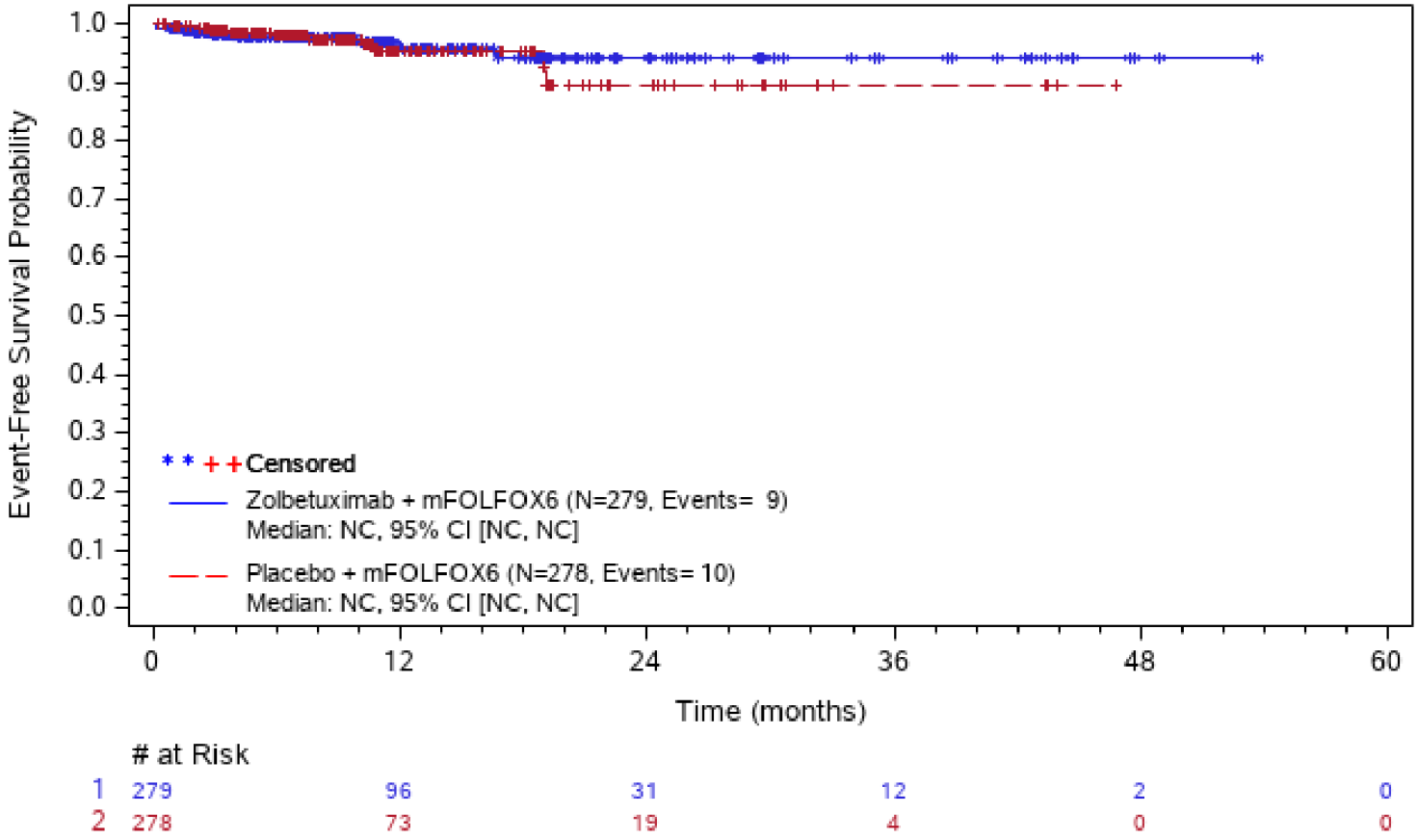


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.193: Kaplan-Meier Plot of Time to first Severe TEAE - Hepatobiliary 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: 08SEP23

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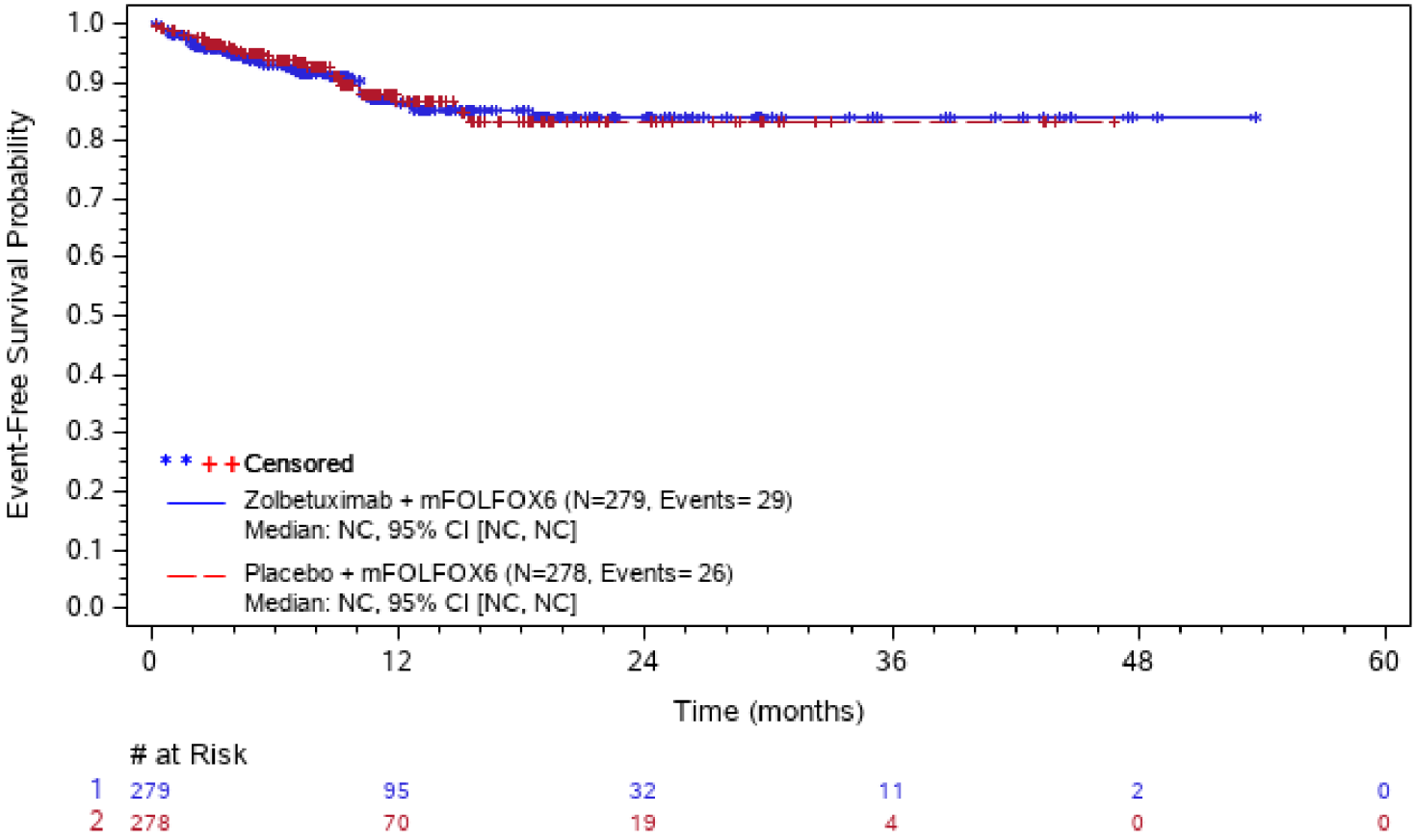
Figure 301.3.2001.194: Kaplan-Meier Plot of Time to first Severe TEAE - Infections And Infestations (SOC) - Safety Analysis Set



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: 08SEP23

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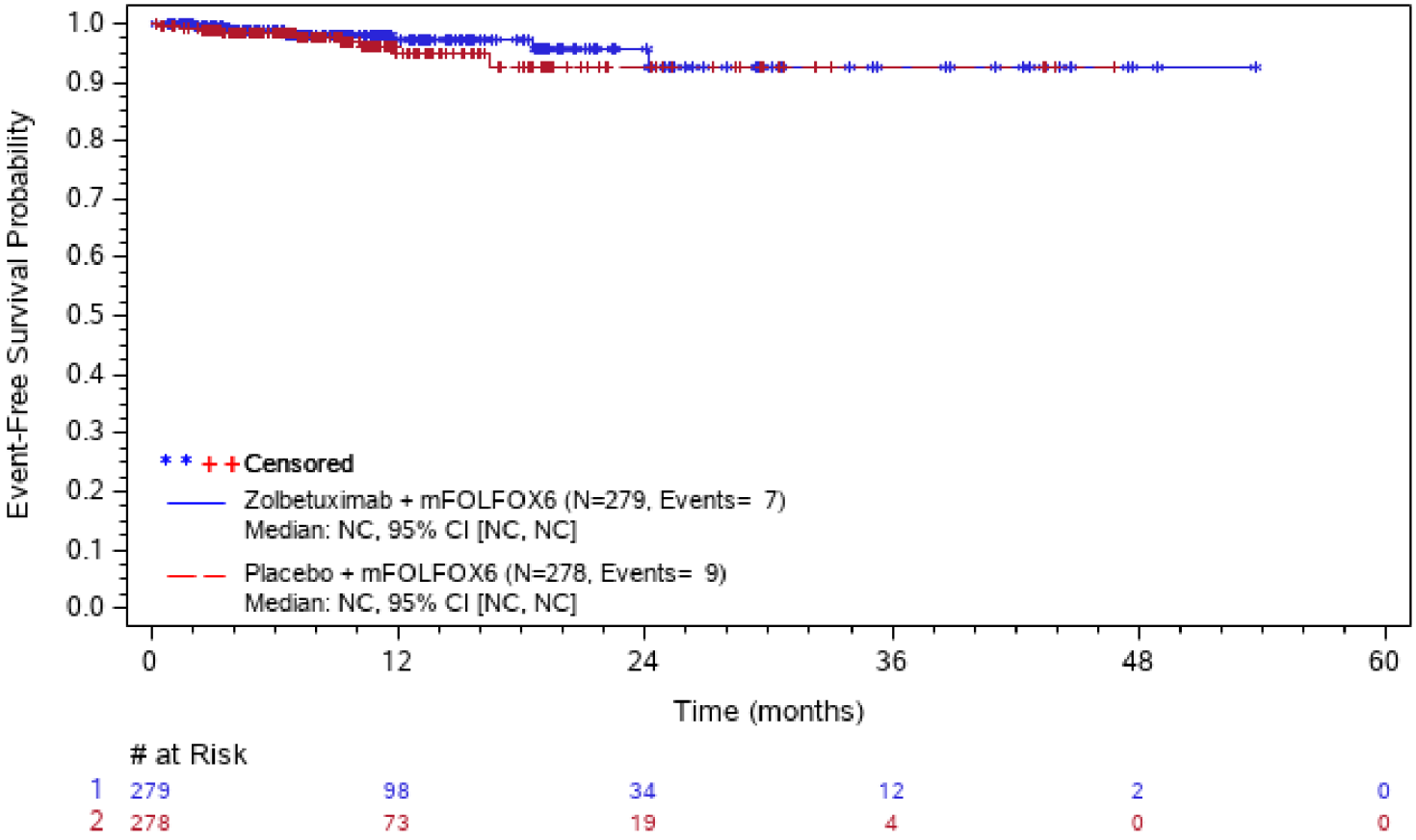
Figure 301.3.2001.195: Kaplan-Meier Plot of Time to first Severe TEAE - Pneumonia (PT) - Safety Analysis Set



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: 08SEP23

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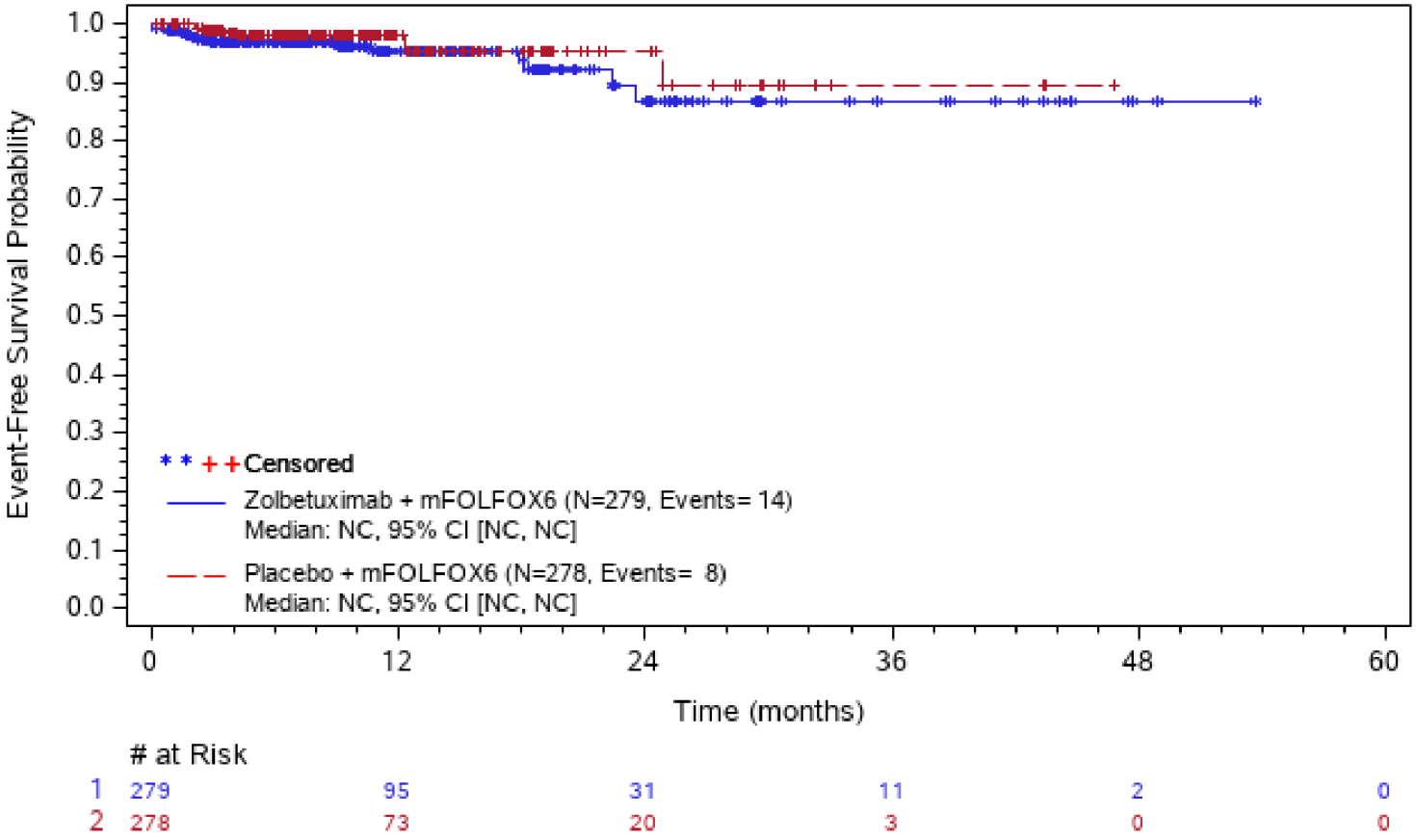
Figure 301.3.2001.196: Kaplan-Meier Plot of Time to first Severe TEAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

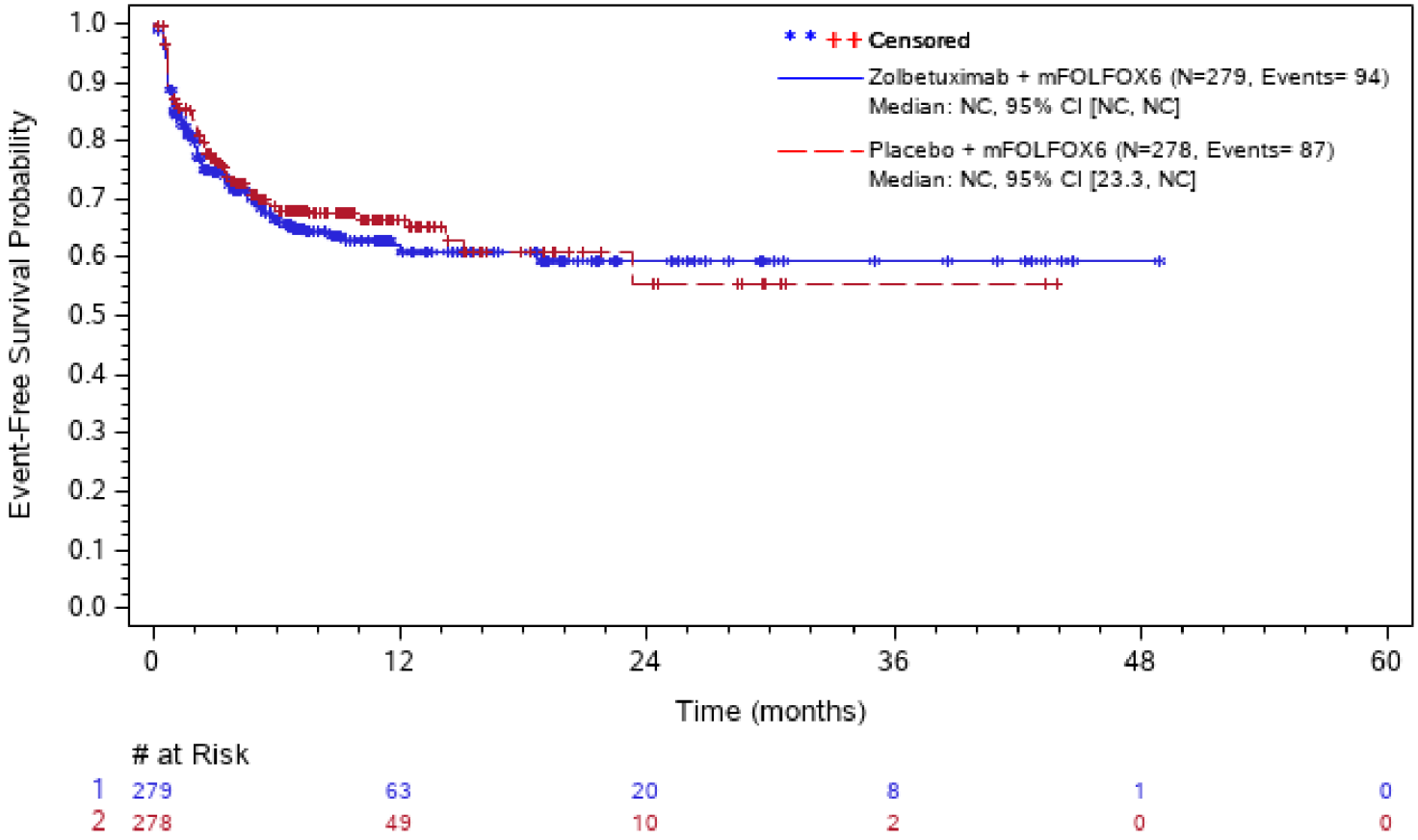


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.197: Kaplan-Meier Plot of Time to first Severe TEAE - Investigations (SOC) - Safety Analysis Set

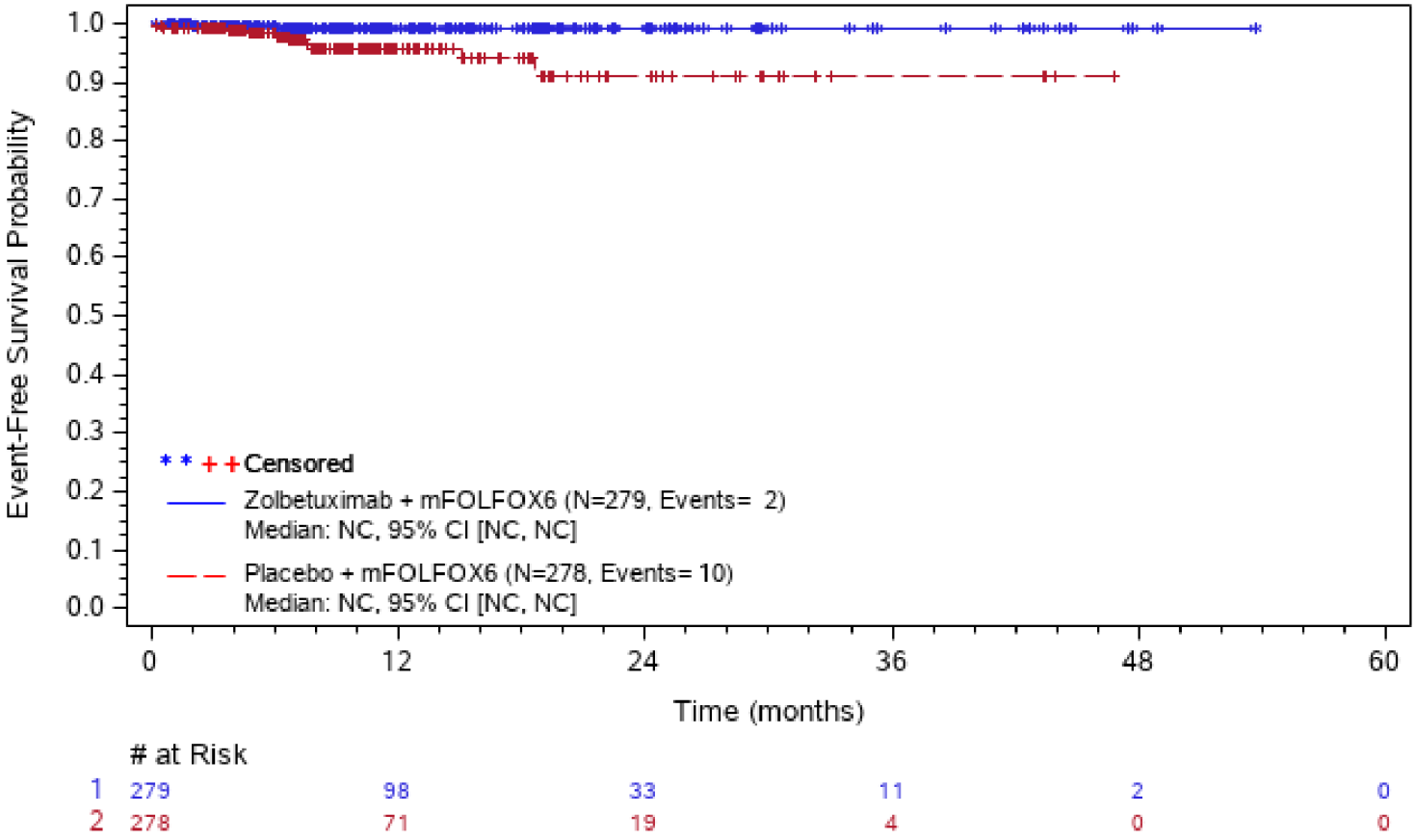


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.198: Kaplan-Meier Plot of Time to first Severe TEAE - Alanine Aminotransferase Increased (PT) - Safety Analysis Set

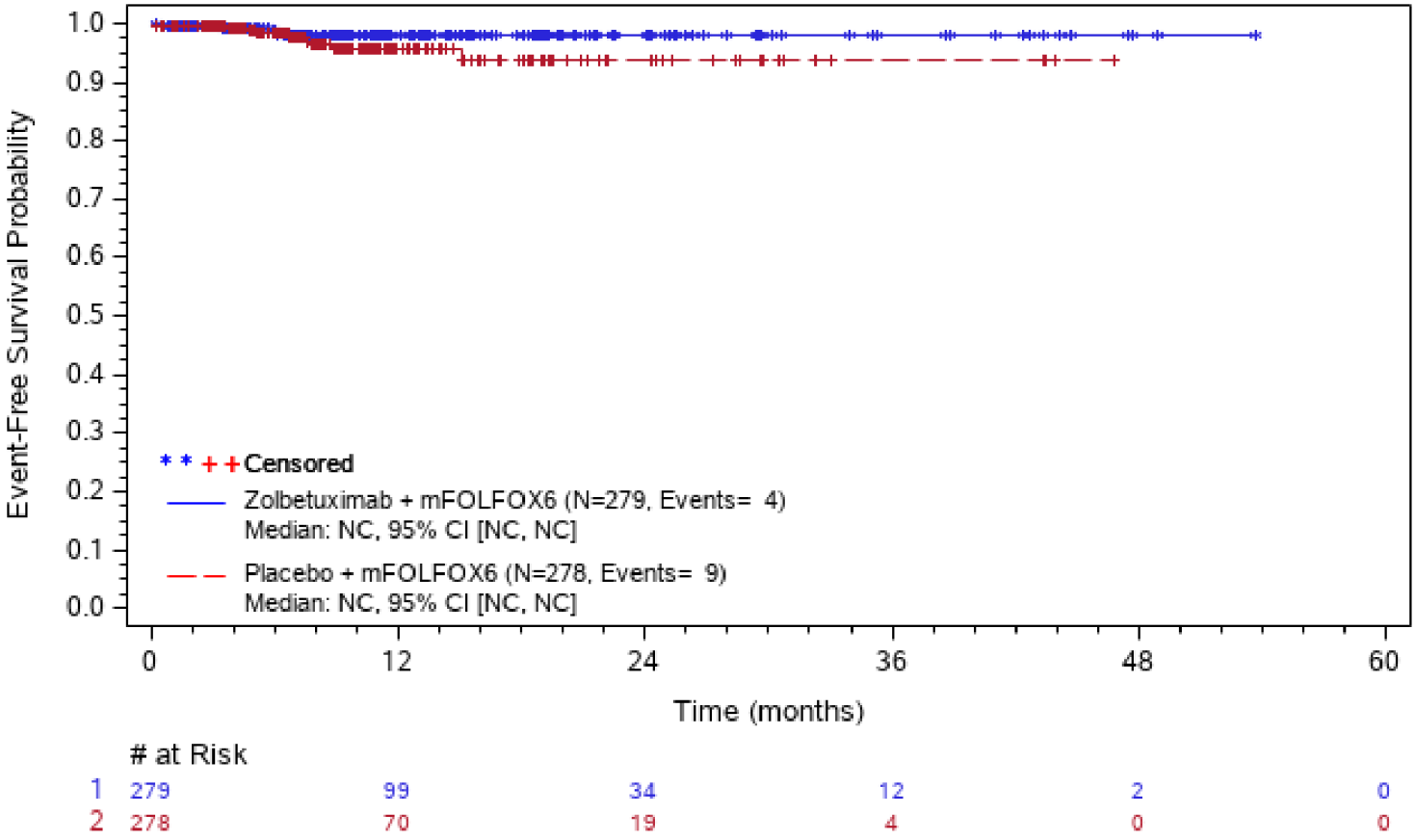


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.199: Kaplan-Meier Plot of Time to first Severe 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: 08SEP23

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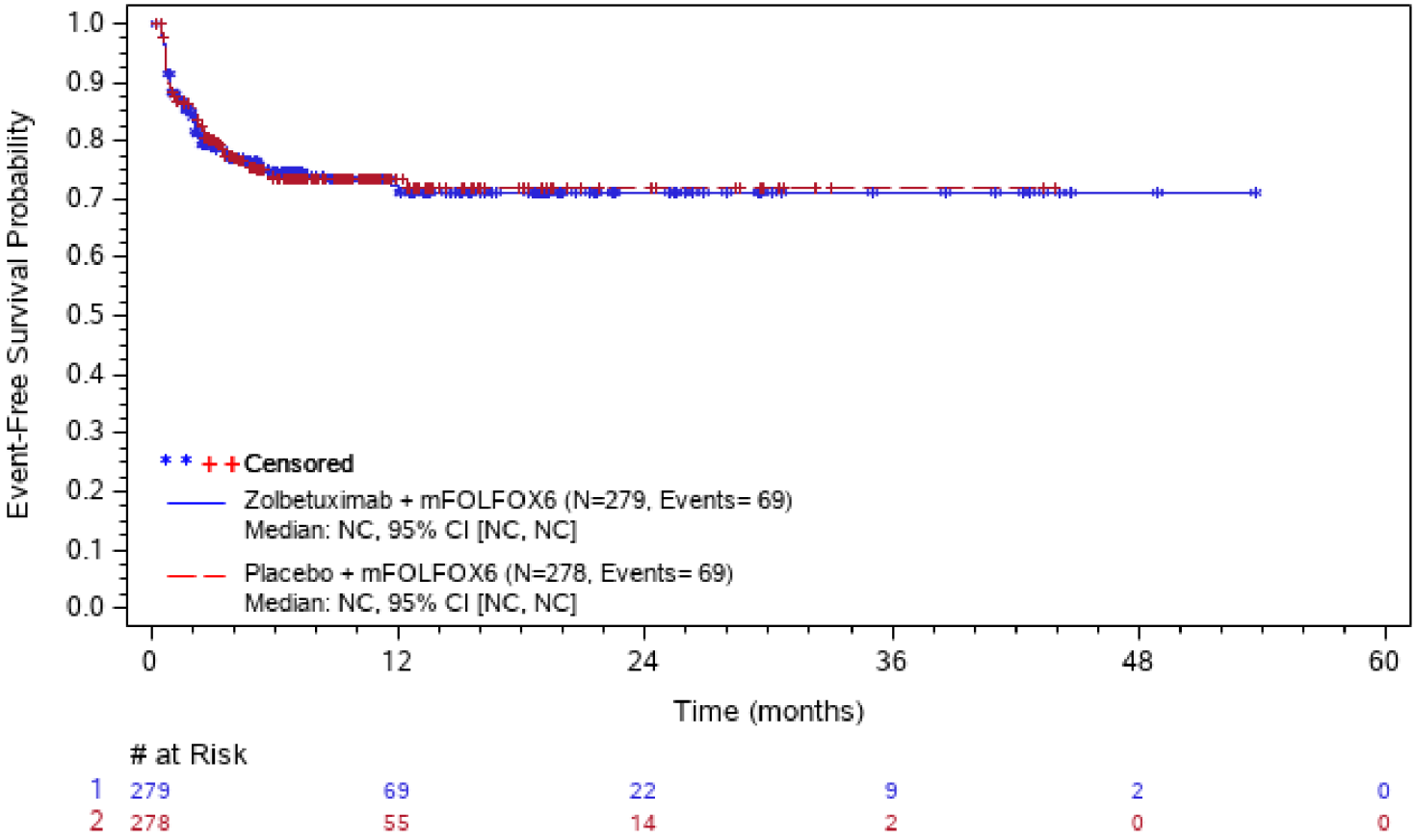
Figure 301.3.2001.200: Kaplan-Meier Plot of Time to first Severe TEAE - Neutrophil Count Decreased (PT) - Safety Analysis Set

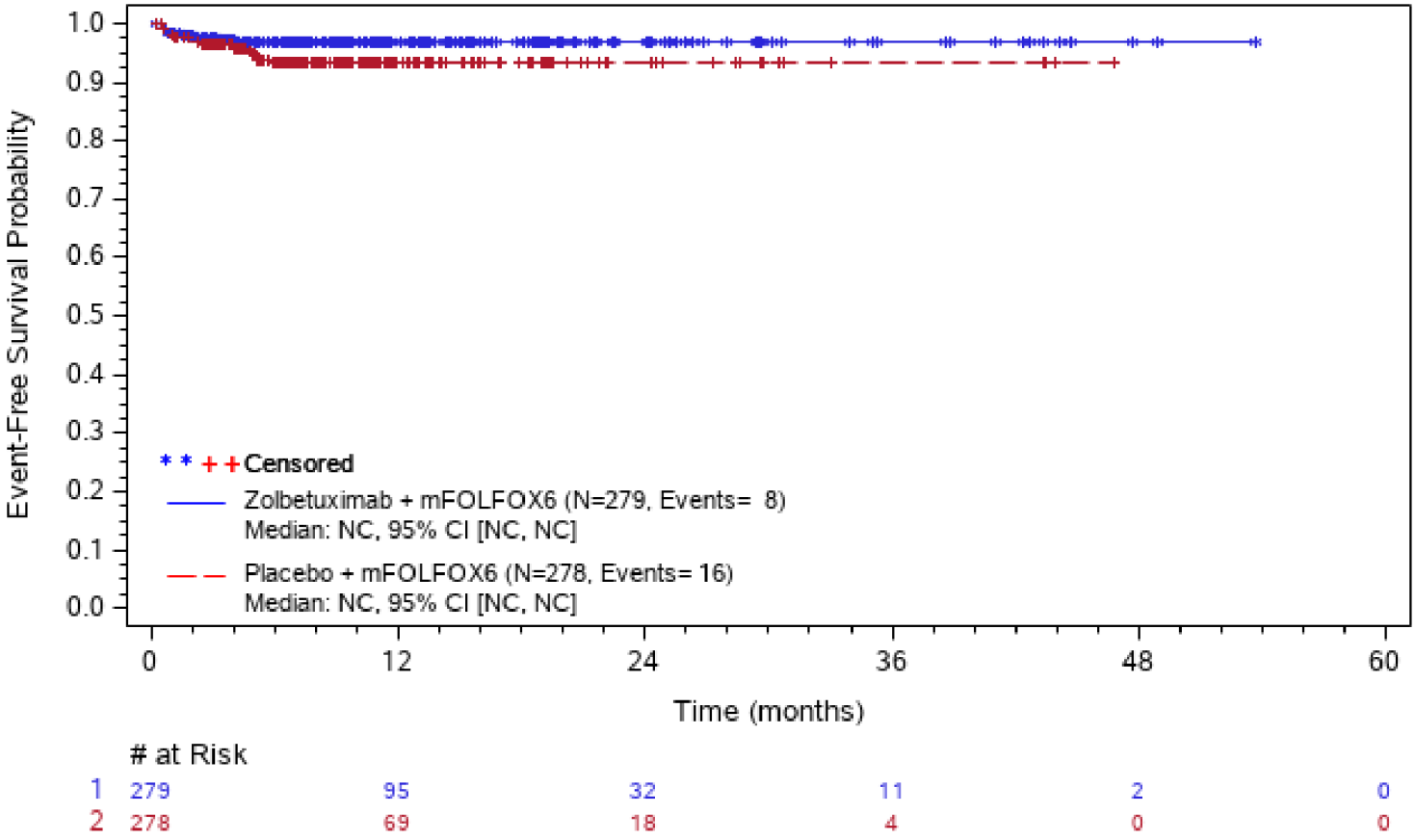


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.201: Kaplan-Meier Plot of Time to first Severe TEAE - White Blood Cell Count Decreased (PT) - Safety Analysis Set

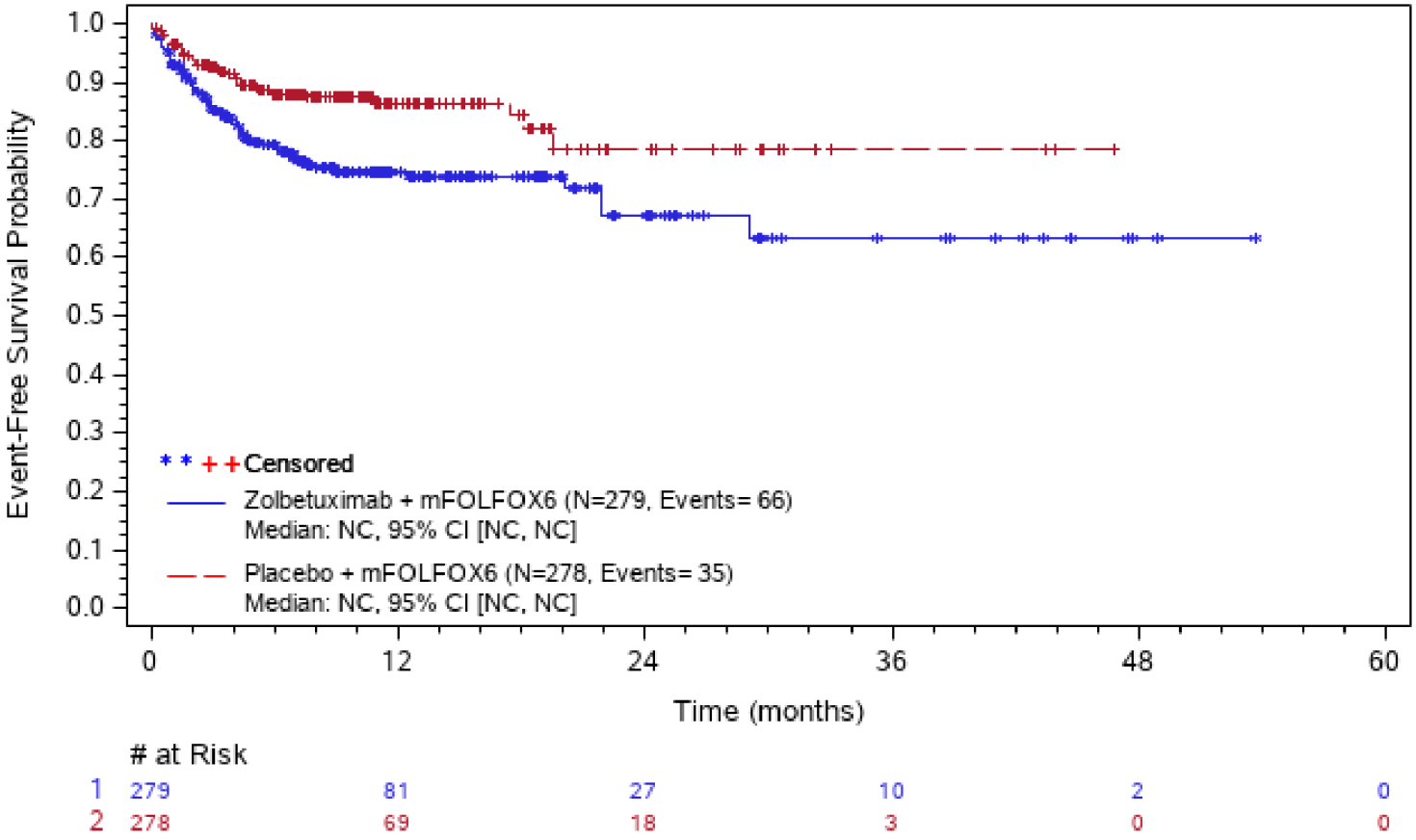


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.202: Kaplan-Meier Plot of Time to first Severe TEAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

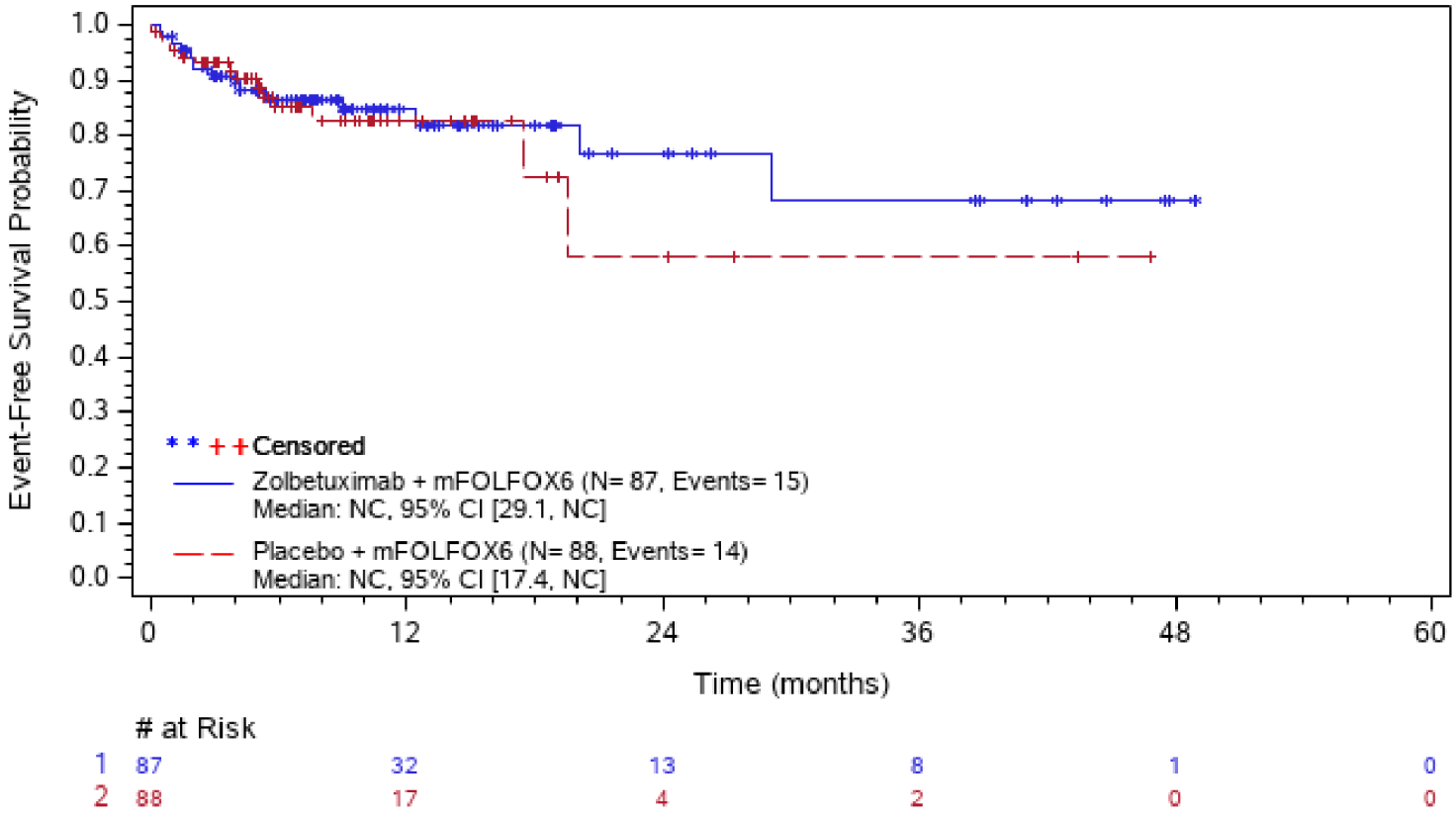


# at Risk						
1	279	81	27	10	2	0
2	278	69	18	3	0	0

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: 08SEP23

The SAS System

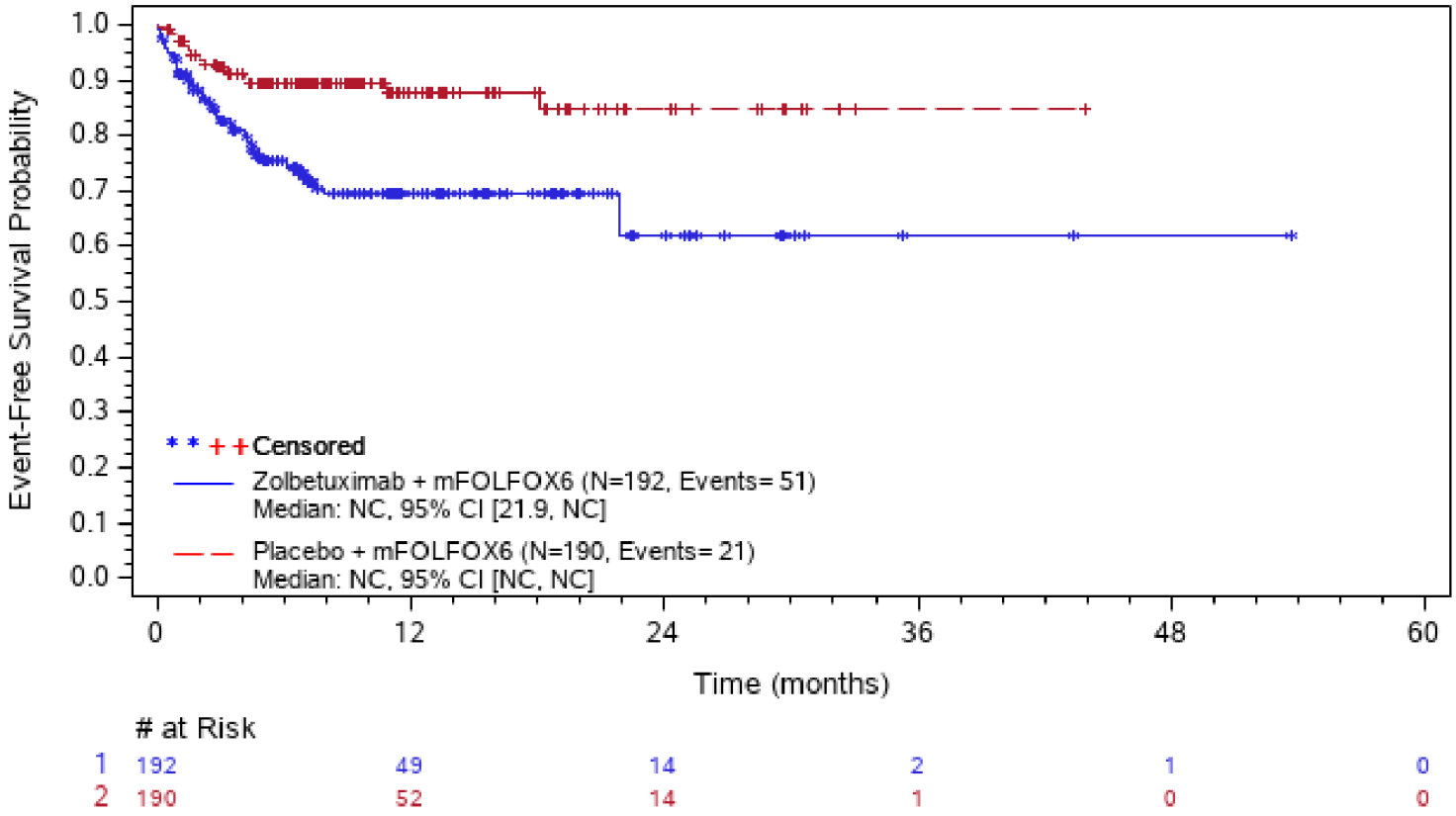
Figure 301.3.2001.202.3: Kaplan-Meier Plot of Time to first Severe TEAE by Region - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set
IRT- Region Subject is Enrolling In: Asia



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: 08SEP23

The SAS System

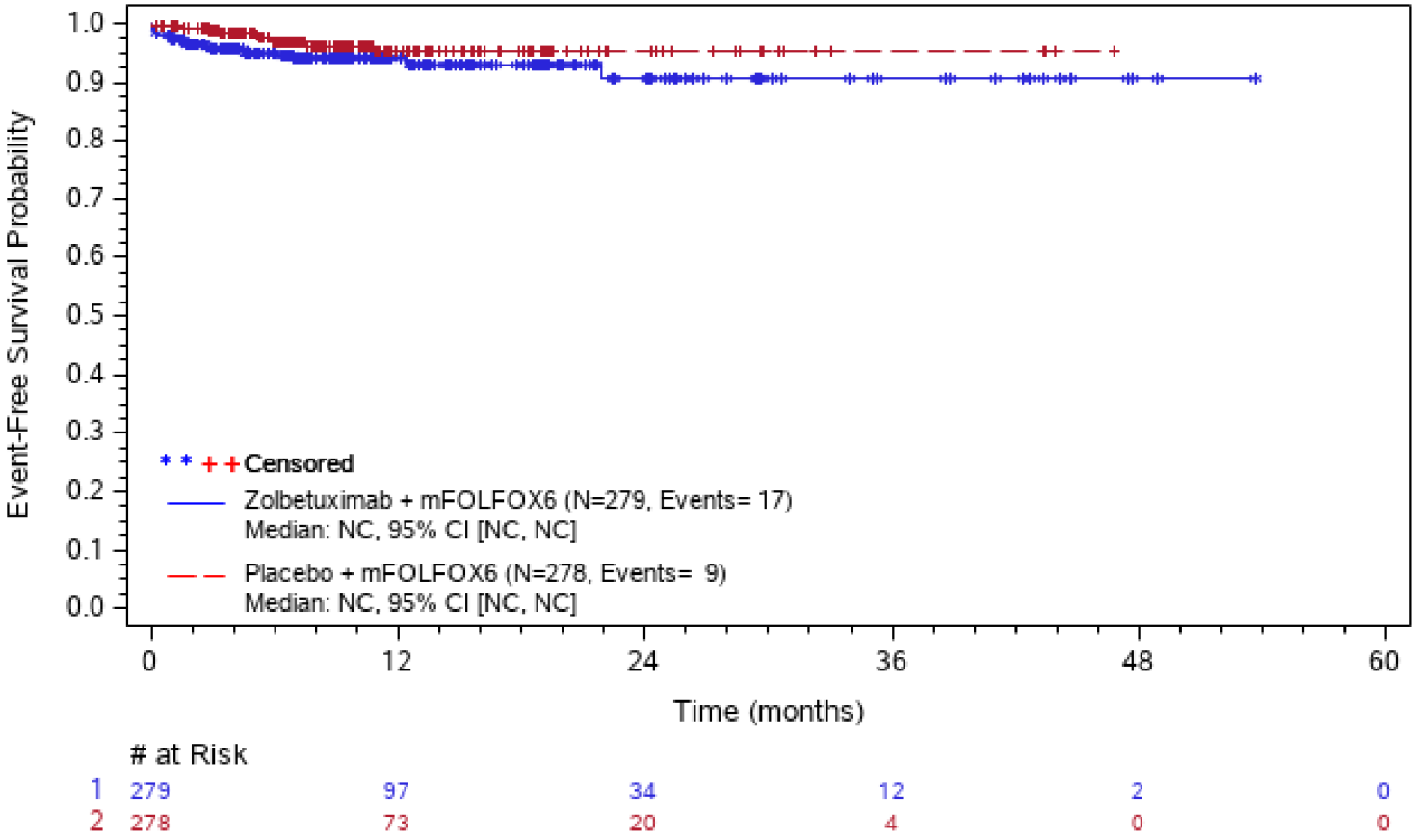
Figure 301.3.2001.202.3: Kaplan-Meier Plot of Time to first Severe TEAE by Region - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set
IRT- Region Subject is Enrolling In: Non-Asia



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: 08SEP23

The SAS System

Figure 301.3.2001.203: Kaplan-Meier Plot of Time to first Severe TEAE - Decreased Appetite (PT) - Safety Analysis Set

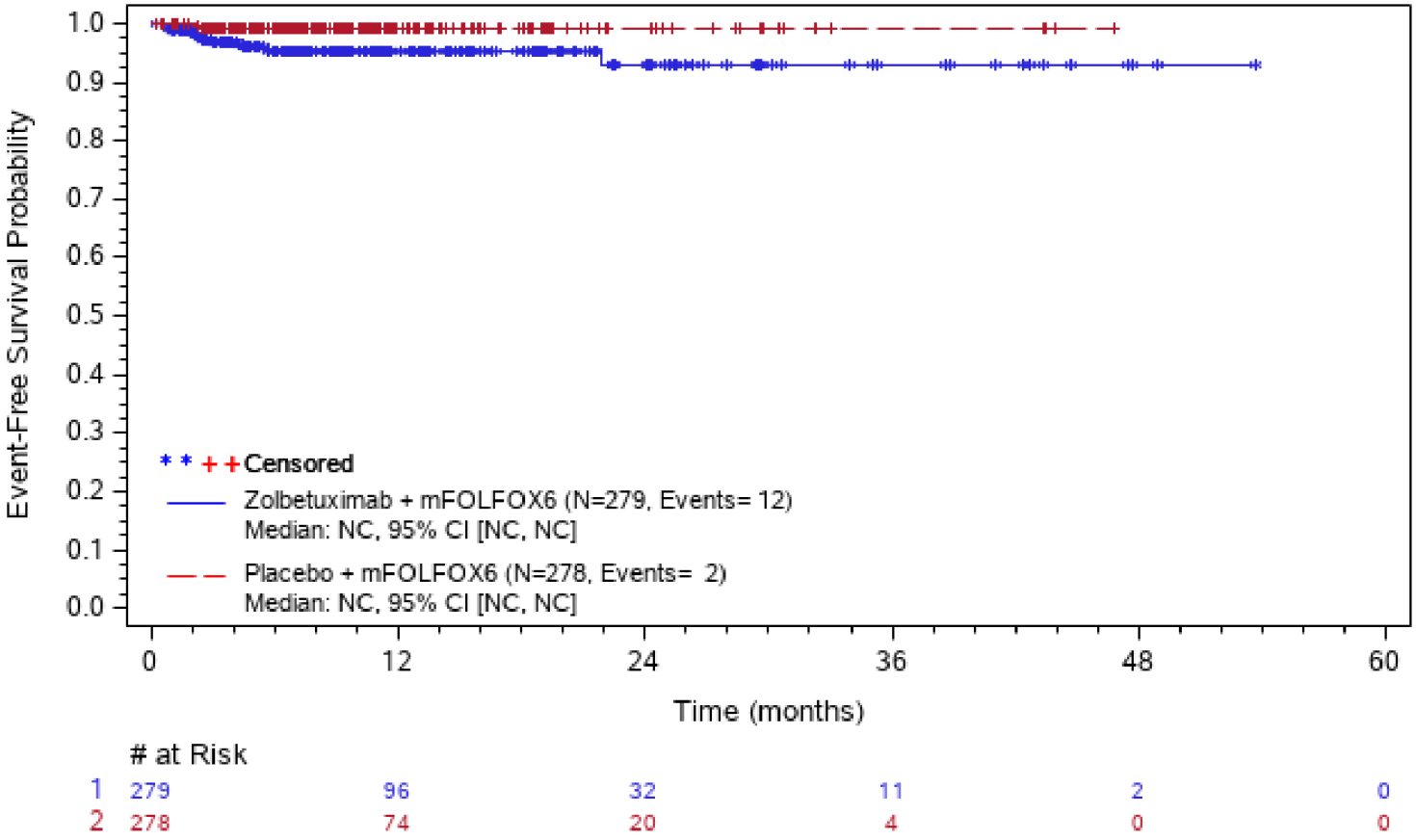


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.204: Kaplan-Meier Plot of Time to first Severe TEAE - Hypoalbuminaemia (PT) - Safety Analysis Set

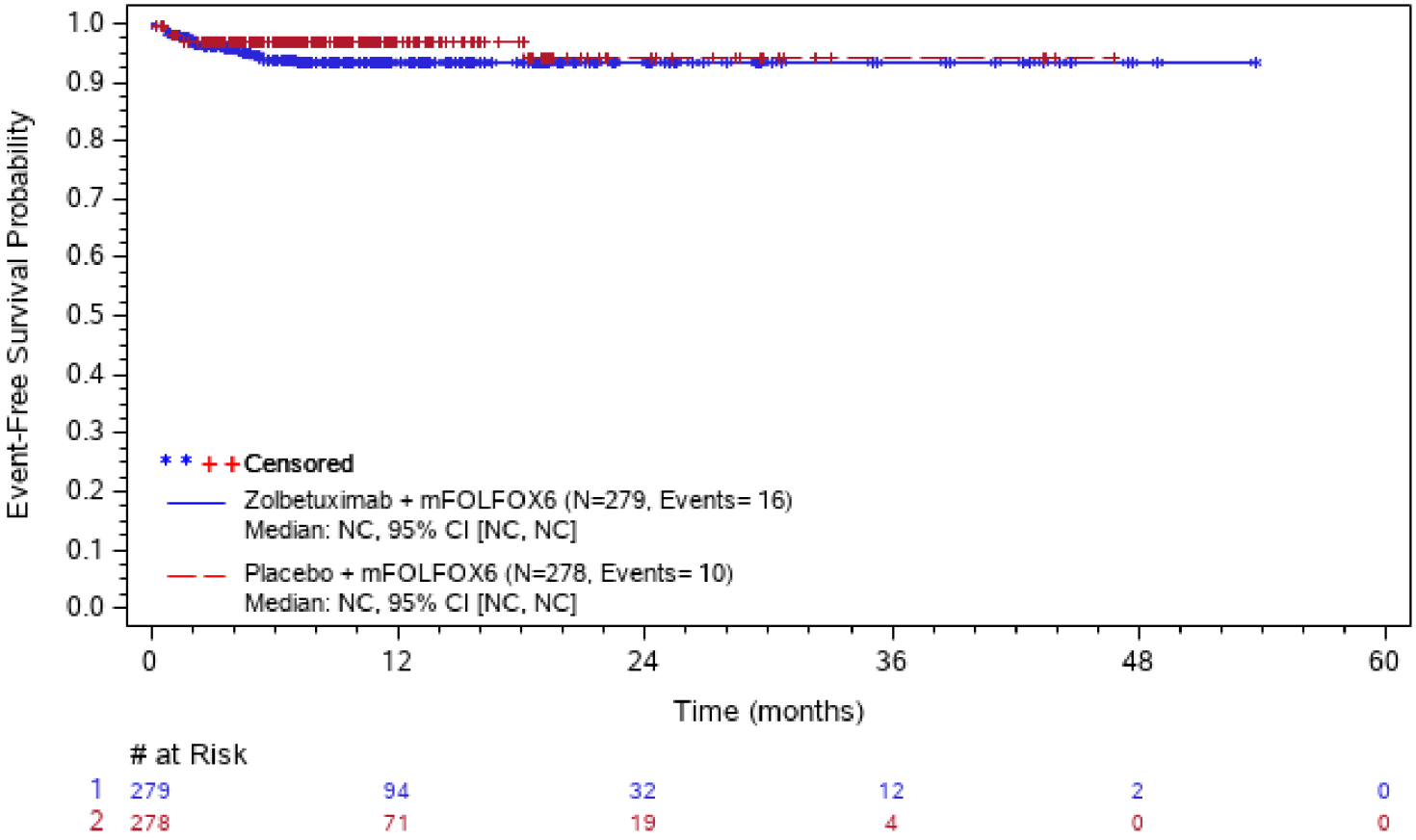


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.205: Kaplan-Meier Plot of Time to first Severe TEAE - Hypokalaemia (PT) - Safety Analysis Set

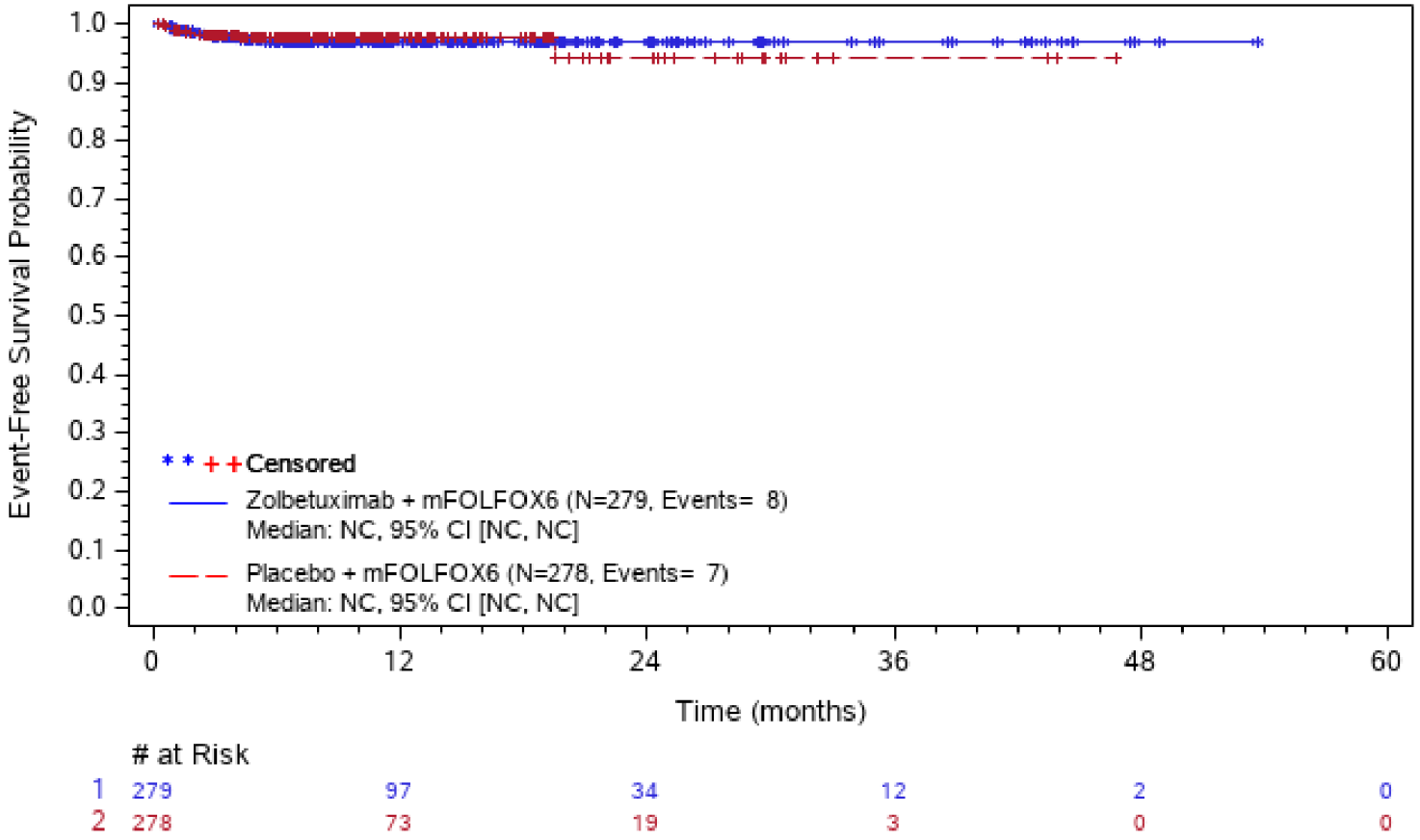


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.206: Kaplan-Meier Plot of Time to first Severe TEAE - Hypophosphataemia (PT) - Safety Analysis Set

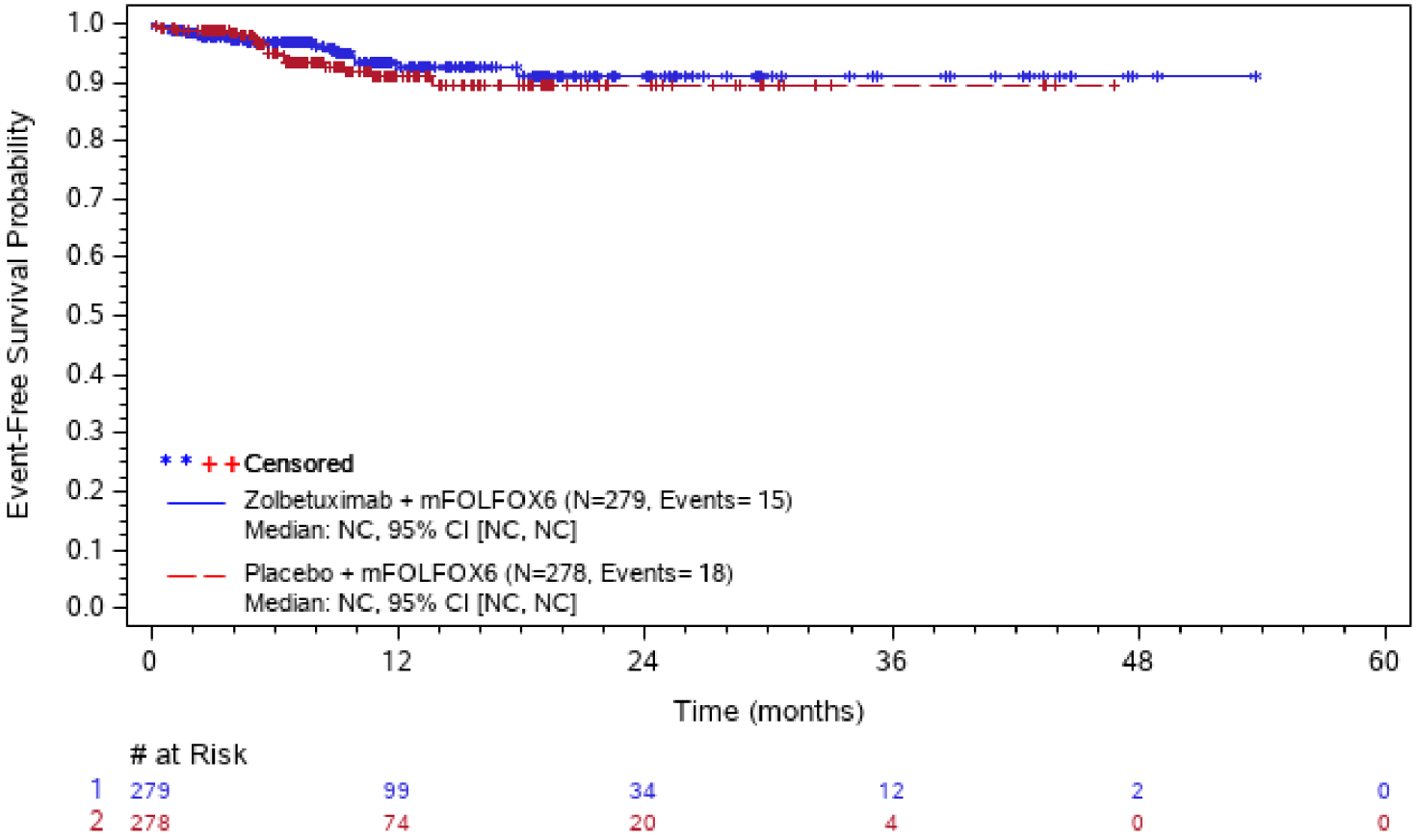


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.207: Kaplan-Meier Plot of Time to first Severe TEAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

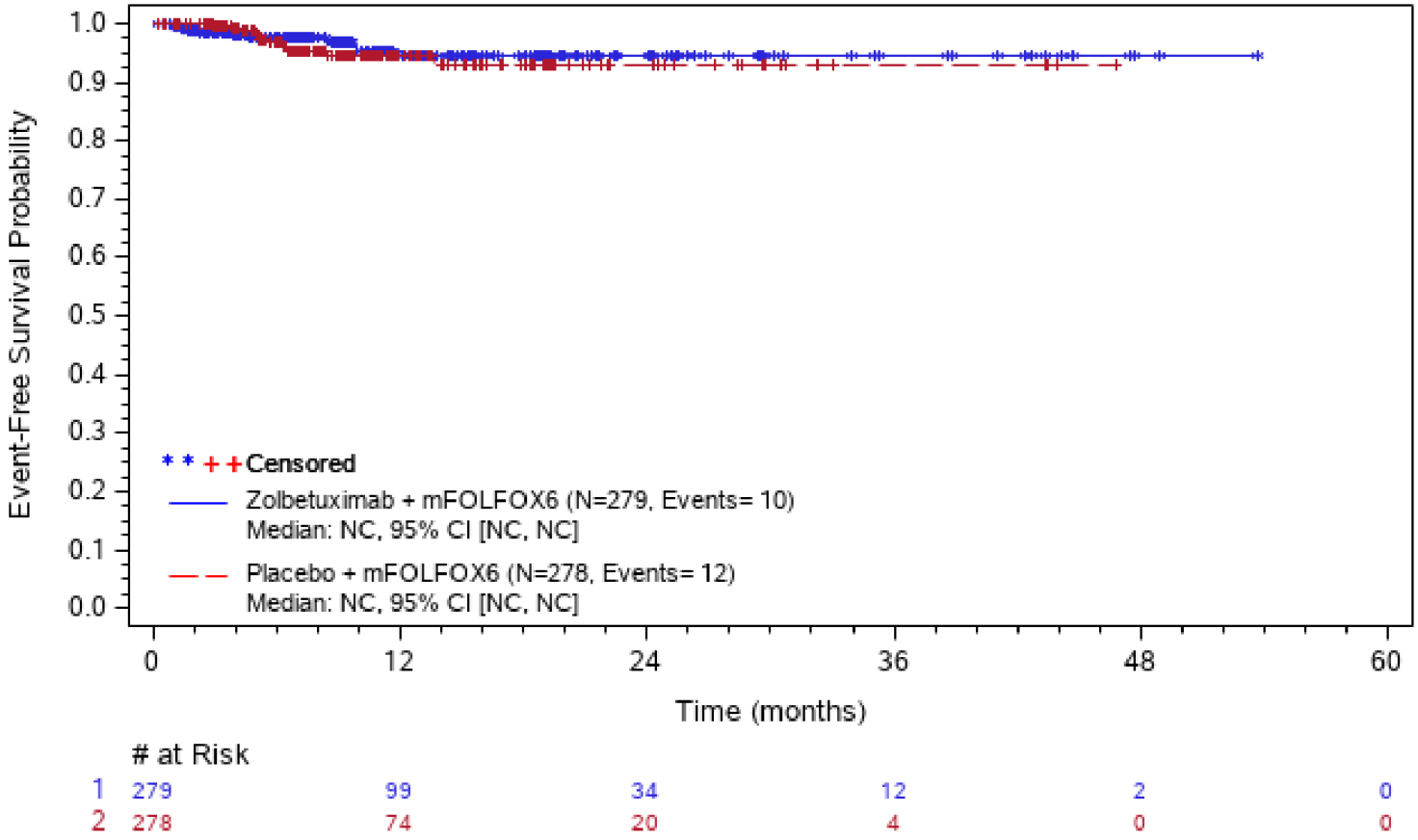


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.208: Kaplan-Meier Plot of Time to first Severe TEAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set

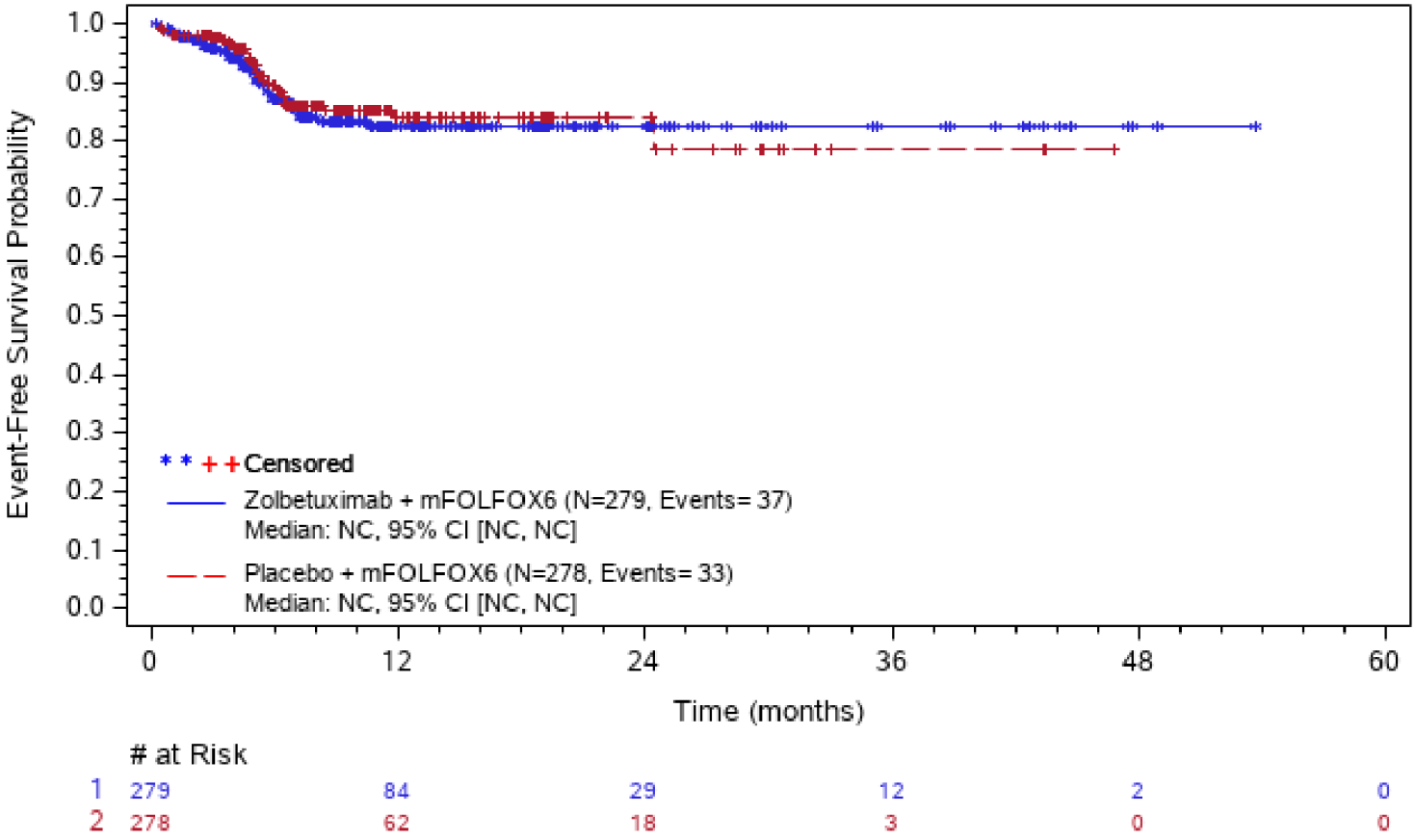


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.209: Kaplan-Meier Plot of Time to first Severe TEAE - Nervous System Disorders (SOC) - Safety Analysis Set

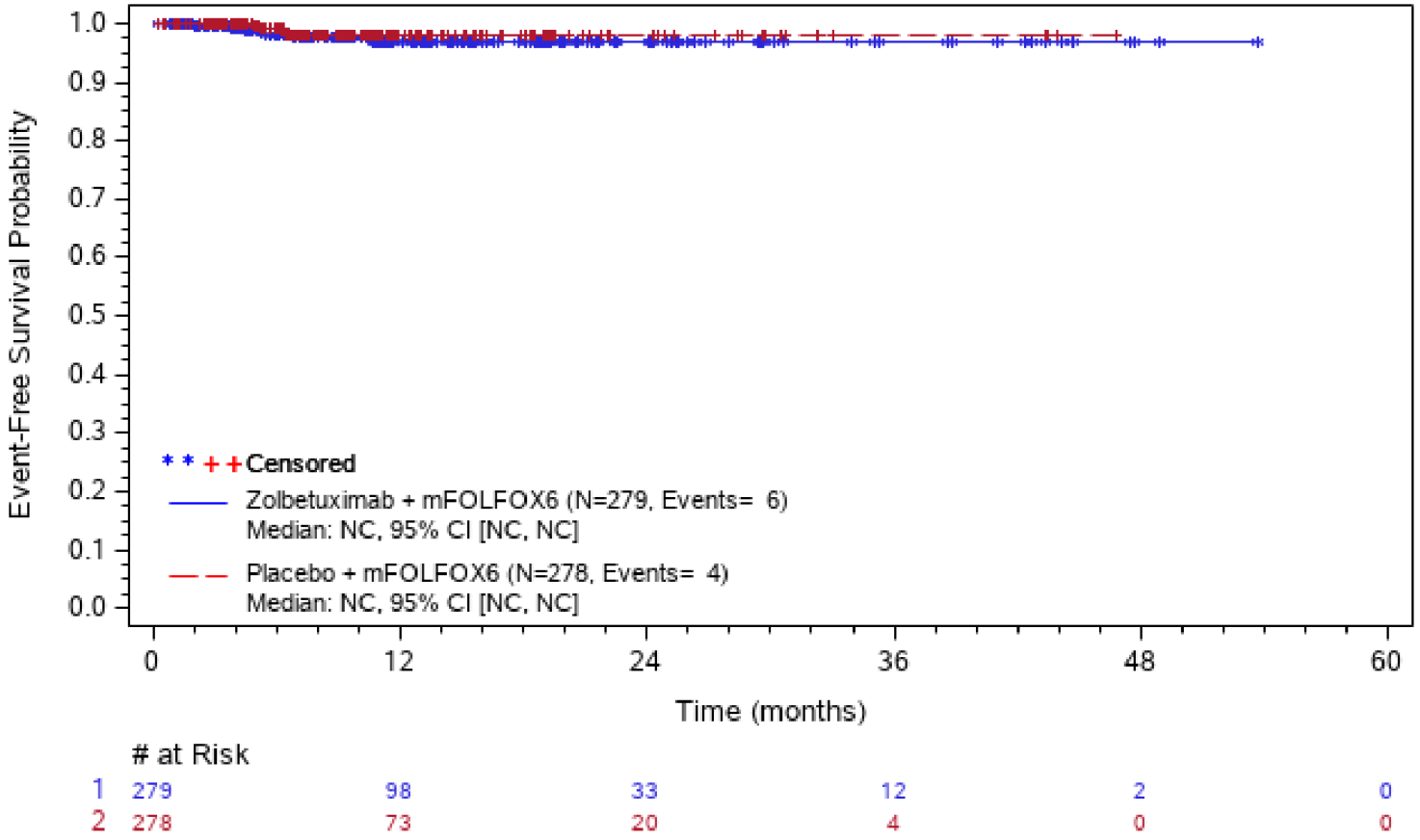


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.210: Kaplan-Meier Plot of Time to first Severe TEAE - Paraesthesia (PT) - Safety Analysis Set

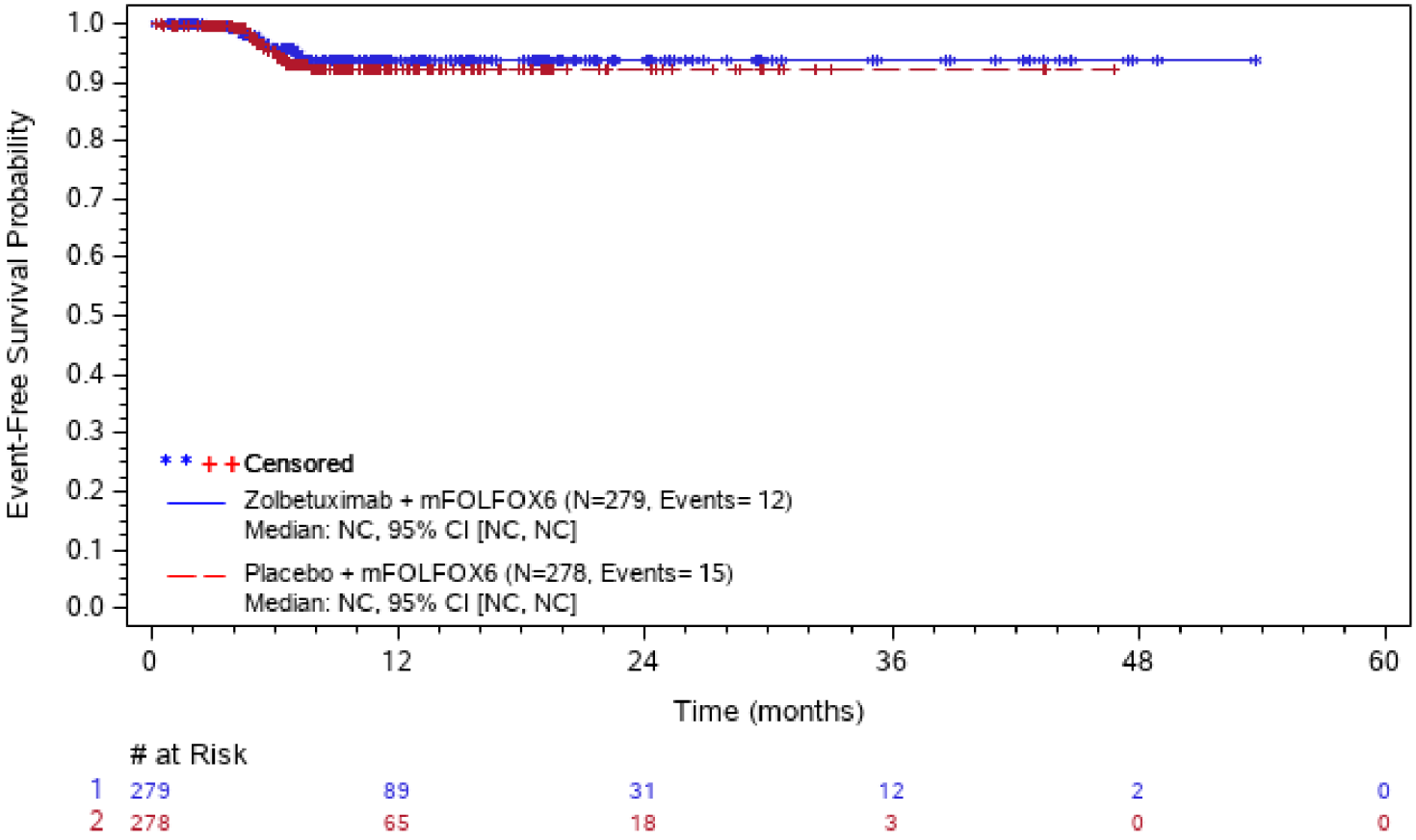


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.211: Kaplan-Meier Plot of Time to first Severe TEAE - Peripheral Sensory Neuropathy (PT) - Safety Analysis Set

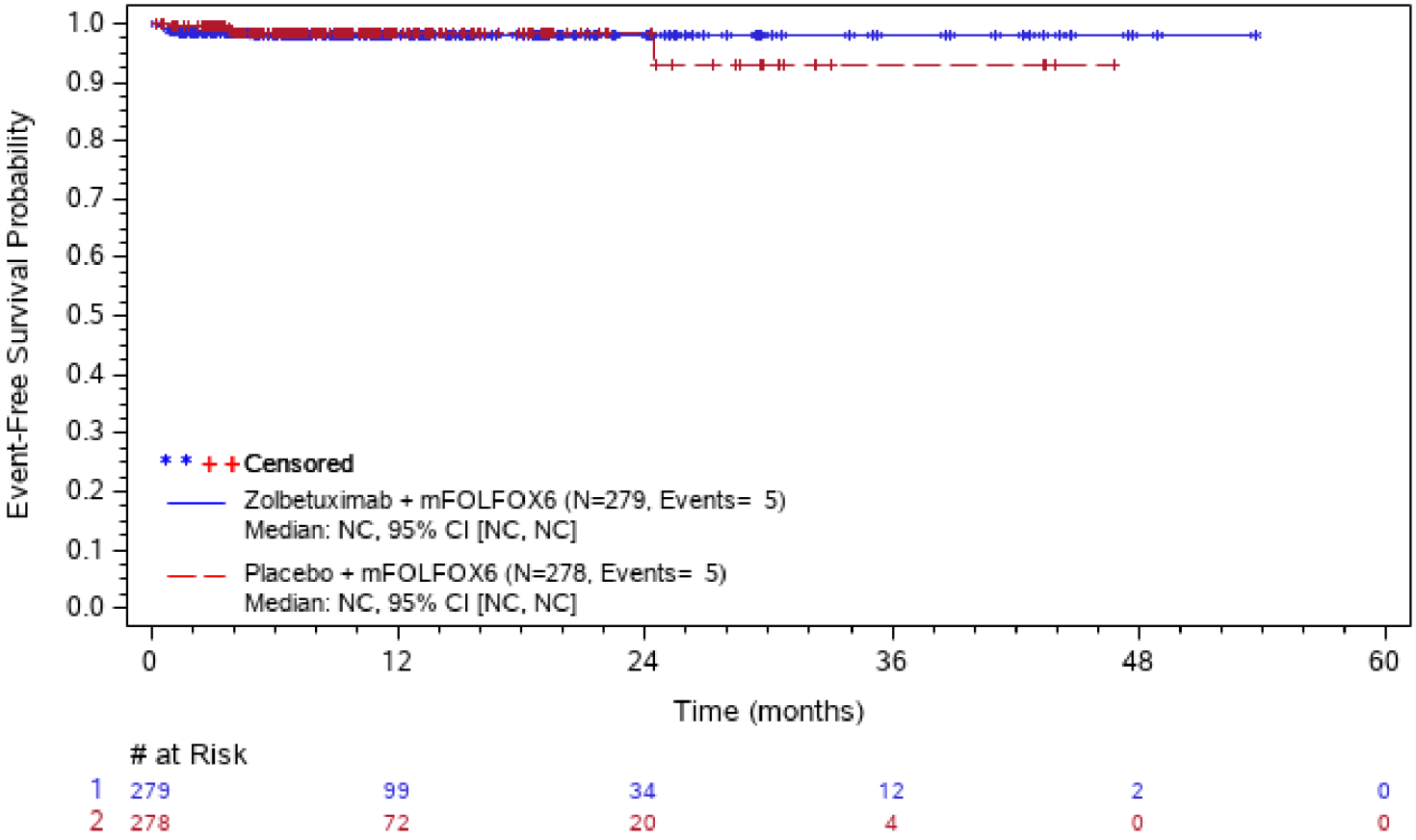


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.212: Kaplan-Meier Plot of Time to first Severe TEAE - Syncope (PT) - Safety Analysis Set

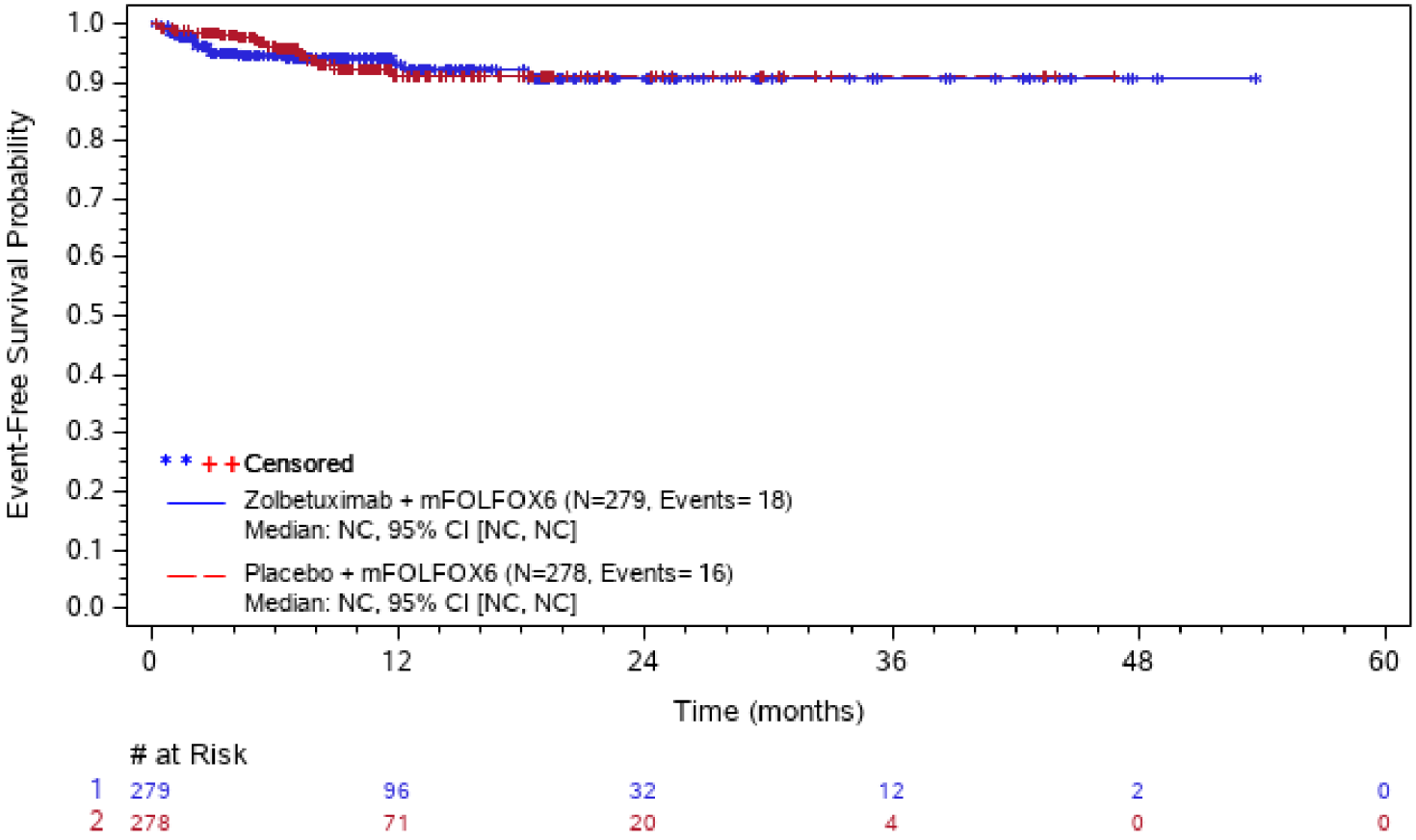


# at Risk						
1	279	99	34	12	2	0
2	278	72	20	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.213: Kaplan-Meier Plot of Time to first Severe TEAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

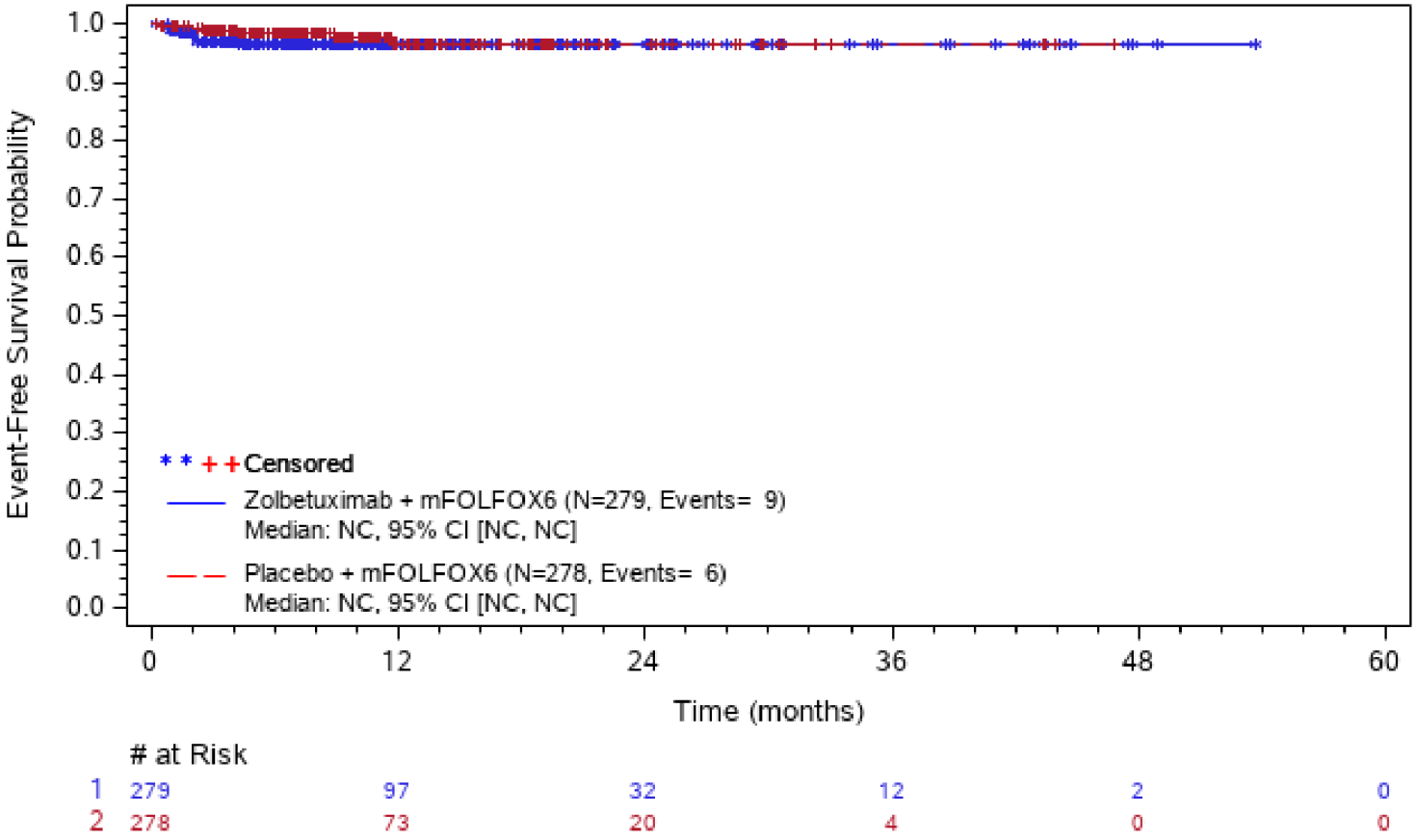


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.214: Kaplan-Meier Plot of Time to first Severe TEAE - Pulmonary Embolism (PT) - Safety Analysis Set

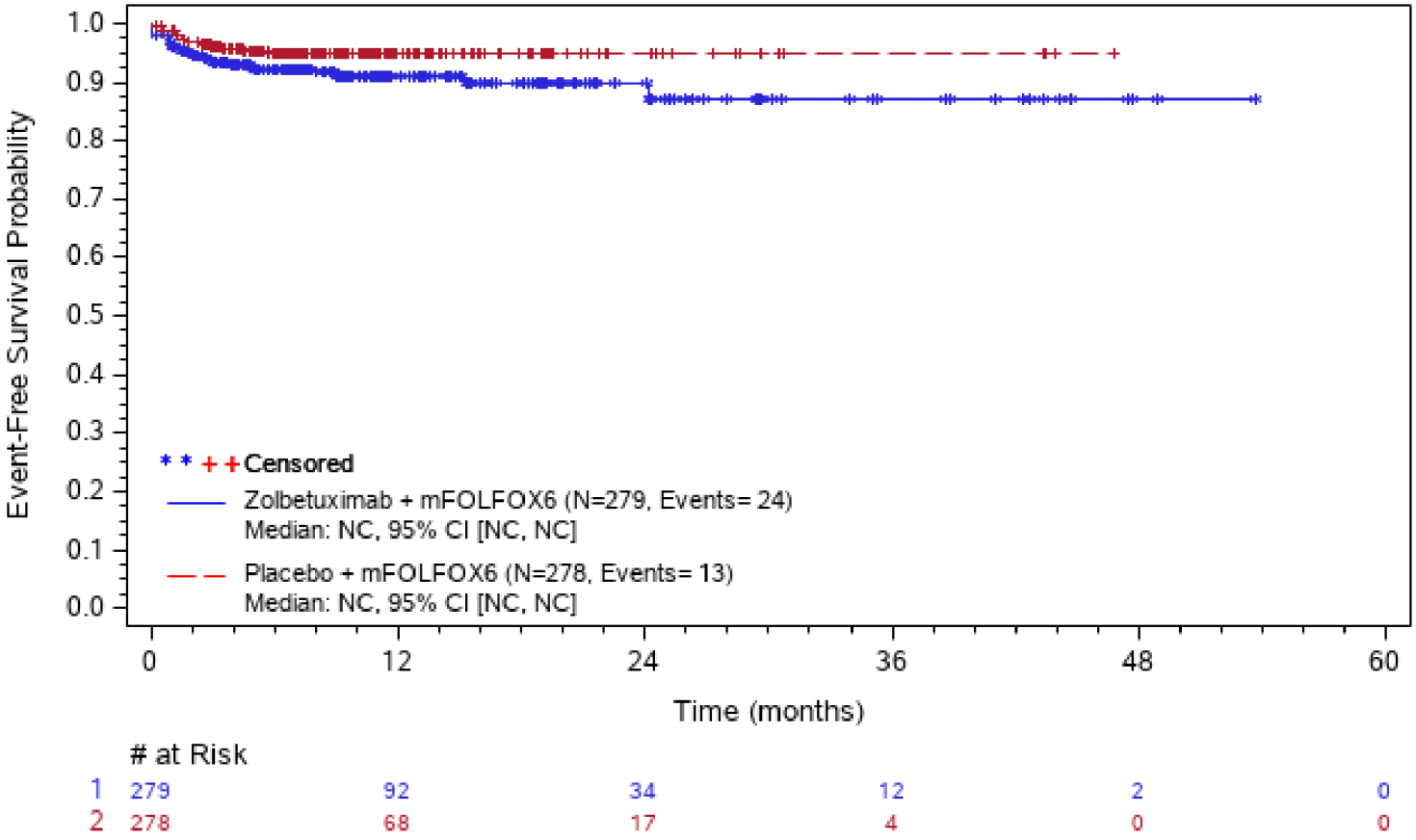


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.215: Kaplan-Meier Plot of Time to first Severe 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.

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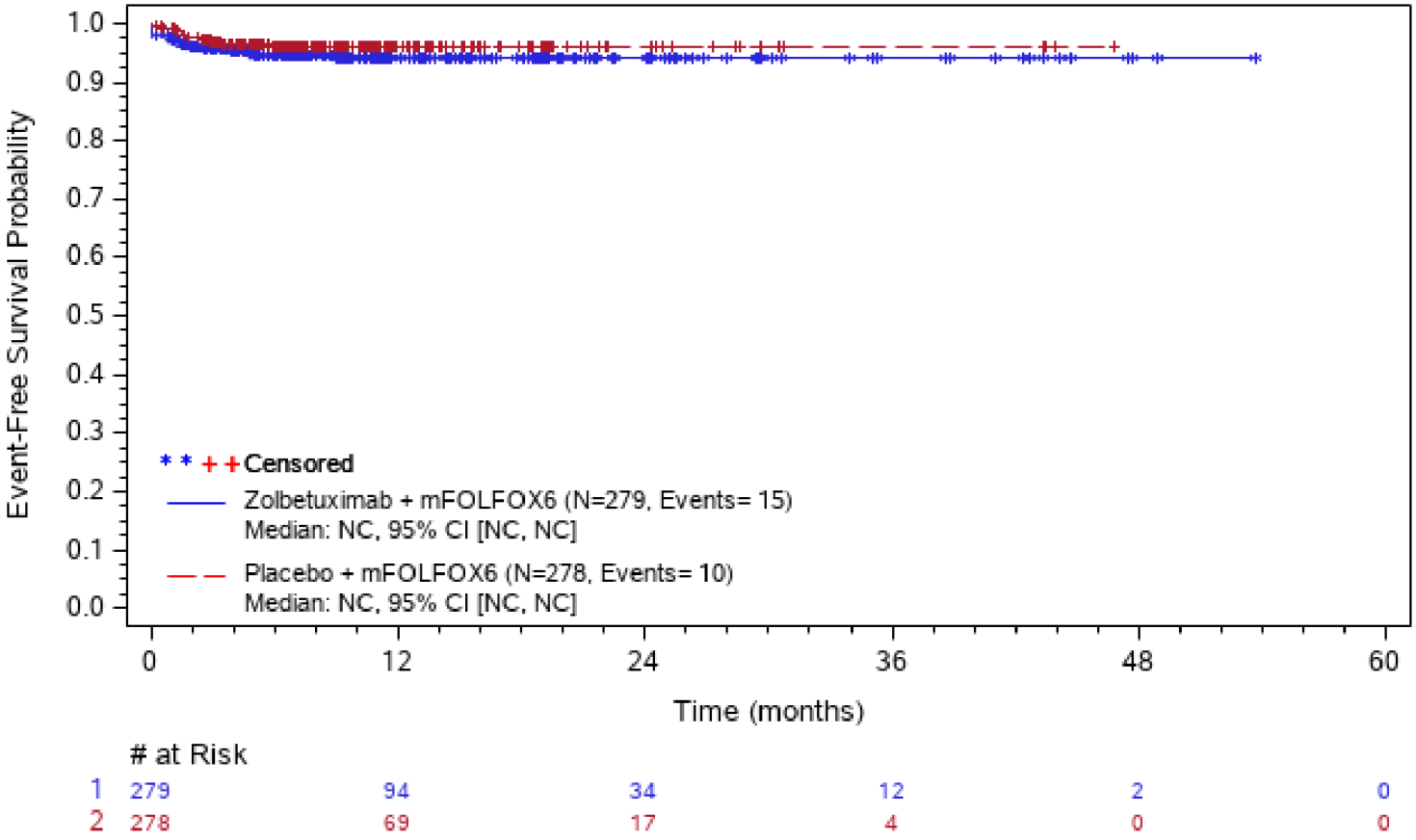
The SAS System

Figure 301.3.2001.216: Kaplan-Meier Plot of Time to first Severe 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.

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Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse - SOC und PT

1. Time-to-Event-Analysen

Table 301.3.2001.155.1: Summary and Results of TESAEs - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	9 (3.2%)	
Number of patients censored	262 (93.9%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.930 [0.860, 4.335]
Log-rank test			
Two-sided stratified log-rank p-value			0.1048

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.156.1: Summary and Results of TESAEs - Cardiac Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	8 (2.9%)	
Number of patients censored	274 (98.2%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.662 [0.216, 2.028]
Log-rank test			
Two-sided stratified log-rank p-value			0.4674

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.157.1: Summary and Results of TESAEs - Gastrointestinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	55 (19.7%)	44 (15.8%)	
Number of patients censored	224 (80.3%)	234 (84.2%)	
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			1.281 [0.861, 1.907]
Log-rank test			
Two-sided stratified log-rank p-value			0.2248

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.158.1: Summary and Results of TESAEs - Abdominal Pain (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	9 (3.2%)	
Number of patients censored	274 (98.2%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.562 [0.188, 1.681]
Log-rank test			
Two-sided stratified log-rank p-value			0.2960

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.159.1: Summary and Results of TESAEs - Diarrhoea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	5 (1.8%)	
Number of patients censored	271 (97.1%)	273 (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			1.595 [0.520, 4.888]
Log-rank test			
Two-sided stratified log-rank p-value			0.4100

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.160.1: Summary and Results of TESAEs - Intestinal Obstruction (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	5 (1.8%)	
Number of patients censored	272 (97.5%)	273 (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			1.347 [0.426, 4.262]
Log-rank test			
Two-sided stratified log-rank p-value			0.6105

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.161.1: Summary and Results of TESAEs - Nausea (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	19 (6.8%)	12 (4.3%)	
Number of patients censored	260 (93.2%)	266 (95.7%)	
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			1.619 [0.784, 3.344]
Log-rank test			
Two-sided stratified log-rank p-value			0.1893

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.162.1: Summary and Results of TESAEs - Vomiting (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	14 (5.0%)	
Number of patients censored	255 (91.4%)	264 (95.0%)	
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			1.832 [0.948, 3.543]
Log-rank test			
Two-sided stratified log-rank p-value			0.0692

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.163.1: Summary and Results of TESAEs - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	23 (8.3%)	
Number of patients censored	254 (91.0%)	255 (91.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [45.8, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.096 [0.620, 1.938]
Log-rank test			
Two-sided stratified log-rank p-value			0.7513

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.164.1: Summary and Results of TESAEs - Pyrexia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	6 (2.2%)	
Number of patients censored	272 (97.5%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.207 [0.405, 3.595]
Log-rank test			
Two-sided stratified log-rank p-value			0.7367

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.165.1: Summary and Results of TESAEs - Hepatobiliary Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	15 (5.4%)	
Number of patients censored	271 (97.1%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.470 [0.197, 1.122]
Log-rank test			
Two-sided stratified log-rank p-value			0.0821

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.166.1: Summary and Results of TESAEs - Infections And Infestations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	33 (11.8%)	25 (9.0%)	
Number of patients censored	246 (88.2%)	253 (91.0%)	
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			1.223 [0.724, 2.065]
Log-rank test			
Two-sided stratified log-rank p-value			0.4509

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.167.1: Summary and Results of TESAEs - Pneumonia (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	7 (2.5%)	8 (2.9%)	
Number of patients censored	272 (97.5%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.746 [0.267, 2.081]
Log-rank test			
Two-sided stratified log-rank p-value			0.5739

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.168.1: Summary and Results of TESAEs - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	12 (4.3%)	5 (1.8%)	
Number of patients censored	267 (95.7%)	273 (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			2.089 [0.730, 5.978]
Log-rank test			
Two-sided stratified log-rank p-value			0.1604

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
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Table 301.3.2001.169.1: Summary and Results of TESAEs - Investigations (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	10 (3.6%)	
Number of patients censored	273 (97.8%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.604 [0.219, 1.663]
Log-rank test			
Two-sided stratified log-rank p-value			0.3236

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.170.1: Summary and Results of TESAEs - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	9 (3.2%)	
Number of patients censored	264 (94.6%)	269 (96.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.651 [0.721, 3.782]
Log-rank test			
Two-sided stratified log-rank p-value			0.2311

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.171.1: Summary and Results of TESAEs - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	17 (6.1%)	
Number of patients censored	263 (94.3%)	261 (93.9%)	
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			0.946 [0.476, 1.878]
Log-rank test			
Two-sided stratified log-rank p-value			0.8736

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.172.1: Summary and Results of TESAEs - Malignant Neoplasm Progression (PT) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	12 (4.3%)	
Number of patients censored	269 (96.4%)	266 (95.7%)	
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			0.876 [0.378, 2.033]
Log-rank test			
Two-sided stratified log-rank p-value			0.7579

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.173.1: Summary and Results of TESAEs - Nervous System Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	13 (4.7%)	
Number of patients censored	269 (96.4%)	265 (95.3%)	
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			0.746 [0.325, 1.713]
Log-rank test			
Two-sided stratified log-rank p-value			0.4876

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.174.1: Summary and Results of TESAEs - Renal And Urinary Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	6 (2.2%)	
Number of patients censored	273 (97.8%)	272 (97.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.925 [0.295, 2.901]
Log-rank test			
Two-sided stratified log-rank p-value			0.8944

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.175.1: Summary and Results of TESAEs - Respiratory, Thoracic And Mediastinal Disorders (SOC) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	15 (5.4%)	15 (5.4%)	
Number of patients censored	264 (94.6%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.061 [0.518, 2.174]
Log-rank test			
Two-sided stratified log-rank p-value			0.8721

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.176.1: Summary and Results of TESAEs - Pulmonary Embolism (PT)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	4 (1.4%)	
Number of patients censored	273 (97.8%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.548 [0.436, 5.496]
Log-rank test			
Two-sided stratified log-rank p-value			0.4955

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2001.177.1: Summary and Results of TESAEs - Vascular Disorders (SOC)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	10 (3.6%)	5 (1.8%)	
Number of patients censored	269 (96.4%)	273 (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			2.092 [0.712, 6.146]
Log-rank test			
Two-sided stratified log-rank p-value			0.1701

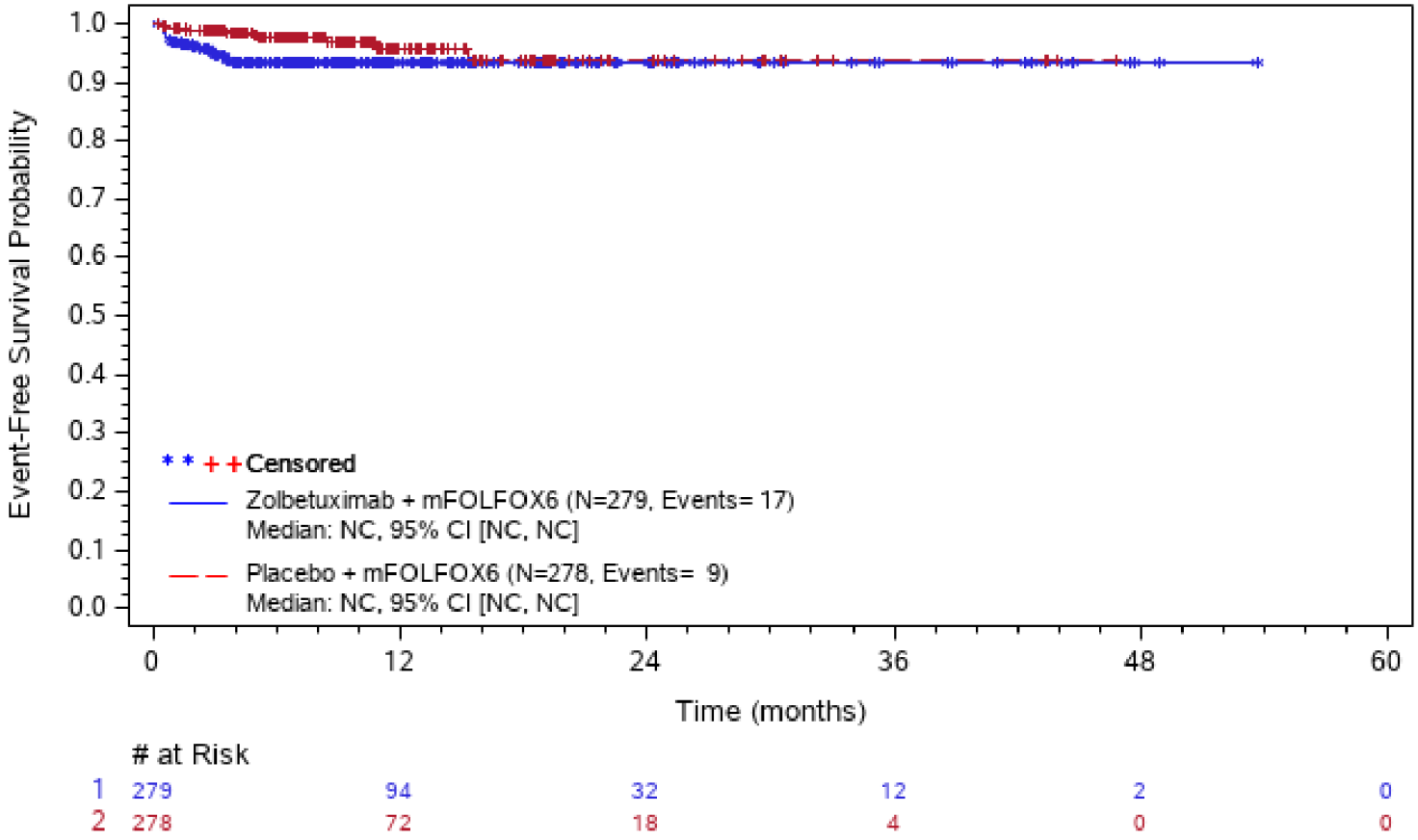
Abbreviations: CI=confidence interval; HR=hazard ratio; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No). 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 at least 1% of subjects in at least one treatment group.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Schwerwiegende unerwünschte Ereignisse - SOC und PT

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.155: Kaplan-Meier Plot of Time to first TESAE - Blood and Lymphatic System Disorders (SOC) - Safety Analysis Set

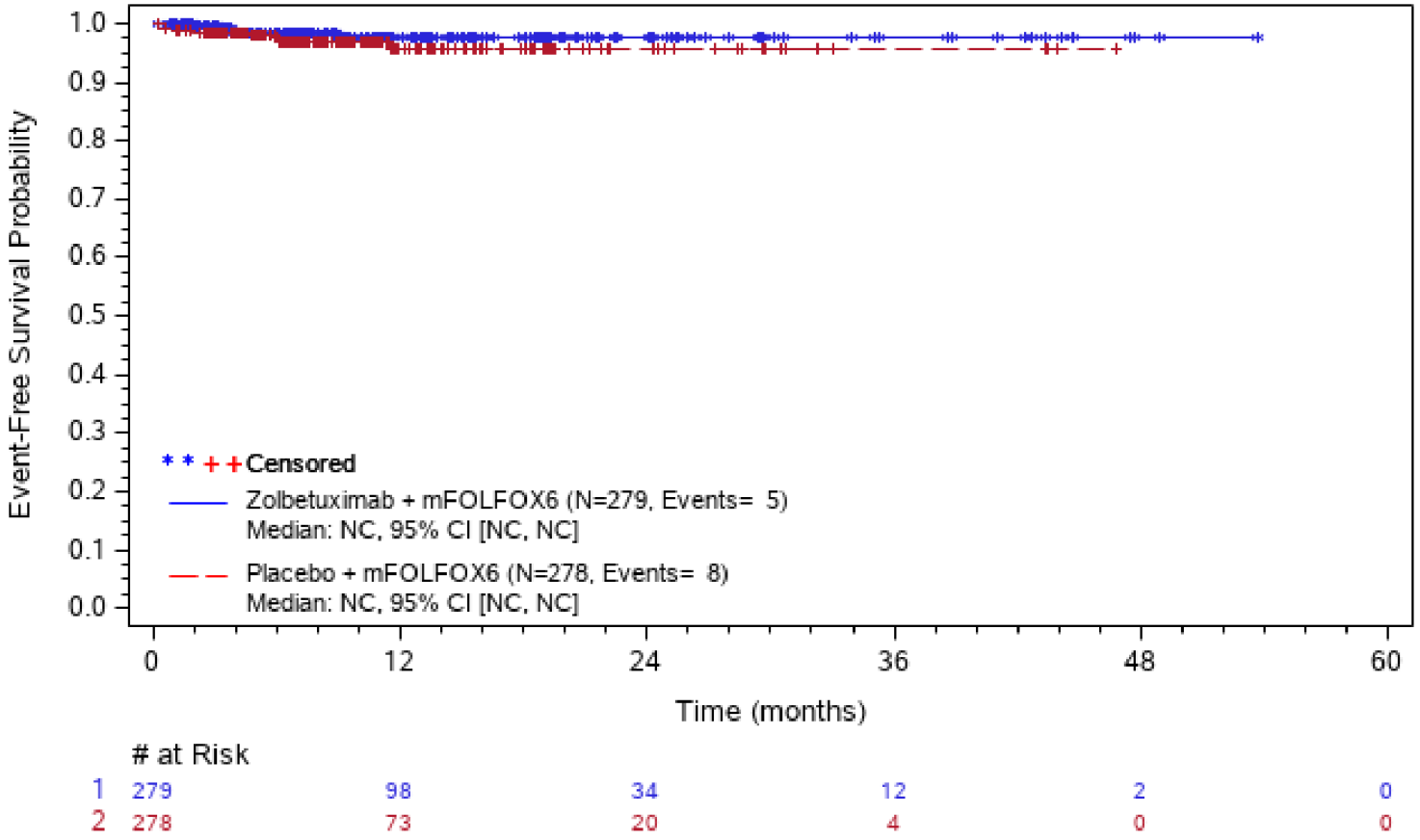


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.156: Kaplan-Meier Plot of Time to first TESAE - Cardiac Disorders (SOC) - Safety Analysis Set

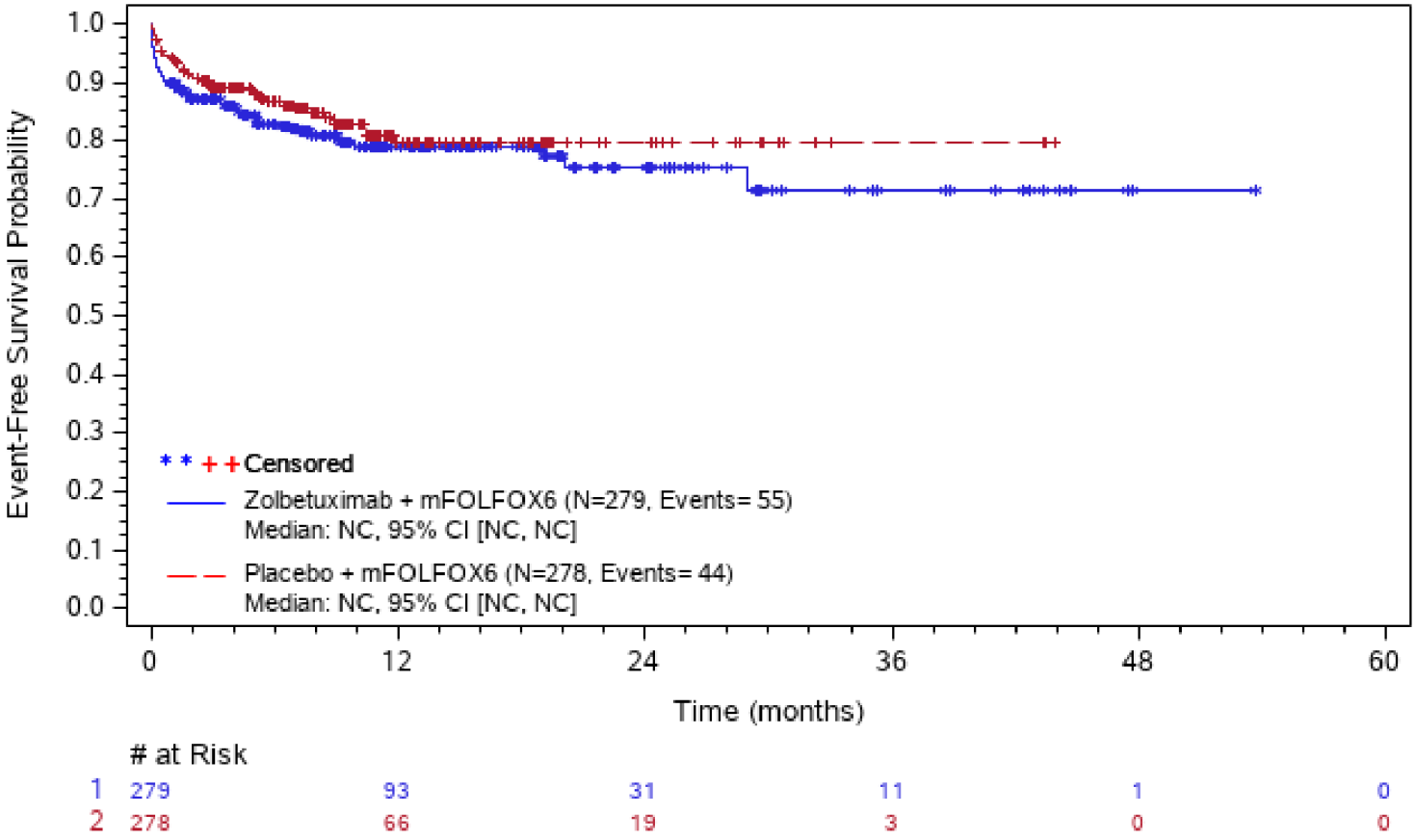


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.157: Kaplan-Meier Plot of Time to first TESAE - Gastrointestinal Disorders (SOC) - Safety Analysis Set

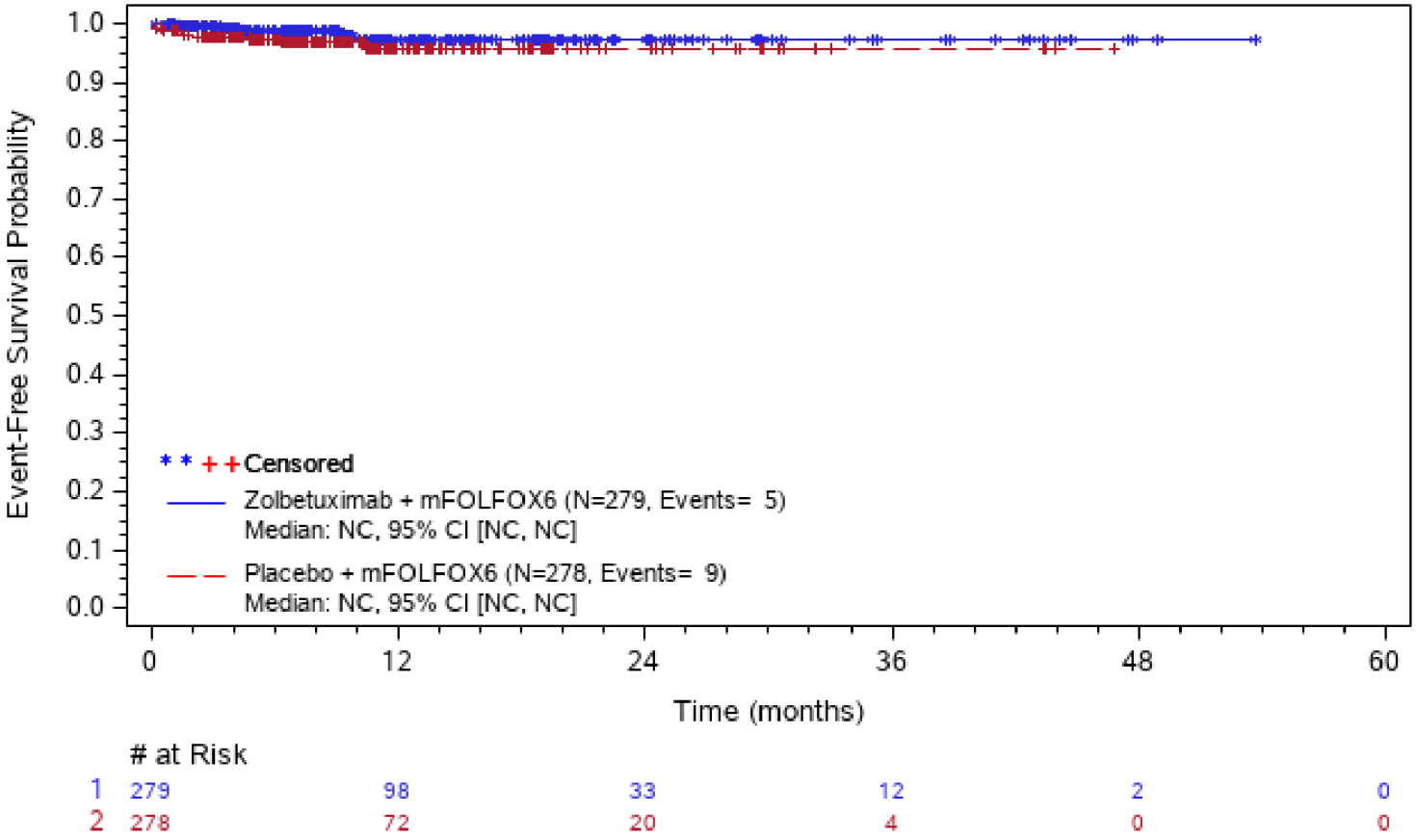


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.158: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (PT) - Safety Analysis Set

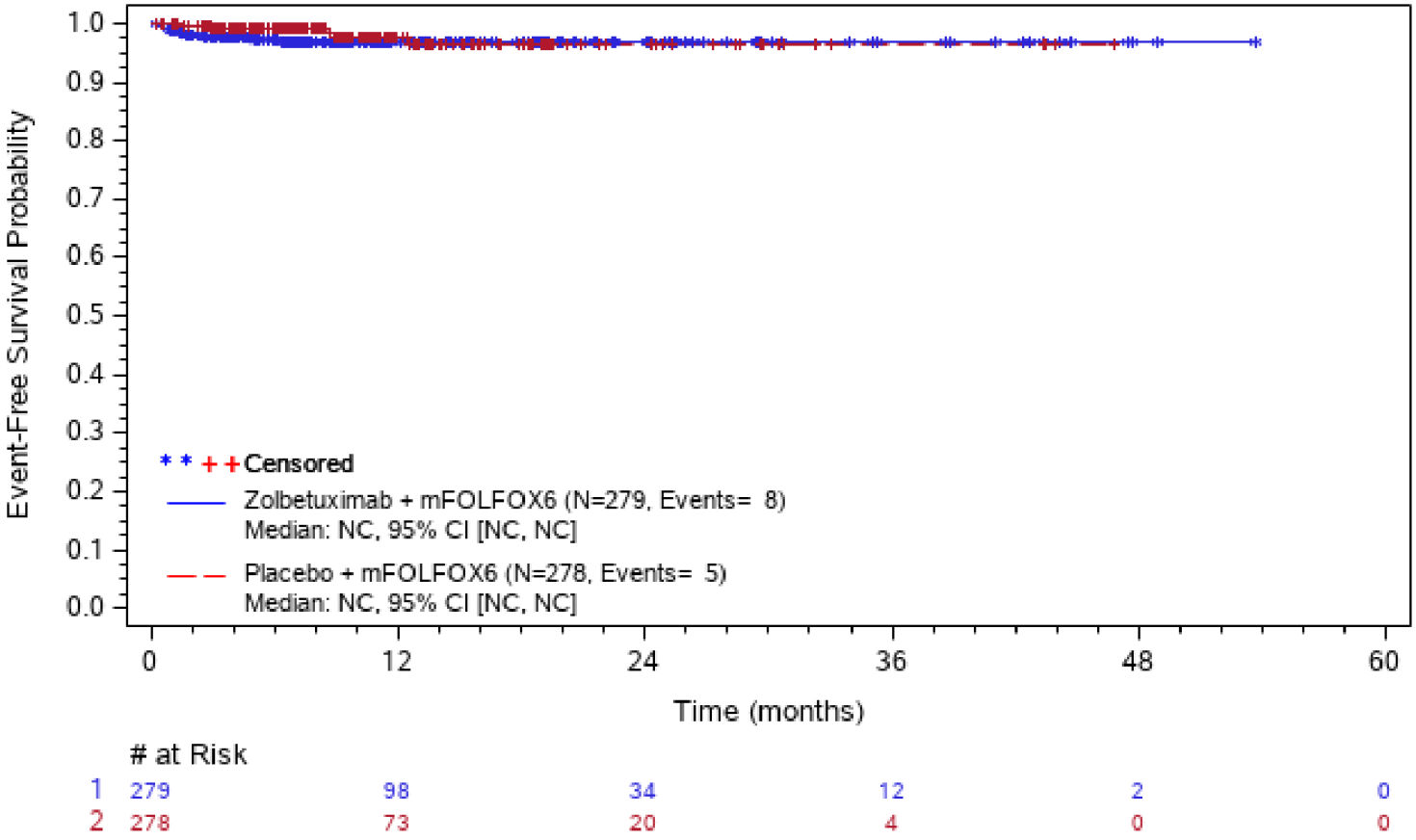


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.159: Kaplan-Meier Plot of Time to first TESAE - Diarrhoea (PT) - Safety Analysis Set

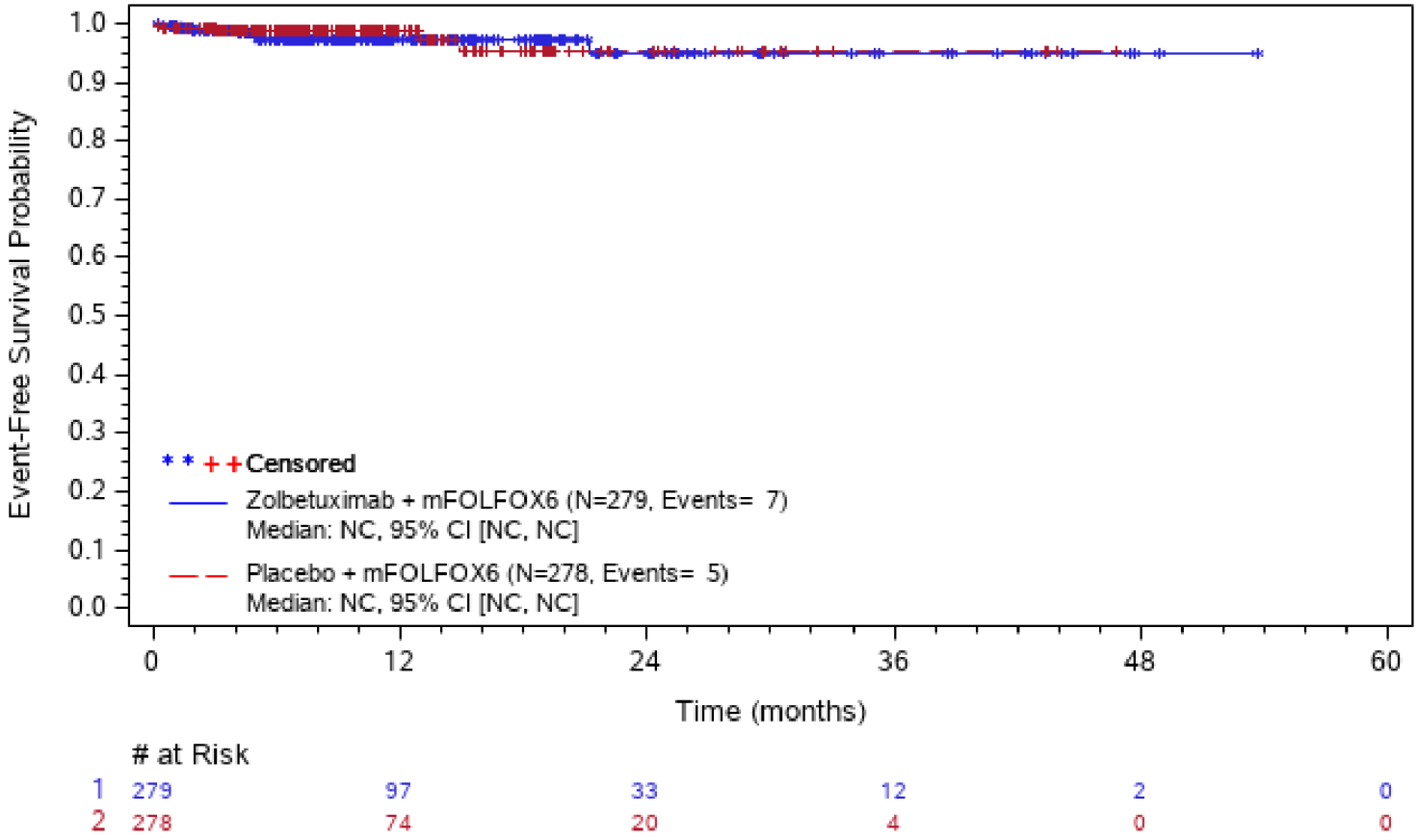


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.160: Kaplan-Meier Plot of Time to first TESAE - Intestinal Obstruction (PT) - Safety Analysis Set

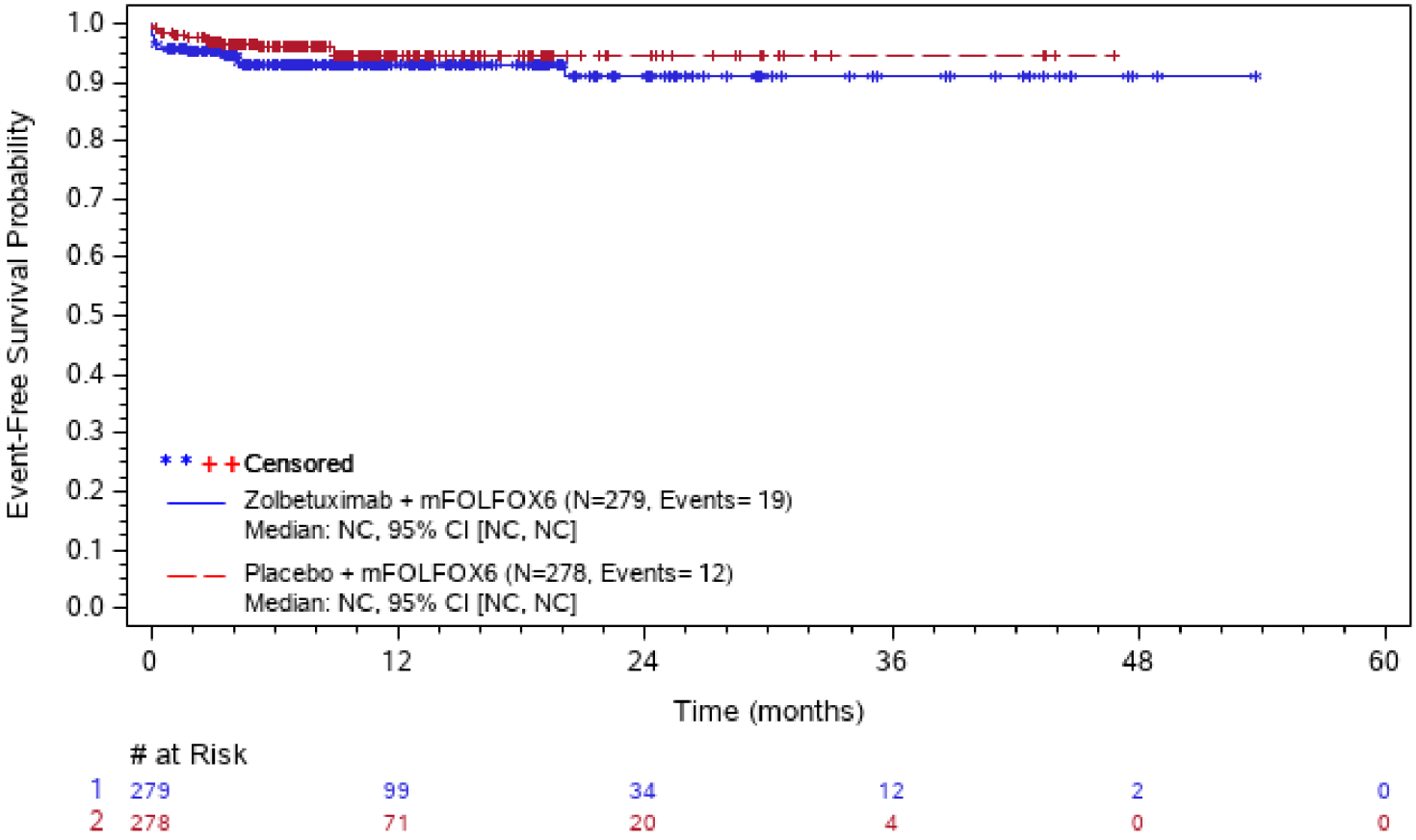


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.161: Kaplan-Meier Plot of Time to first TESAE - Nausea (PT) - Safety Analysis Set

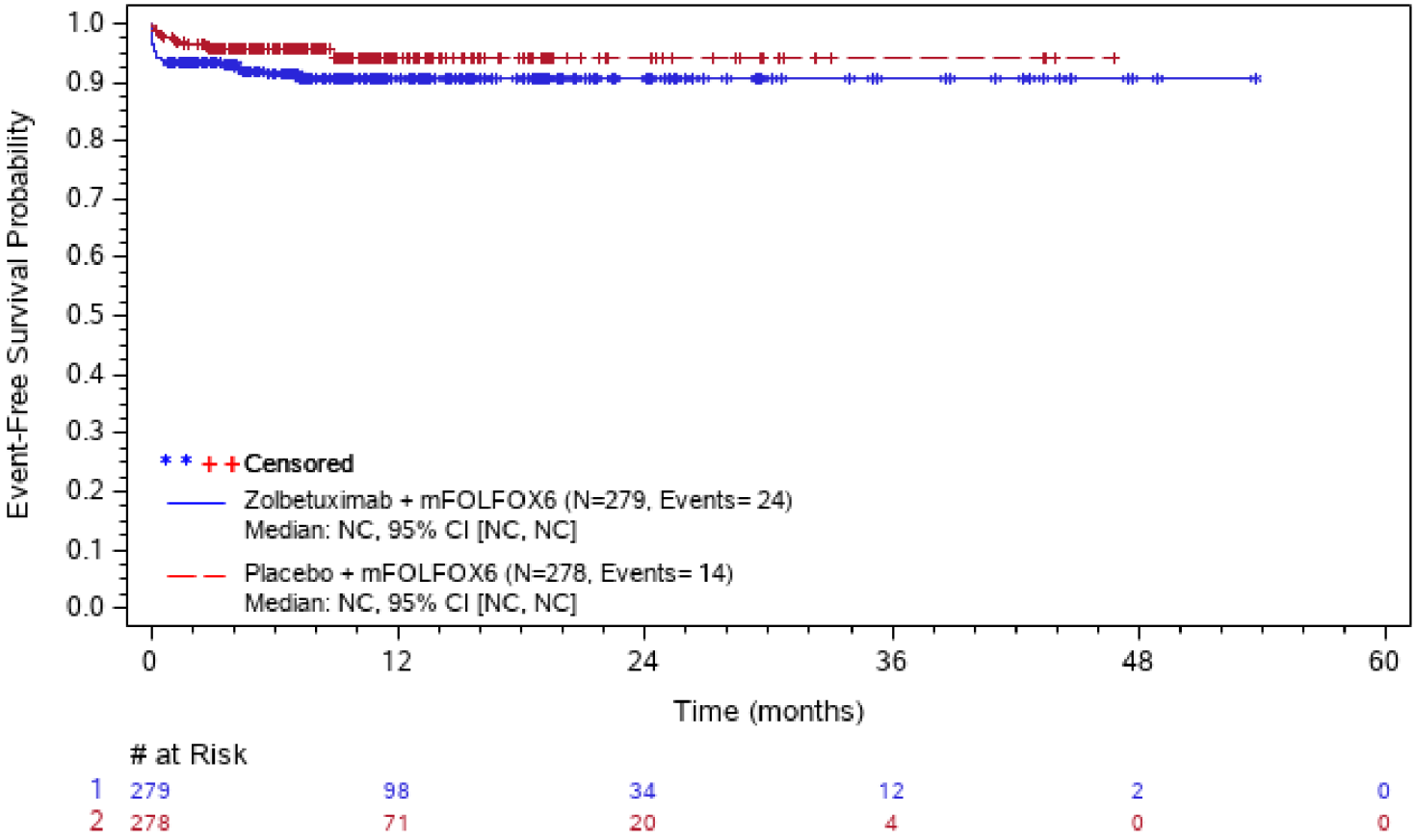


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.162: Kaplan-Meier Plot of Time to first TESAE - Vomiting (PT) - Safety Analysis Set

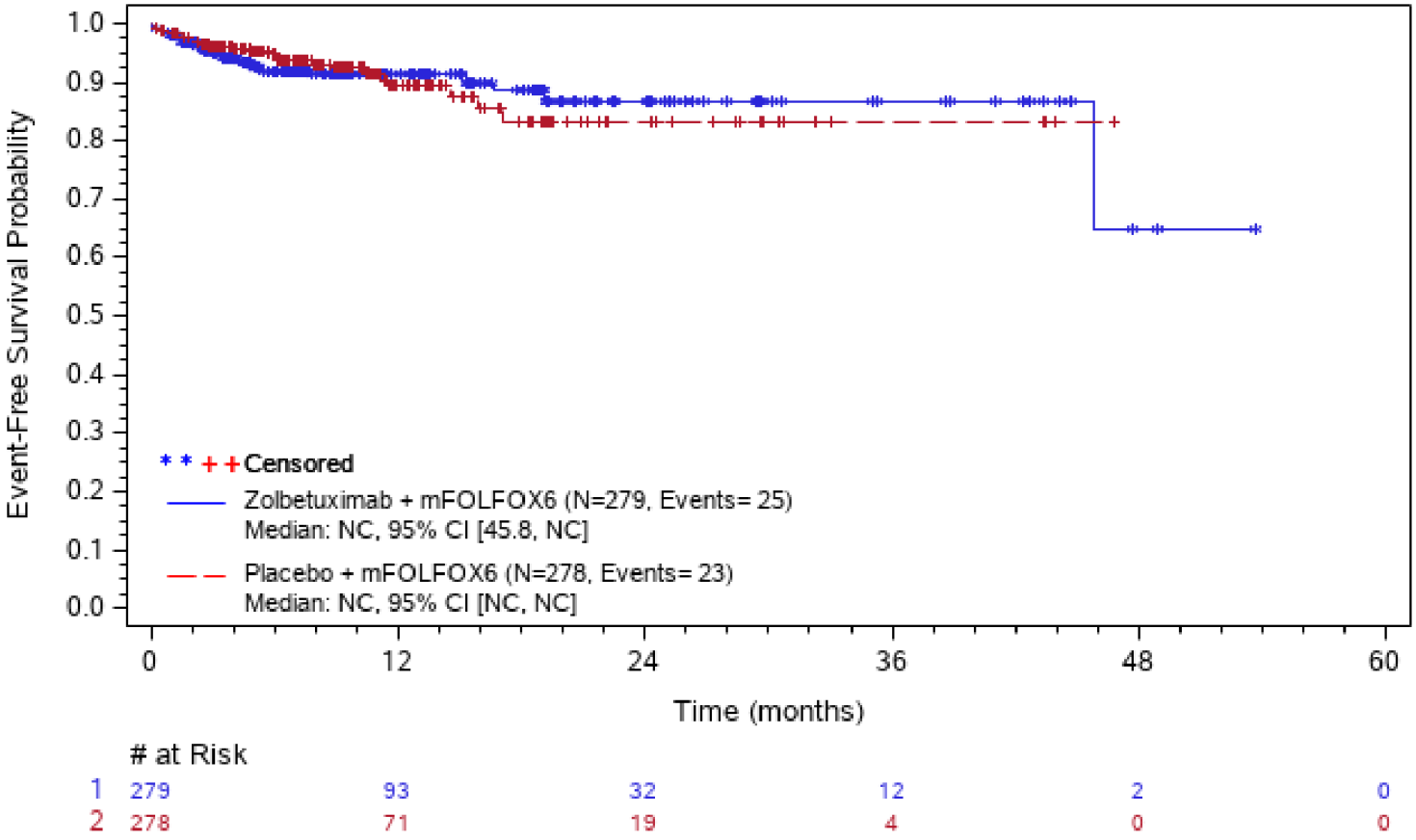


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.163: Kaplan-Meier Plot of Time to first TESAE - General Disorders And Administration Site Conditions (SOC) - Safety Analysis Set

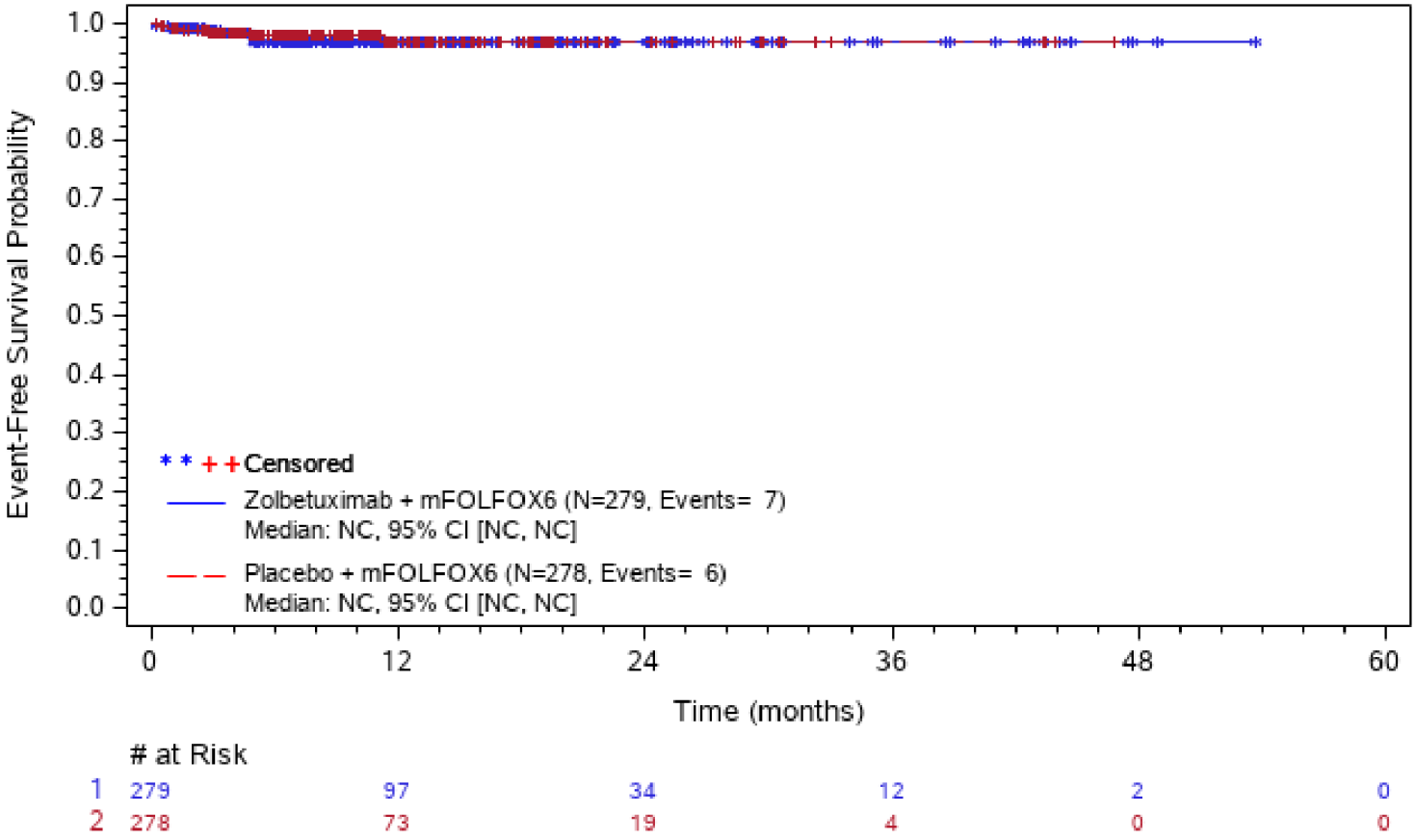


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.164: Kaplan-Meier Plot of Time to first TESAE - Pyrexia (PT) - Safety Analysis Set

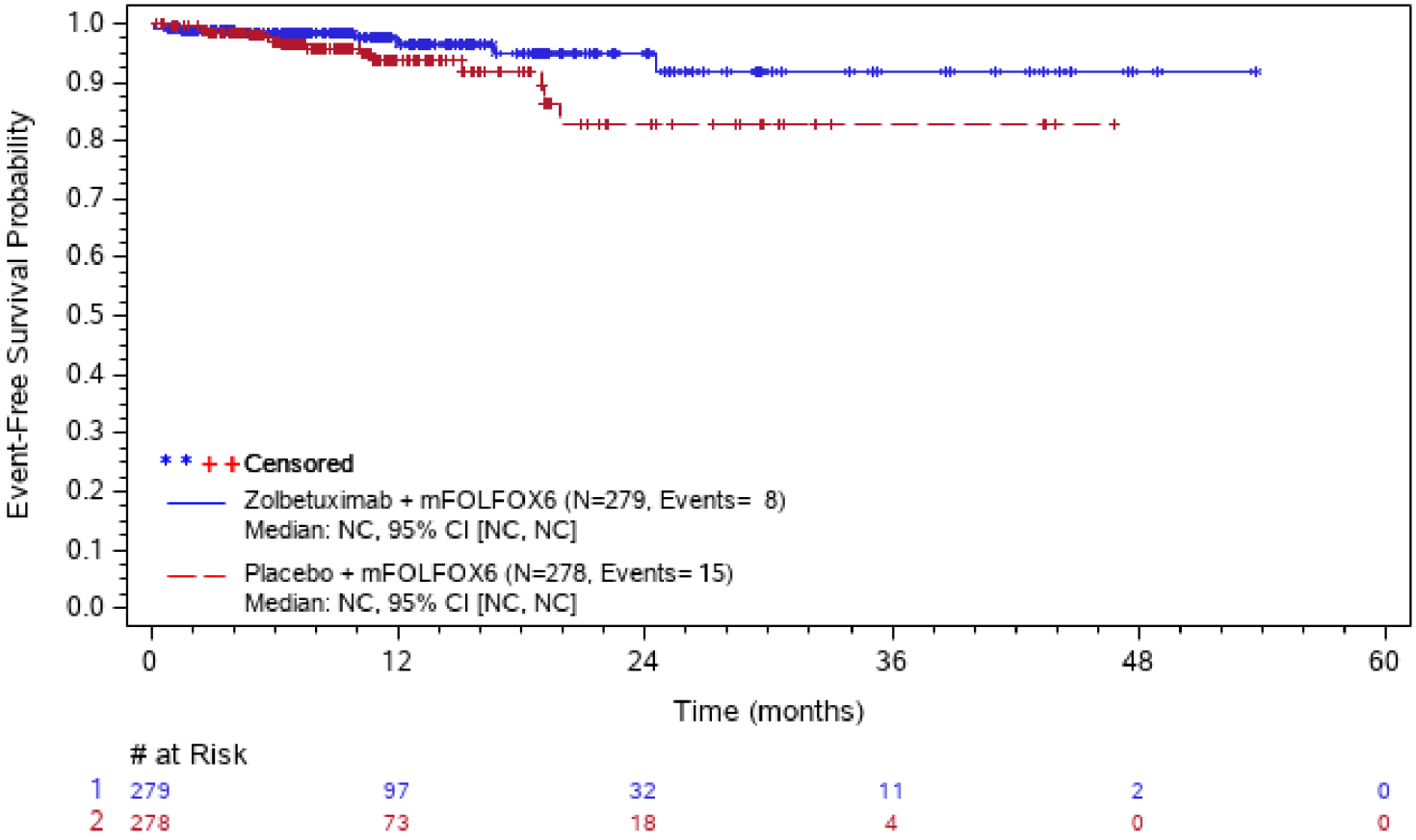


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.165: Kaplan-Meier Plot of Time to first TESAE - Hepatobiliary Disorders (SOC) - Safety Analysis Set

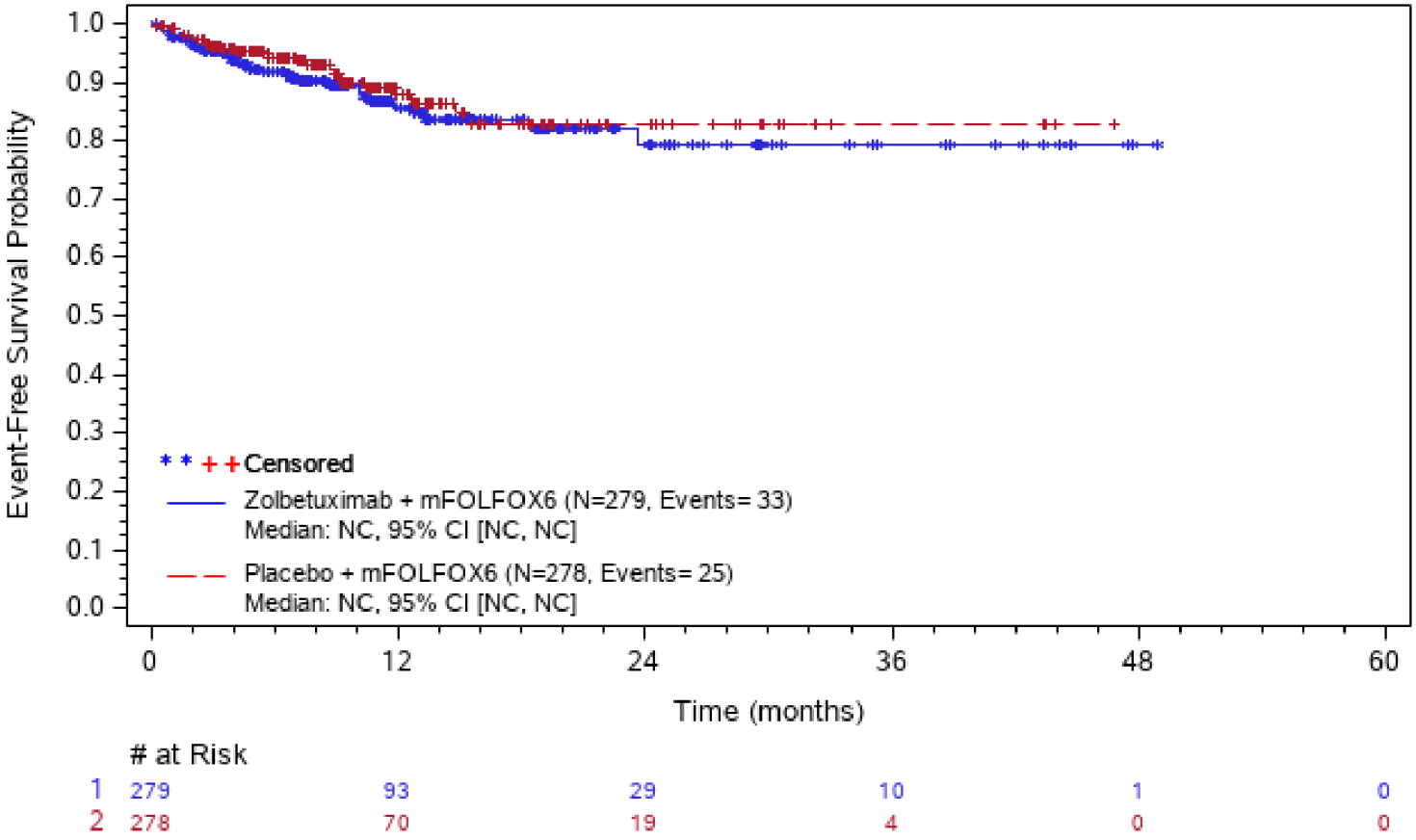


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.166: Kaplan-Meier Plot of Time to first TESAE - Infections And Infestations (SOC) - Safety Analysis Set

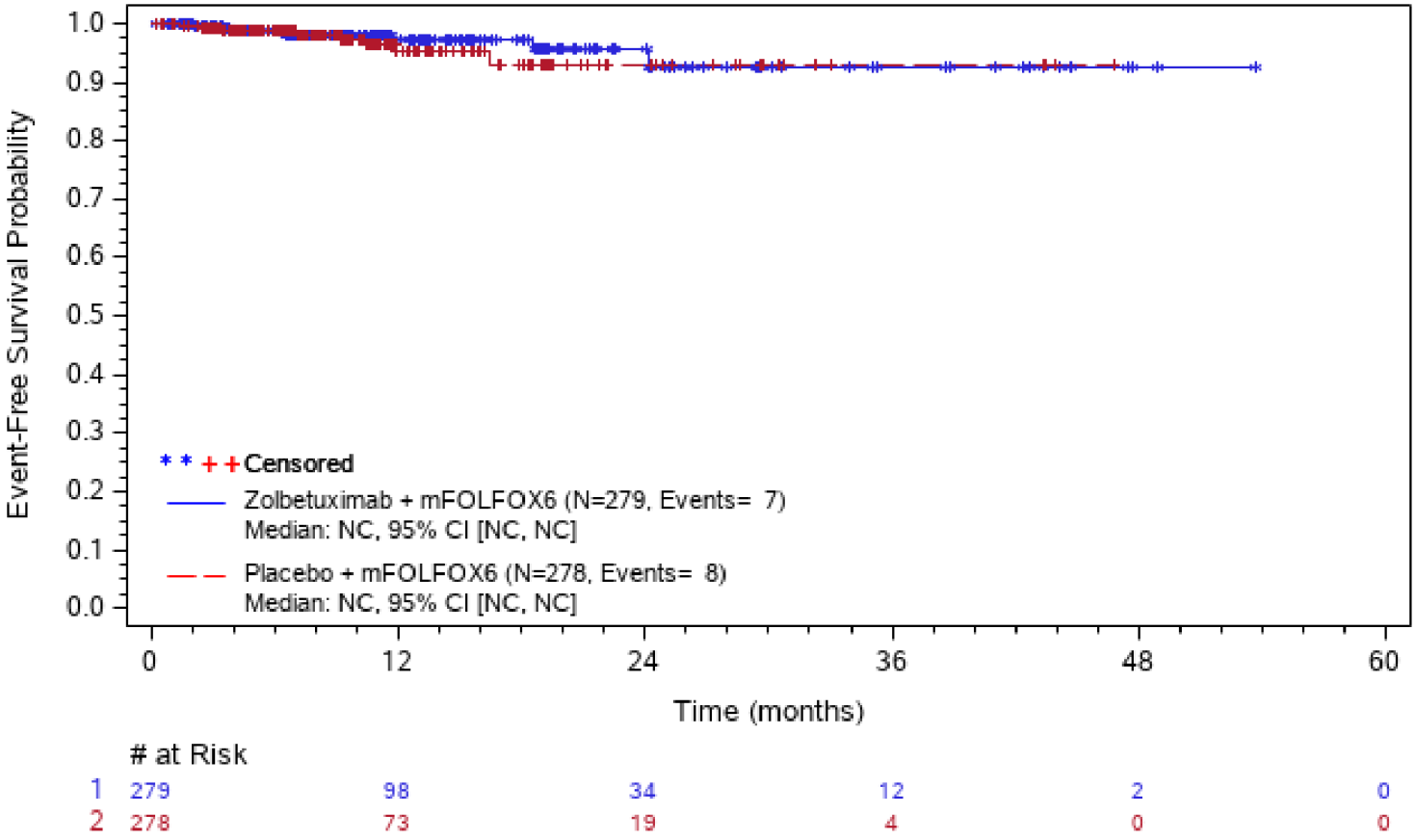


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.167: Kaplan-Meier Plot of Time to first TESAE - Pneumonia (PT) - Safety Analysis Set

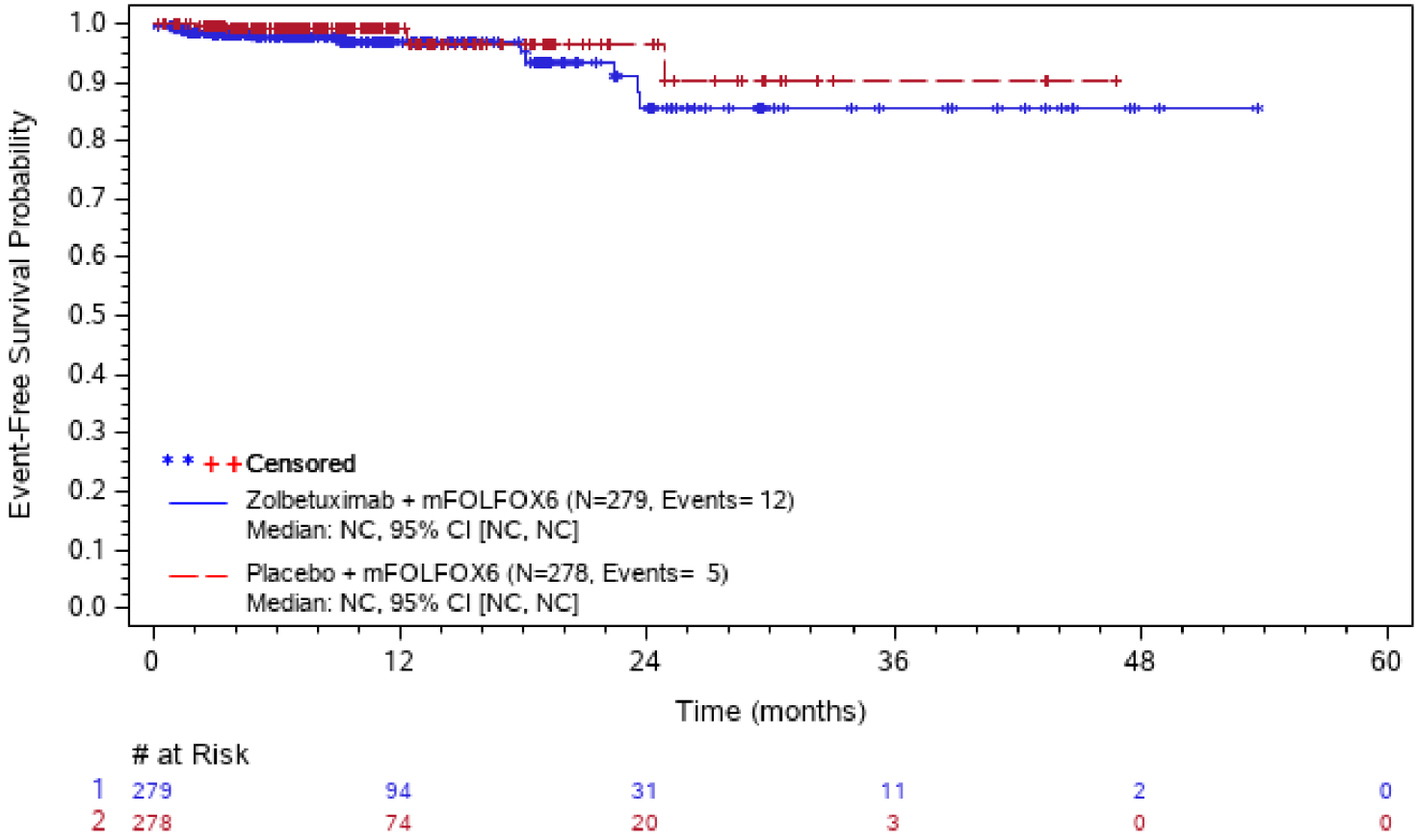


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.168: Kaplan-Meier Plot of Time to first TESAE - Injury, Poisoning And Procedural Complications (SOC) - Safety Analysis Set

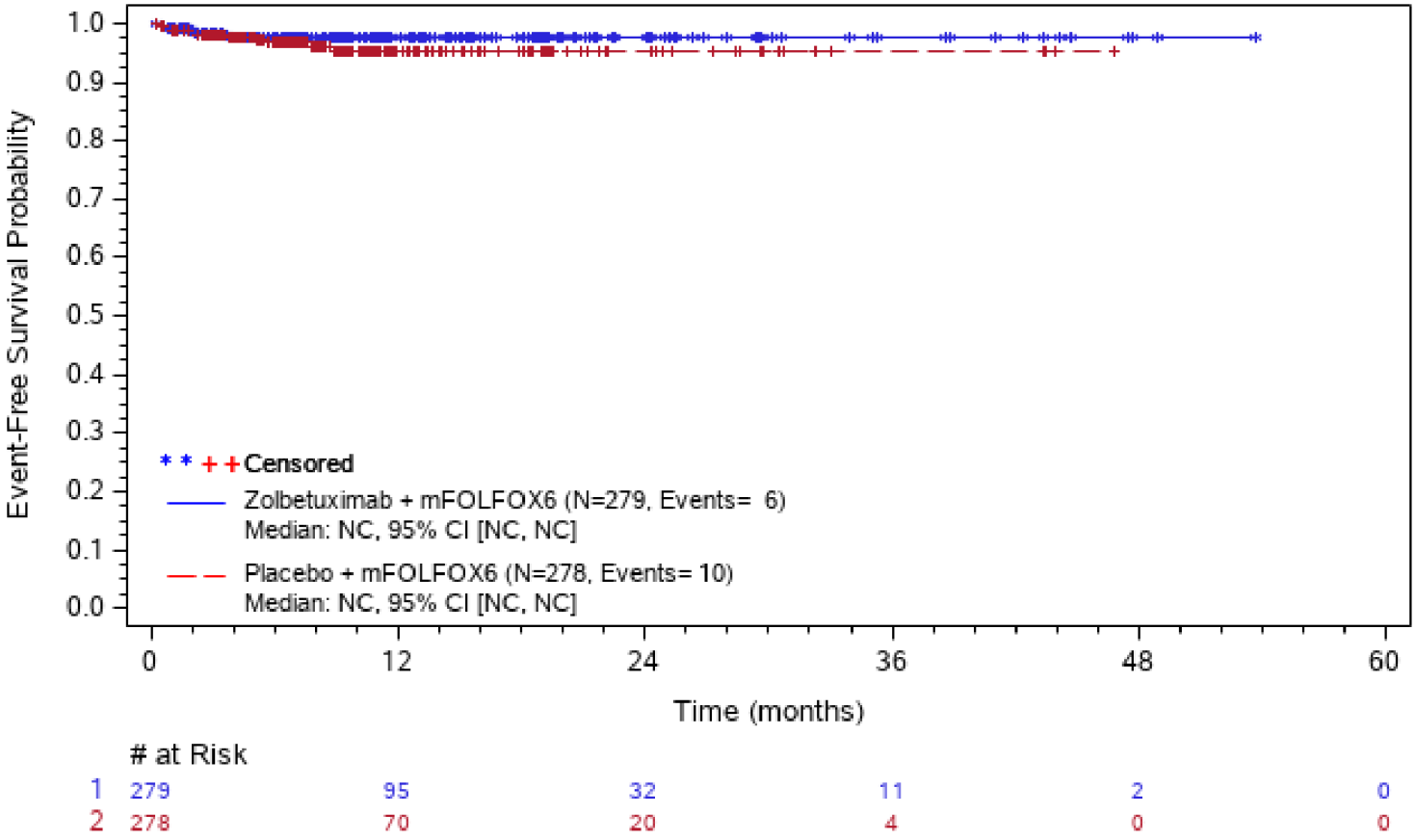


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.169: Kaplan-Meier Plot of Time to first TESAE - Investigations (SOC) - Safety Analysis Set

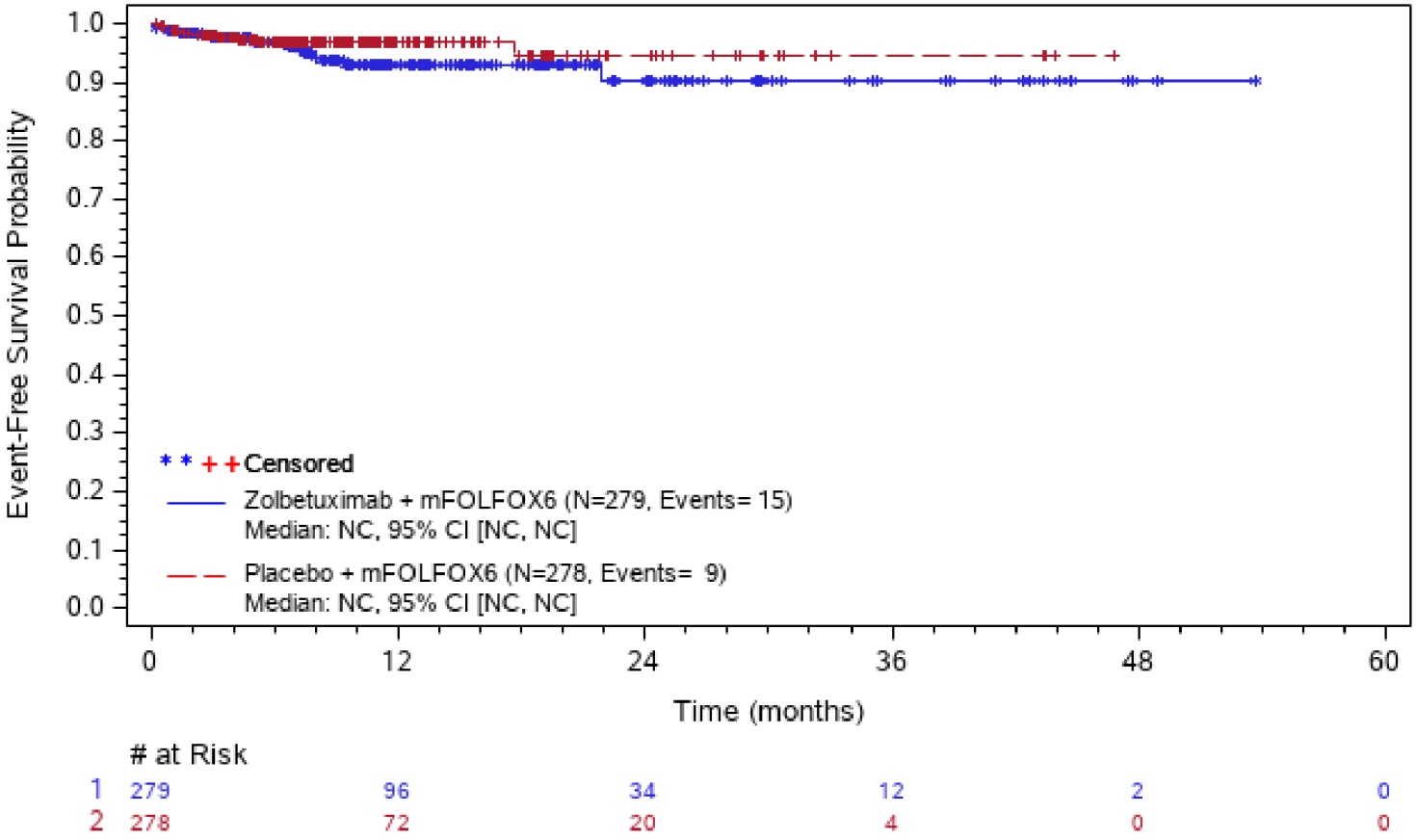


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.170: Kaplan-Meier Plot of Time to first TESAE - Metabolism And Nutrition Disorders (SOC) - Safety Analysis Set

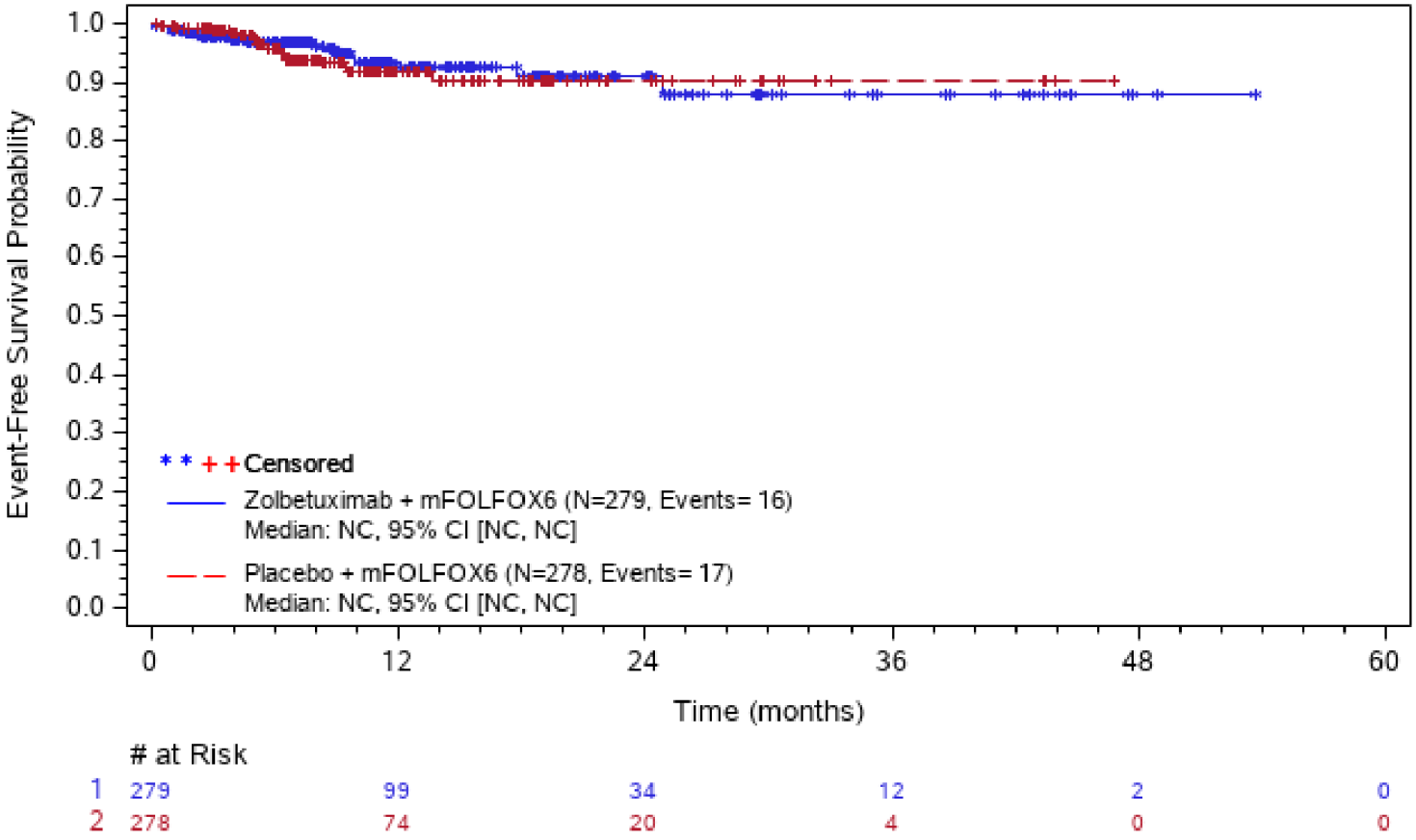


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.171: Kaplan-Meier Plot of Time to first TESAE - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) (SOC) - Safety Analysis Set

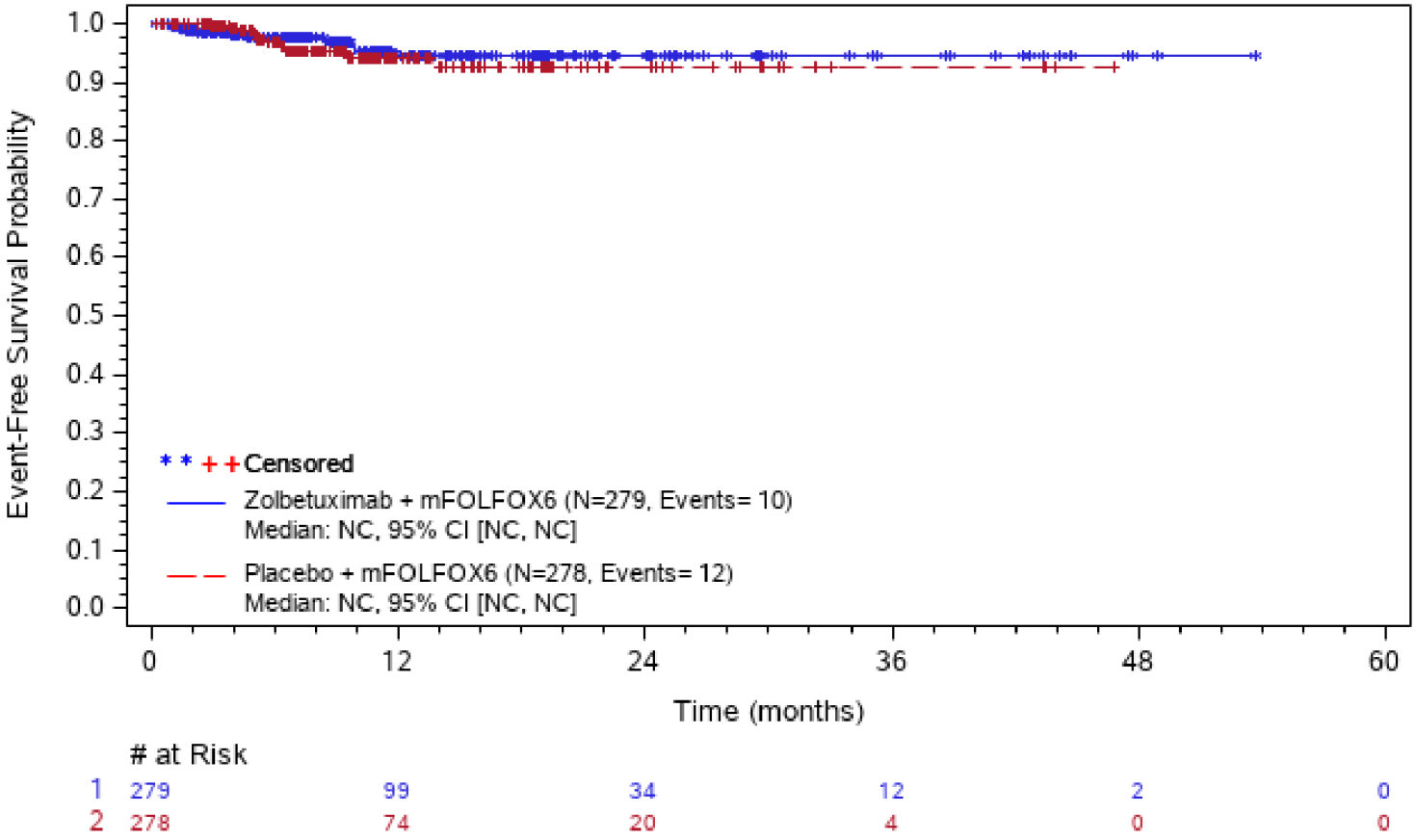


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.172: Kaplan-Meier Plot of Time to first TESAE - Malignant Neoplasm Progression (PT) - Safety Analysis Set

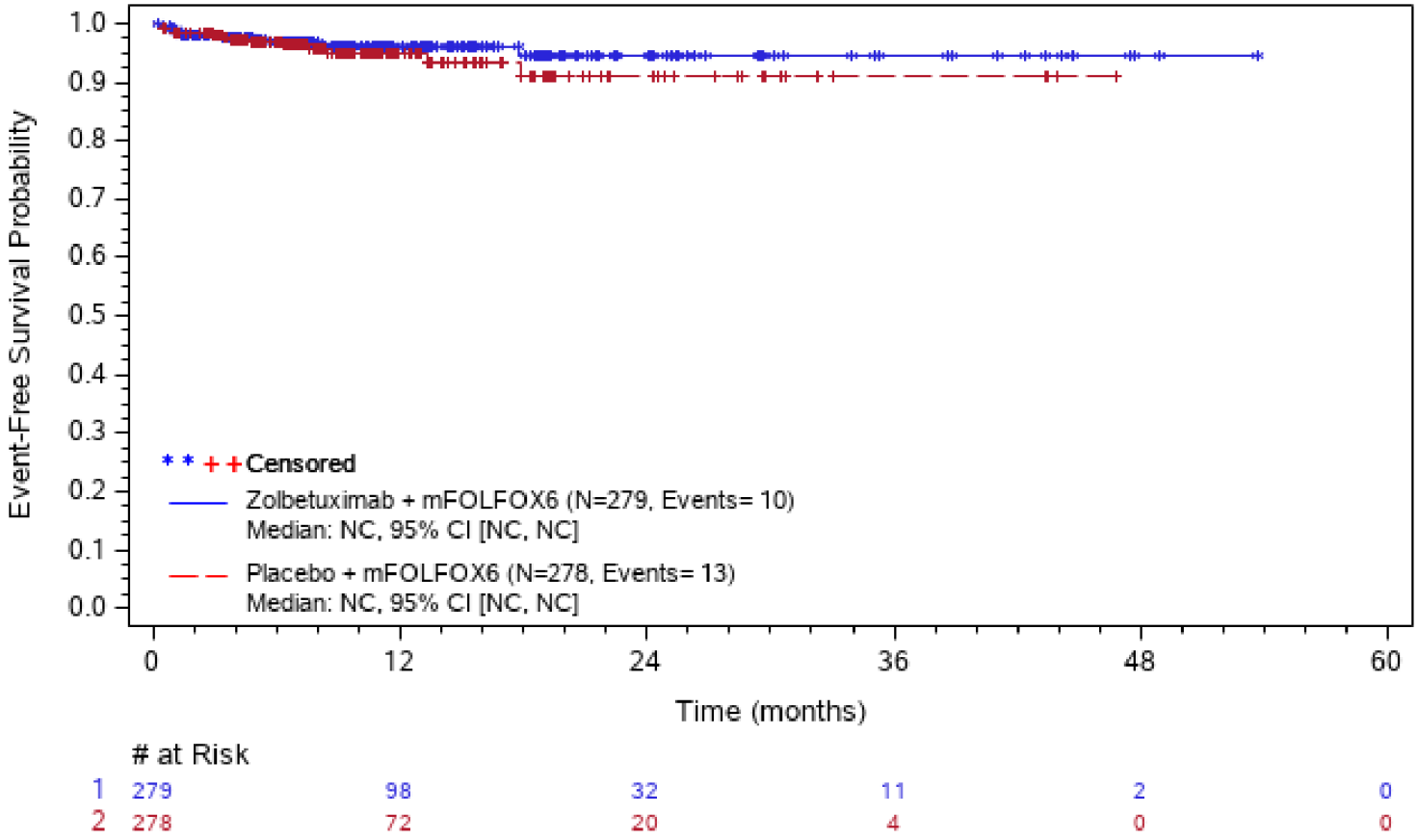


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.173: Kaplan-Meier Plot of Time to first TESAE - Nervous System Disorders (SOC) - Safety Analysis Set

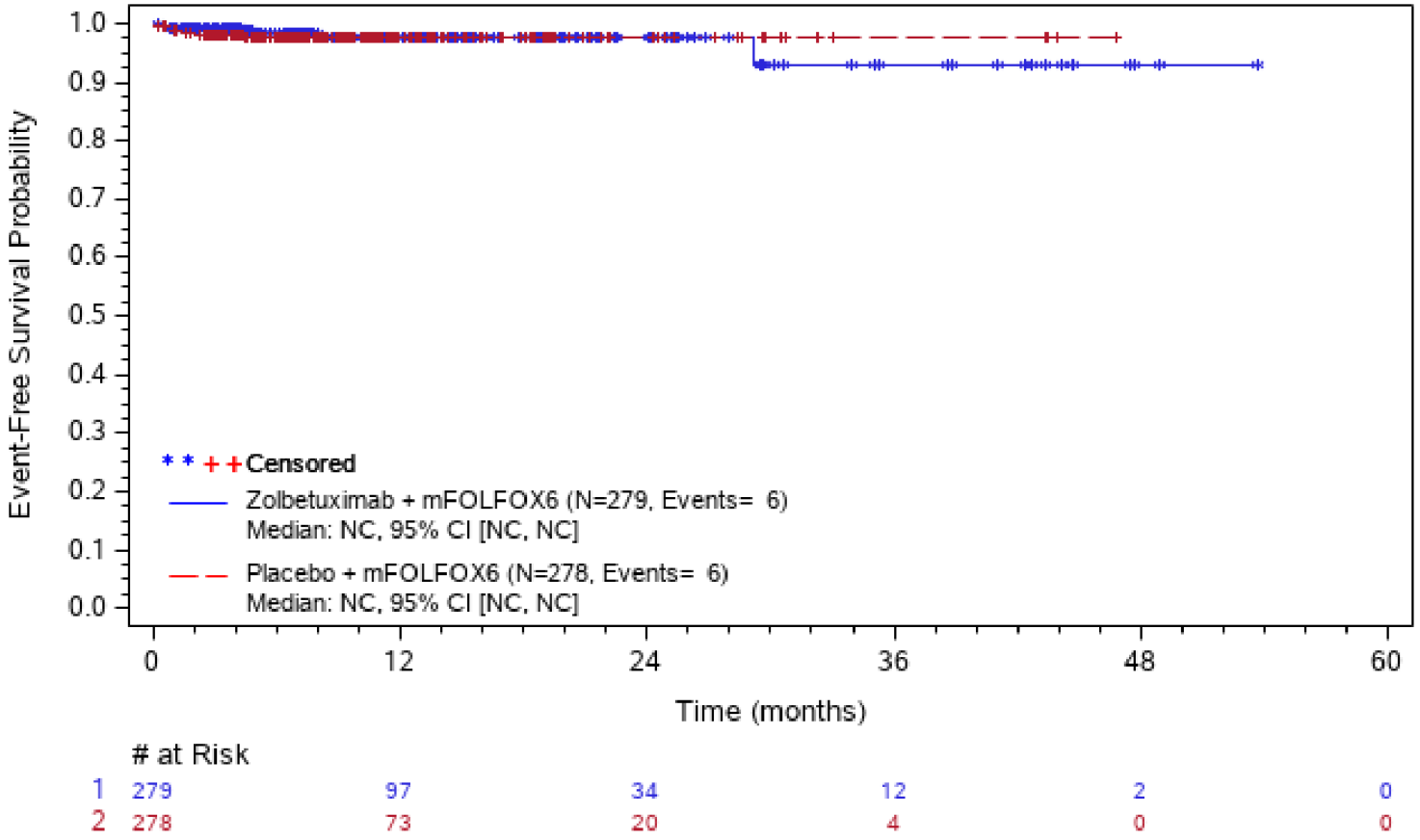


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.174: Kaplan-Meier Plot of Time to first TESAE - Renal And Urinary Disorders (SOC) - Safety Analysis Set

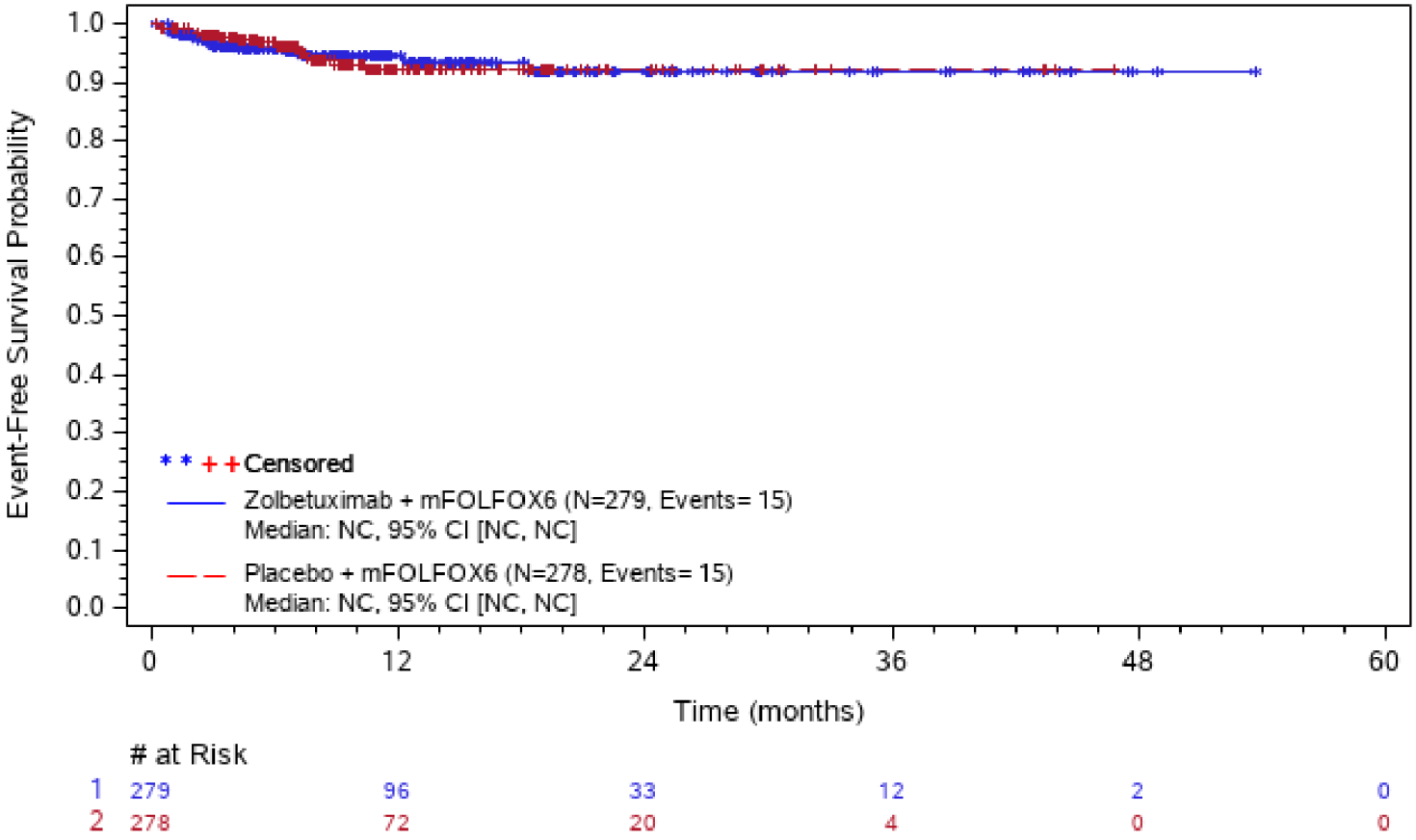


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.175: Kaplan-Meier Plot of Time to first TESAE - Respiratory, Thoracic And Mediastinal Disorderss (SOC) - Safety Analysis Set

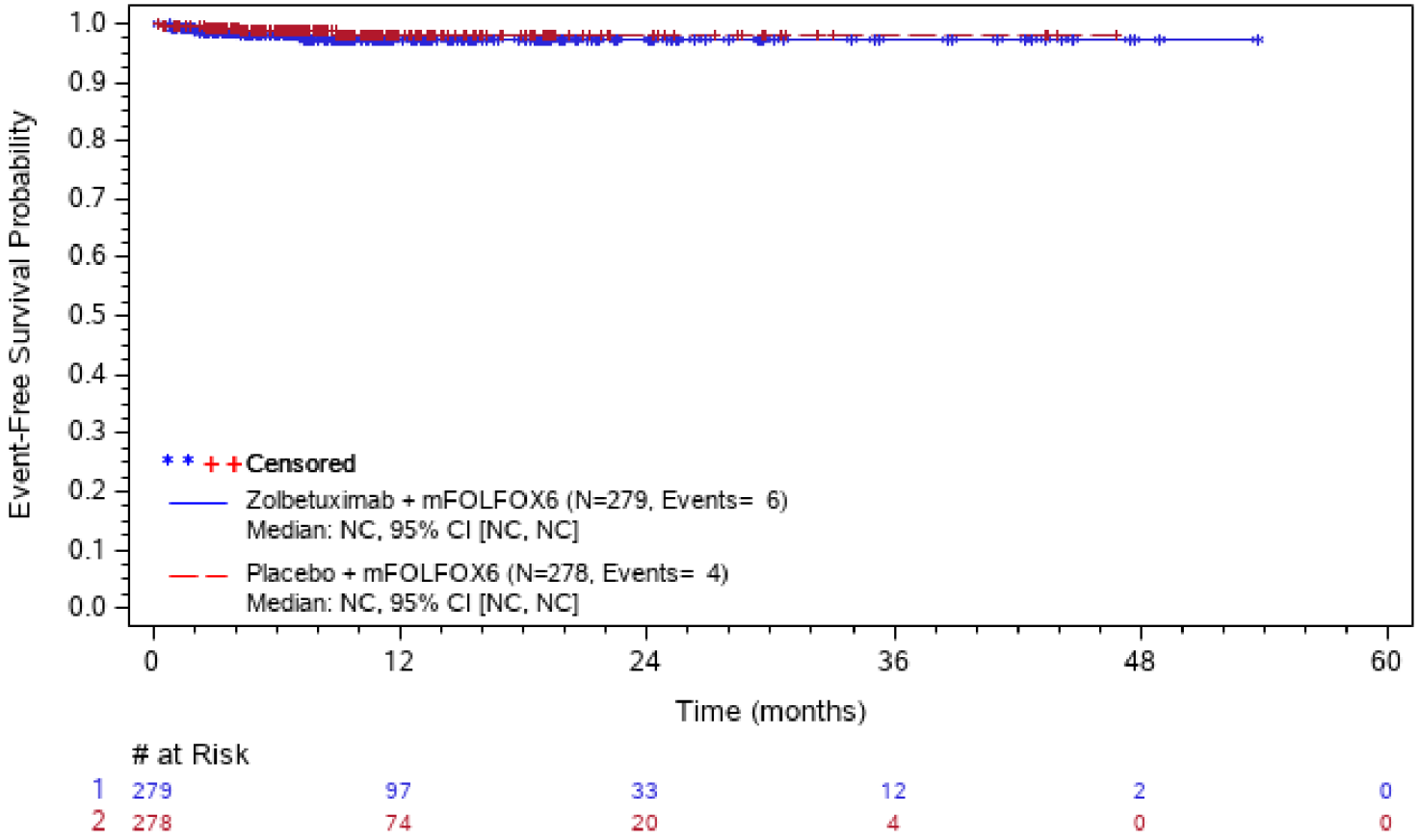


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.176: Kaplan-Meier Plot of Time to first TESAE - Pulmonary Embolism (PT) - Safety Analysis Set

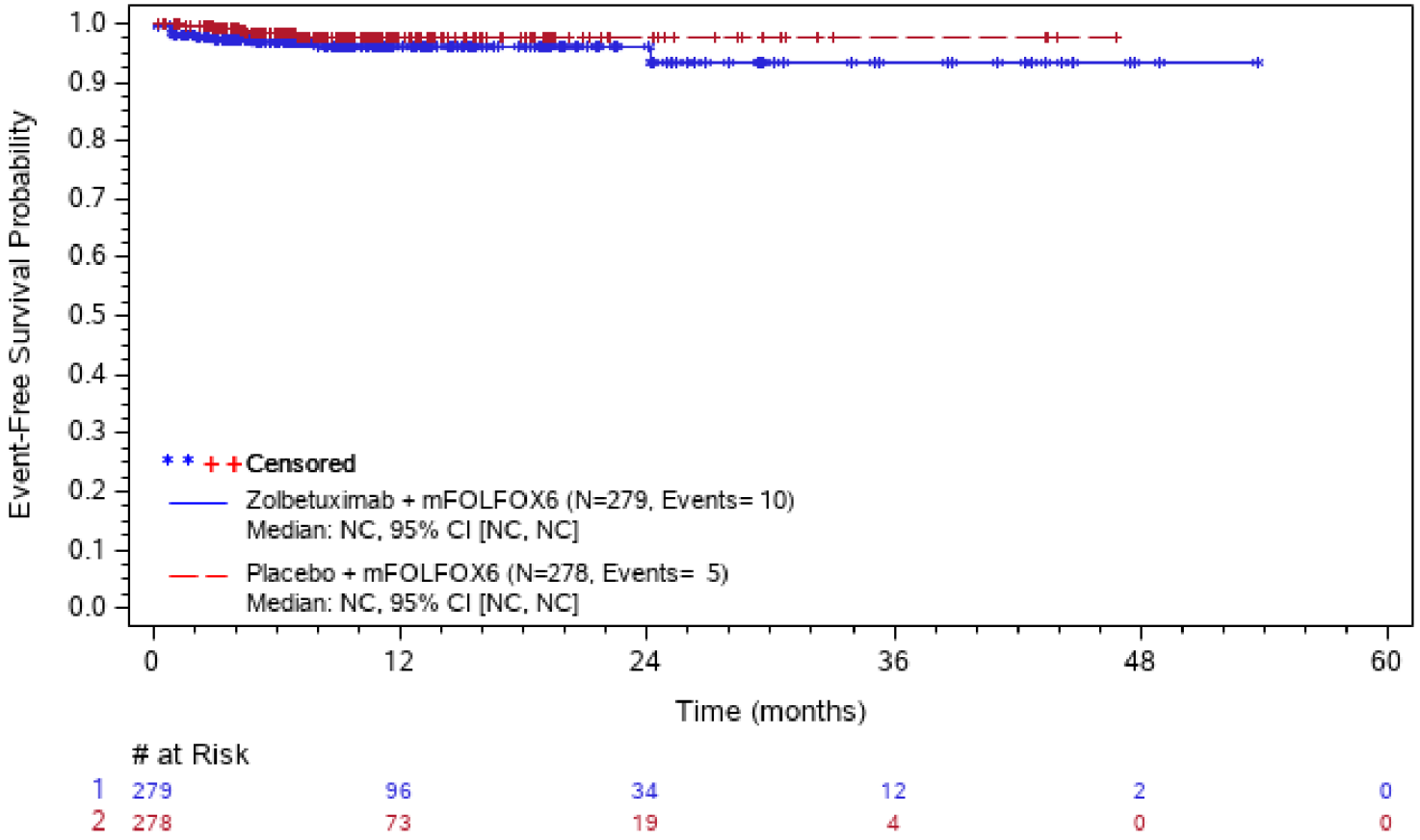


Abbreviations: # at Risk=number of patients at risk; CI=confidence interval; N=number of patients; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.177: Kaplan-Meier Plot of Time to first TESAE - 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Abbruchgründe – SOC und PT

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Overall	125 (44.8%)	107 (38.5%)	232 (41.7%)
Nervous System Disorders	33 (11.8%)	35 (12.6%)	68 (12.2%)
Peripheral Sensory Neuropathy	19 (6.8%)	21 (7.6%)	40 (7.2%)
Neuropathy Peripheral	4 (1.4%)	4 (1.4%)	8 (1.4%)
Paraesthesia	3 (1.1%)	5 (1.8%)	8 (1.4%)
Neurotoxicity	2 (0.7%)	0	2 (0.4%)
Peripheral Motor Neuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Polyneuropathy	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cerebral Haemorrhage	0	1 (0.4%)	1 (0.2%)
Cerebral Ischaemia	1 (0.4%)	0	1 (0.2%)
Cerebrovascular Accident	0	1 (0.4%)	1 (0.2%)
Intracranial Pressure Increased	1 (0.4%)	0	1 (0.2%)
Seizure	0	1 (0.4%)	1 (0.2%)
Slow Speech	0	1 (0.4%)	1 (0.2%)
Wernicke's Encephalopathy	1 (0.4%)	0	1 (0.2%)
Gastrointestinal Disorders	36 (12.9%)	12 (4.3%)	48 (8.6%)
Nausea	18 (6.5%)	3 (1.1%)	21 (3.8%)
Vomiting	20 (7.2%)	1 (0.4%)	21 (3.8%)
Abdominal Pain	2 (0.7%)	1 (0.4%)	3 (0.5%)
Dysphagia	1 (0.4%)	2 (0.7%)	3 (0.5%)
Diarrhoea	2 (0.7%)	0	2 (0.4%)
Intestinal Obstruction	2 (0.7%)	0	2 (0.4%)
Stomatitis	2 (0.7%)	0	2 (0.4%)
Upper Gastrointestinal Haemorrhage	1 (0.4%)	1 (0.4%)	2 (0.4%)
Ascites	0	1 (0.4%)	1 (0.2%)
Constipation	1 (0.4%)	0	1 (0.2%)

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: 08SEP23

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Enteritis	0	1 (0.4%)	1 (0.2%)
Gastrointestinal Obstruction	0	1 (0.4%)	1 (0.2%)
Haematemesis	0	1 (0.4%)	1 (0.2%)
Lip Ulceration	0	1 (0.4%)	1 (0.2%)
Retching	1 (0.4%)	0	1 (0.2%)
Salivary Hypersecretion	1 (0.4%)	0	1 (0.2%)
Small Intestinal Obstruction	1 (0.4%)	0	1 (0.2%)
Investigations	26 (9.3%)	21 (7.6%)	47 (8.4%)
Neutrophil Count Decreased	18 (6.5%)	14 (5.0%)	32 (5.7%)
Platelet Count Decreased	1 (0.4%)	2 (0.7%)	3 (0.5%)
Alanine Aminotransferase Increased	0	2 (0.7%)	2 (0.4%)
Aspartate Aminotransferase Increased	0	2 (0.7%)	2 (0.4%)
Weight Decreased	2 (0.7%)	0	2 (0.4%)
White Blood Cell Count Decreased	1 (0.4%)	1 (0.4%)	2 (0.4%)
Blood Bilirubin Increased	0	1 (0.4%)	1 (0.2%)
Blood Pressure Increased	1 (0.4%)	0	1 (0.2%)
Ejection Fraction Decreased	0	1 (0.4%)	1 (0.2%)
Gamma-Glutamyltransferase Increased	1 (0.4%)	0	1 (0.2%)
General Physical Condition Abnormal	1 (0.4%)	0	1 (0.2%)
Platelet Count Increased	1 (0.4%)	0	1 (0.2%)
Blood And Lymphatic System Disorders	19 (6.8%)	18 (6.5%)	37 (6.6%)
Neutropenia	15 (5.4%)	13 (4.7%)	28 (5.0%)
Anaemia	4 (1.4%)	3 (1.1%)	7 (1.3%)
Thrombocytopenia	1 (0.4%)	3 (1.1%)	4 (0.7%)
Disseminated Intravascular Coagulation	1 (0.4%)	0	1 (0.2%)
Eosinophilia	1 (0.4%)	0	1 (0.2%)

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: 08SEP23

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Febrile Neutropenia	0	1 (0.4%)	1 (0.2%)
Leukocytosis	1 (0.4%)	0	1 (0.2%)
Leukopenia	1 (0.4%)	0	1 (0.2%)
Lymphopenia	1 (0.4%)	0	1 (0.2%)
Neutrophilia	1 (0.4%)	0	1 (0.2%)
Thrombocytosis	1 (0.4%)	0	1 (0.2%)
General Disorders And Administration Site Conditions	15 (5.4%)	9 (3.2%)	24 (4.3%)
Fatigue	6 (2.2%)	3 (1.1%)	9 (1.6%)
Asthenia	2 (0.7%)	2 (0.7%)	4 (0.7%)
Chest Discomfort	1 (0.4%)	1 (0.4%)	2 (0.4%)
Malaise	2 (0.7%)	0	2 (0.4%)
Performance Status Decreased	2 (0.7%)	0	2 (0.4%)
Pyrexia	2 (0.7%)	0	2 (0.4%)
Chills	1 (0.4%)	0	1 (0.2%)
Discomfort	0	1 (0.4%)	1 (0.2%)
Gait Disturbance	0	1 (0.4%)	1 (0.2%)
General Physical Health Deterioration	0	1 (0.4%)	1 (0.2%)
Oedema Peripheral	1 (0.4%)	0	1 (0.2%)
Sudden Death	0	1 (0.4%)	1 (0.2%)
Metabolism And Nutrition Disorders	11 (3.9%)	6 (2.2%)	17 (3.1%)
Decreased Appetite	7 (2.5%)	3 (1.1%)	10 (1.8%)
Hypokalaemia	2 (0.7%)	0	2 (0.4%)
Hyponatraemia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abnormal Loss Of Weight	0	1 (0.4%)	1 (0.2%)
Adult Failure To Thrive	1 (0.4%)	0	1 (0.2%)
Hyperchloraemia	1 (0.4%)	0	1 (0.2%)

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: 08SEP23

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Hyperkalaemia	1 (0.4%)	0	1 (0.2%)
Hypoalbuminaemia	1 (0.4%)	0	1 (0.2%)
Hypophosphataemia	0	1 (0.4%)	1 (0.2%)
Hypoproteinaemia	1 (0.4%)	0	1 (0.2%)
Infections And Infestations	9 (3.2%)	4 (1.4%)	13 (2.3%)
Pneumonia	4 (1.4%)	0	4 (0.7%)
Covid-19 Pneumonia	1 (0.4%)	1 (0.4%)	2 (0.4%)
Abdominal Sepsis	1 (0.4%)	0	1 (0.2%)
Abscess Soft Tissue	0	1 (0.4%)	1 (0.2%)
Covid-19	0	1 (0.4%)	1 (0.2%)
Device Related Infection	0	1 (0.4%)	1 (0.2%)
Neutropenic Sepsis	1 (0.4%)	0	1 (0.2%)
Oral Candidiasis	1 (0.4%)	0	1 (0.2%)
Pulmonary Sepsis	1 (0.4%)	0	1 (0.2%)
Sepsis	1 (0.4%)	0	1 (0.2%)
Septic Shock	1 (0.4%)	0	1 (0.2%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	6 (2.2%)	7 (2.5%)	13 (2.3%)
Malignant Neoplasm Progression	4 (1.4%)	4 (1.4%)	8 (1.4%)
Metastases To Meninges	2 (0.7%)	1 (0.4%)	3 (0.5%)
Malignant Pleural Effusion	0	1 (0.4%)	1 (0.2%)
Tumour Haemorrhage	0	1 (0.4%)	1 (0.2%)
Skin And Subcutaneous Tissue Disorders	4 (1.4%)	6 (2.2%)	10 (1.8%)
Palmar-Plantar Erythrodysaesthesia Syndrome	2 (0.7%)	1 (0.4%)	3 (0.5%)
Erythema	1 (0.4%)	1 (0.4%)	2 (0.4%)
Rash	1 (0.4%)	1 (0.4%)	2 (0.4%)
Dermatitis Exfoliative Generalised	0	1 (0.4%)	1 (0.2%)

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: 08SEP23

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Pruritus	0	1 (0.4%)	1 (0.2%)
Urticaria	0	1 (0.4%)	1 (0.2%)
Respiratory, Thoracic And Mediastinal Disorders	3 (1.1%)	5 (1.8%)	8 (1.4%)
Dyspnoea	0	3 (1.1%)	3 (0.5%)
Interstitial Lung Disease	1 (0.4%)	1 (0.4%)	2 (0.4%)
Acute Respiratory Distress Syndrome	0	1 (0.4%)	1 (0.2%)
Acute Respiratory Failure	1 (0.4%)	0	1 (0.2%)
Cough	1 (0.4%)	0	1 (0.2%)
Injury, Poisoning And Procedural Complications	4 (1.4%)	2 (0.7%)	6 (1.1%)
Infusion Related Reaction	2 (0.7%)	2 (0.7%)	4 (0.7%)
Fall	1 (0.4%)	0	1 (0.2%)
Fat Embolism	1 (0.4%)	0	1 (0.2%)
Cardiac Disorders	2 (0.7%)	3 (1.1%)	5 (0.9%)
Acute Myocardial Infarction	2 (0.7%)	1 (0.4%)	3 (0.5%)
Cardiac Arrest	0	1 (0.4%)	1 (0.2%)
Cardiac Failure	0	1 (0.4%)	1 (0.2%)
Immune System Disorders	2 (0.7%)	3 (1.1%)	5 (0.9%)
Drug Hypersensitivity	1 (0.4%)	2 (0.7%)	3 (0.5%)
Hypersensitivity	1 (0.4%)	1 (0.4%)	2 (0.4%)
Vascular Disorders	3 (1.1%)	2 (0.7%)	5 (0.9%)
Flushing	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypertension	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hypotension	1 (0.4%)	0	1 (0.2%)
Hepatobiliary Disorders	1 (0.4%)	3 (1.1%)	4 (0.7%)
Bile Duct Stenosis	0	1 (0.4%)	1 (0.2%)
Hepatic Cytolysis	1 (0.4%)	0	1 (0.2%)

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: 08SEP23

Table 301.3.2000.5: Frequency Summary of (Permanent) Treatment Discontinuation due to Treatment Emergent Adverse Event - Safety Analysis Set

MedDRA SOC and PT	Zolbetuximab + mFOLFOX6 (N=279)	Placebo + mFOLFOX6 (N=278)	Total (N=557)
Hepatic Function Abnormal	0	1 (0.4%)	1 (0.2%)
Jaundice Cholestatic	0	1 (0.4%)	1 (0.2%)
Musculoskeletal And Connective Tissue Disorders	3 (1.1%)	0	3 (0.5%)
Arthralgia	1 (0.4%)	0	1 (0.2%)
Musculoskeletal Chest Pain	1 (0.4%)	0	1 (0.2%)
Pain In Extremity	1 (0.4%)	0	1 (0.2%)
Renal And Urinary Disorders	2 (0.7%)	0	2 (0.4%)
Renal Failure	1 (0.4%)	0	1 (0.2%)
Urge Incontinence	1 (0.4%)	0	1 (0.2%)
Congenital, Familial And Genetic Disorders	0	1 (0.4%)	1 (0.2%)
Dihydropyrimidine Dehydrogenase Deficiency	0	1 (0.4%)	1 (0.2%)
Psychiatric Disorders	0	1 (0.4%)	1 (0.2%)
Suicidal Ideation	0	1 (0.4%)	1 (0.2%)

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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse von besonderem Interesse

1. Time-to-Event-Analysen

Table 301.3.2001.217.1: Summary and Results of TEAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	99 (35.5%)	111 (39.9%)	
Number of patients censored	180 (64.5%)	167 (60.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [22.4, NC]	14.0 [10.7, 18.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.948 [0.721, 1.245]
Log-rank test			
Two-sided stratified log-rank p-value			0.6700

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.217.2: Summary and Results of TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	71 (39.9)	22.4 [10.8, NC]	177	74 (41.8)	13.6 [8.3, 17.4]	1.008 [0.727, 1.397]	0.9933	0.3385
>65 years	101	28 (27.7)	NC [NC, NC]	101	37 (36.6)	19.8 [7.0, NC]	0.789 [0.483, 1.290]	0.3375	
Sex									
Male	174	57 (32.8)	NC [NC, NC]	173	69 (39.9)	16.4 [10.7, 19.8]	0.844 [0.594, 1.200]	0.3325	0.3955
Female	105	42 (40.0)	22.4 [7.6, NC]	105	42 (40.0)	13.6 [7.6, NC]	1.081 [0.705, 1.660]	0.7518	
Region									
Asia	87	27 (31.0)	NC [13.2, NC]	88	29 (33.0)	14.5 [7.5, NC]	0.848 [0.500, 1.440]	0.5334	0.7025
Non-Asia	192	72 (37.5)	28.8 [22.4, NC]	190	82 (43.2)	13.6 [7.8, 18.5]	0.968 [0.705, 1.329]	0.8094	
Number of Organs with Metastatic Sites									
0-2	216	79 (36.6)	28.8 [22.4, NC]	216	86 (39.8)	14.5 [10.7, 19.8]	0.978 [0.720, 1.328]	0.8531	0.4521
>=3	63	20 (31.7)	NC [8.3, NC]	62	25 (40.3)	10.9 [6.5, NC]	0.759 [0.421, 1.371]	0.3509	

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.
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: 08SEP23

Table 301.3.2001.218.1: Summary and Results of TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	108 (38.7%)	107 (38.5%)	
Number of patients censored	171 (61.3%)	171 (61.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	26.2 [12.6, NC]	27.4 [11.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.971 [0.741, 1.272]
Log-rank test			
Two-sided stratified log-rank p-value			0.8388

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.218.2: Summary and Results of TEAEs by Subgroups - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	68 (38.2)	26.2 [9.3, NC]	177	73 (41.2)	14.6 [8.2, 27.4]	0.854 [0.613, 1.190]	0.3529	0.2806
>65 years	101	40 (39.6)	34.3 [10.4, NC]	101	34 (33.7)	NC [12.5, NC]	1.154 [0.729, 1.828]	0.5387	
Sex									
Male	174	57 (32.8)	34.3 [14.9, NC]	173	60 (34.7)	27.4 [14.6, NC]	0.872 [0.606, 1.256]	0.4621	0.5037
Female	105	51 (48.6)	9.3 [3.9, NC]	105	47 (44.8)	8.7 [5.3, NC]	1.056 [0.709, 1.573]	0.7807	
Region									
Asia	87	35 (40.2)	34.3 [9.2, NC]	88	30 (34.1)	27.4 [8.5, 27.4]	0.996 [0.608, 1.631]	0.9877	0.7890
Non-Asia	192	73 (38.0)	26.2 [10.4, NC]	190	77 (40.5)	18.1 [8.7, NC]	0.932 [0.676, 1.284]	0.6737	
Number of Organs with Metastatic Sites									
0-2	216	76 (35.2)	34.3 [13.3, NC]	216	80 (37.0)	27.4 [14.6, NC]	0.870 [0.635, 1.193]	0.3936	0.2031
>=3	63	32 (50.8)	8.3 [3.4, 26.2]	62	27 (43.5)	12.5 [6.2, NC]	1.278 [0.765, 2.135]	0.3483	

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.
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: 08SEP23

Table 301.3.2001.219.1: Summary and Results of TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	61 (21.9%)	72 (25.9%)	
Number of patients censored	218 (78.1%)	206 (74.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	36.3 [36.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.758 [0.537, 1.068]
Log-rank test			
Two-sided stratified log-rank p-value			0.1118

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.219.2: Summary and Results of TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	38 (21.3)	NC [NC, NC]	177	47 (26.6)	36.3 [17.5, NC]	0.747 [0.486, 1.147]	0.1810	0.8015
>65 years	101	23 (22.8)	NC [NC, NC]	101	25 (24.8)	NC [17.6, NC]	0.827 [0.469, 1.460]	0.5166	
Sex									
Male	174	34 (19.5)	NC [NC, NC]	173	48 (27.7)	36.3 [17.5, 36.3]	0.607 [0.390, 0.945]	0.0258	0.1109
Female	105	27 (25.7)	NC [NC, NC]	105	24 (22.9)	NC [17.6, NC]	1.121 [0.646, 1.945]	0.6845	
Region									
Asia	87	27 (31.0)	NC [14.3, NC]	88	30 (34.1)	36.3 [17.6, NC]	0.716 [0.424, 1.208]	0.2099	0.9107
Non-Asia	192	34 (17.7)	NC [NC, NC]	190	42 (22.1)	NC [NC, NC]	0.783 [0.497, 1.231]	0.2866	
Number of Organs with Metastatic Sites									
0-2	216	43 (19.9)	NC [NC, NC]	216	58 (26.9)	36.3 [36.3, NC]	0.656 [0.441, 0.975]	0.0358	0.1093
>=3	63	18 (28.6)	NC [16.6, NC]	62	14 (22.6)	NC [10.7, NC]	1.263 [0.626, 2.548]	0.5163	

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.
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: 08SEP23

Table 301.3.2001.220.1: Summary and Results of TEAEs - Infusion Related Reaction (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	125 (44.8%)	33 (11.9%)	
Number of patients censored	154 (55.2%)	245 (88.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [5.3, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			5.039 [3.427, 7.409]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.220.2: Summary and Results of TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	72 (40.4)	NC [9.5, NC]	177	26 (14.7)	NC [NC, NC]	3.421 [2.183, 5.362]	<.0001	0.0187
>65 years	101	53 (52.5)	4.7 [1.6, NC]	101	7 (6.9)	NC [NC, NC]	10.468 [4.751, 23.062]	<.0001	
Sex									
Male	174	76 (43.7)	NC [4.7, NC]	173	21 (12.1)	NC [NC, NC]	4.630 [2.853, 7.514]	<.0001	0.7202
Female	105	49 (46.7)	13.5 [2.1, NC]	105	12 (11.4)	NC [NC, NC]	5.293 [2.812, 9.964]	<.0001	
Region									
Asia	87	30 (34.5)	NC [NC, NC]	88	14 (15.9)	NC [NC, NC]	2.527 [1.339, 4.768]	0.0036	0.0147
Non-Asia	192	95 (49.5)	6.4 [2.2, NC]	190	19 (10.0)	NC [NC, NC]	6.818 [4.160, 11.175]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	93 (43.1)	NC [5.6, NC]	216	29 (13.4)	NC [NC, NC]	4.042 [2.662, 6.137]	<.0001	0.0851
>=3	63	32 (50.8)	5.5 [1.4, NC]	62	4 (6.5)	NC [NC, NC]	11.196 [3.949, 31.744]	<.0001	

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.
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: 08SEP23

Table 301.3.2001.221.1: Summary and Results of TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	230 (82.4%)	171 (61.5%)	
Number of patients censored	49 (17.6%)	107 (38.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.0 [0.0, 0.1]	2.0 [0.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.149 [1.755, 2.630]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.221.2: Summary and Results of TEAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	146 (82.0)	0.0 [0.0, 0.1]	177	119 (67.2)	1.0 [0.6, 2.2]	1.913 [1.499, 2.441]	<.0001	0.0868
>65 years	101	84 (83.2)	0.1 [0.0, 0.4]	101	52 (51.5)	3.5 [1.5, NC]	2.762 [1.947, 3.918]	<.0001	
Sex									
Male	174	137 (78.7)	0.1 [0.0, 0.4]	173	107 (61.8)	2.0 [0.8, 3.3]	1.869 [1.449, 2.410]	<.0001	0.1032
Female	105	93 (88.6)	0.0 [0.0, 0.1]	105	64 (61.0)	2.1 [0.7, 5.0]	2.860 [2.069, 3.952]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.1]	88	60 (68.2)	1.1 [0.5, 2.4]	2.029 [1.442, 2.857]	<.0001	0.5163
Non-Asia	192	155 (80.7)	0.0 [0.0, 0.1]	190	111 (58.4)	2.4 [0.9, 4.8]	2.253 [1.762, 2.880]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	182 (84.3)	0.0 [0.0, 0.1]	216	134 (62.0)	1.6 [0.9, 3.3]	2.285 [1.824, 2.861]	<.0001	0.4459
>=3	63	48 (76.2)	0.1 [0.0, 0.7]	62	37 (59.7)	2.2 [0.5, NC]	1.827 [1.187, 2.812]	0.0119	

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.
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: 08SEP23

Table 301.3.2001.222.1: Summary and Results of TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	187 (67.0%)	179 (64.4%)	
Number of patients censored	92 (33.0%)	99 (35.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	2.0 [1.6, 2.2]	2.3 [1.9, 3.0]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.106 [0.900, 1.360]
Log-rank test			
Two-sided stratified log-rank p-value			0.3150

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.222.2: Summary and Results of TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	120 (67.4)	2.1 [1.6, 2.2]	177	113 (63.8)	2.3 [1.5, 3.4]	1.150 [0.889, 1.487]	0.2751	0.8145
>65 years	101	67 (66.3)	1.8 [1.1, 3.5]	101	66 (65.3)	2.1 [1.4, 3.3]	1.083 [0.771, 1.522]	0.6195	
Sex									
Male	174	107 (61.5)	2.1 [2.0, 3.5]	173	101 (58.4)	3.1 [2.1, 5.1]	1.162 [0.885, 1.526]	0.2621	0.6703
Female	105	80 (76.2)	1.4 [0.8, 2.0]	105	78 (74.3)	1.2 [0.7, 2.1]	1.062 [0.777, 1.451]	0.6798	
Region									
Asia	87	68 (78.2)	1.3 [0.7, 2.0]	88	59 (67.0)	1.9 [0.7, 2.5]	1.237 [0.873, 1.754]	0.2073	0.4951
Non-Asia	192	119 (62.0)	2.1 [1.9, 2.3]	190	120 (63.2)	2.6 [2.0, 3.5]	1.073 [0.832, 1.383]	0.5722	
Number of Organs with Metastatic Sites									
0-2	216	143 (66.2)	2.0 [1.7, 2.3]	216	147 (68.1)	2.1 [1.4, 2.6]	0.991 [0.787, 1.247]	0.9635	0.0250
>=3	63	44 (69.8)	1.4 [0.7, 2.6]	62	32 (51.6)	4.0 [1.9, NC]	1.758 [1.113, 2.777]	0.0127	

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.
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: 08SEP23

Table 301.3.2001.223.1: Summary and Results of TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	188 (67.4%)	103 (37.1%)	
Number of patients censored	91 (32.6%)	175 (62.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.7 [0.3, 1.4]	NC [16.0, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.834 [2.219, 3.620]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.223.2: Summary and Results of TEAEs by Subgroups - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	127 (71.3)	0.5 [0.0, 0.9]	177	75 (42.4)	16.6 [7.9, NC]	2.599 [1.951, 3.464]	<.0001	0.4726
>65 years	101	61 (60.4)	1.6 [0.7, 5.9]	101	28 (27.7)	NC [NC, NC]	3.081 [1.967, 4.826]	<.0001	
Sex									
Male	174	111 (63.8)	0.9 [0.5, 2.9]	173	58 (33.5)	NC [16.6, NC]	2.779 [2.020, 3.823]	<.0001	0.7776
Female	105	77 (73.3)	0.2 [0.0, 1.1]	105	45 (42.9)	NC [4.8, NC]	2.672 [1.847, 3.867]	<.0001	
Region									
Asia	87	54 (62.1)	1.2 [0.1, 12.2]	88	29 (33.0)	16.6 [13.2, NC]	2.430 [1.541, 3.834]	0.0002	0.7541
Non-Asia	192	134 (69.8)	0.5 [0.1, 1.2]	190	74 (38.9)	NC [25.9, NC]	2.844 [2.138, 3.785]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	148 (68.5)	0.7 [0.1, 1.1]	216	78 (36.1)	25.9 [16.0, NC]	2.895 [2.197, 3.814]	<.0001	0.3146
>=3	63	40 (63.5)	1.4 [0.2, 5.1]	62	25 (40.3)	NC [3.1, NC]	2.157 [1.307, 3.560]	0.0031	

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.
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: 08SEP23

Table 301.3.2001.224.1: Summary and Results of Non-Severe TEAEs - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	96 (34.4%)	111 (39.9%)	
Number of patients censored	183 (65.6%)	167 (60.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [22.4, NC]	14.0 [10.7, 18.5]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.905 [0.687, 1.191]
Log-rank test			
Two-sided stratified log-rank p-value			0.4579

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.224.2: Summary and Results of Non-Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	69 (38.8)	22.4 [10.8, NC]	177	74 (41.8)	13.6 [8.3, 17.4]	0.966 [0.696, 1.343]	0.8166	0.3368
>65 years	101	27 (26.7)	NC [NC, NC]	101	37 (36.6)	19.8 [7.0, NC]	0.754 [0.459, 1.239]	0.2587	
Sex									
Male	174	54 (31.0)	NC [NC, NC]	173	69 (39.9)	16.4 [10.7, 19.8]	0.787 [0.551, 1.125]	0.1820	0.2861
Female	105	42 (40.0)	22.4 [8.0, NC]	105	42 (40.0)	13.6 [7.6, NC]	1.074 [0.699, 1.648]	0.7683	
Region									
Asia	87	27 (31.0)	NC [13.2, NC]	88	29 (33.0)	14.5 [7.5, NC]	0.850 [0.500, 1.443]	0.5378	0.8506
Non-Asia	192	69 (35.9)	28.8 [22.4, NC]	190	82 (43.2)	13.6 [7.8, 18.5]	0.910 [0.660, 1.253]	0.5442	
Number of Organs with Metastatic Sites									
0-2	216	76 (35.2)	NC [22.4, NC]	216	86 (39.8)	14.5 [10.7, 19.8]	0.926 [0.680, 1.262]	0.6062	0.5509
>=3	63	20 (31.7)	NC [8.3, NC]	62	25 (40.3)	10.9 [6.5, NC]	0.759 [0.421, 1.371]	0.3509	

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.
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: 08SEP23

Table 301.3.2001.225.1: Summary and Results of Non-Severe TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	102 (36.6%)	101 (36.3%)	
Number of patients censored	177 (63.4%)	177 (63.7%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	34.3 [13.1, NC]	27.4 [14.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.968 [0.732, 1.278]
Log-rank test			
Two-sided stratified log-rank p-value			0.8263

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.225.2: Summary and Results of Non-Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	63 (35.4)	NC [9.8, NC]	177	69 (39.0)	27.4 [8.7, 27.4]	0.839 [0.596, 1.183]	0.3197	0.2229
>65 years	101	39 (38.6)	34.3 [10.4, NC]	101	32 (31.7)	NC [18.1, NC]	1.190 [0.743, 1.905]	0.4653	
Sex									
Male	174	55 (31.6)	34.3 [14.9, NC]	173	57 (32.9)	27.4 [14.6, NC]	0.884 [0.609, 1.283]	0.5171	0.5768
Female	105	47 (44.8)	9.8 [4.6, NC]	105	44 (41.9)	18.1 [7.0, NC]	1.044 [0.691, 1.579]	0.8272	
Region									
Asia	87	33 (37.9)	34.3 [9.3, NC]	88	28 (31.8)	27.4 [11.8, 27.4]	0.993 [0.596, 1.654]	0.9806	0.7921
Non-Asia	192	69 (35.9)	26.2 [12.6, NC]	190	73 (38.4)	NC [10.3, NC]	0.934 [0.672, 1.299]	0.6910	
Number of Organs with Metastatic Sites									
0-2	216	72 (33.3)	NC [14.9, NC]	216	77 (35.6)	27.4 [14.6, NC]	0.862 [0.624, 1.191]	0.3739	0.1674
>=3	63	30 (47.6)	8.3 [4.4, 26.2]	62	24 (38.7)	12.5 [8.2, NC]	1.328 [0.775, 2.275]	0.2999	

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.
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: 08SEP23

Table 301.3.2001.226.1: Summary and Results of Non-Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	56 (20.1%)	70 (25.2%)	
Number of patients censored	223 (79.9%)	208 (74.8%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	36.3 [36.3, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.711 [0.499, 1.013]
Log-rank test			
Two-sided stratified log-rank p-value			0.0577

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.226.2: Summary and Results of Non-Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	35 (19.7)	NC [NC, NC]	177	46 (26.0)	36.3 [17.5, NC]	0.696 [0.448, 1.082]	0.1058	0.7806
>65 years	101	21 (20.8)	NC [NC, NC]	101	24 (23.8)	NC [17.6, NC]	0.781 [0.434, 1.406]	0.4112	
Sex									
Male	174	31 (17.8)	NC [NC, NC]	173	47 (27.2)	36.3 [17.5, 36.3]	0.560 [0.355, 0.885]	0.0119	0.1049
Female	105	25 (23.8)	NC [NC, NC]	105	23 (21.9)	NC [NC, NC]	1.070 [0.606, 1.888]	0.8150	
Region									
Asia	87	26 (29.9)	NC [14.3, NC]	88	29 (33.0)	36.3 [17.6, NC]	0.708 [0.416, 1.207]	0.2044	0.8554
Non-Asia	192	30 (15.6)	NC [NC, NC]	190	41 (21.6)	NC [NC, NC]	0.699 [0.436, 1.121]	0.1341	
Number of Organs with Metastatic Sites									
0-2	216	39 (18.1)	NC [NC, NC]	216	57 (26.4)	36.3 [36.3, NC]	0.598 [0.397, 0.901]	0.0130	0.0703
>=3	63	17 (27.0)	NC [16.6, NC]	62	13 (21.0)	NC [10.7, NC]	1.282 [0.621, 2.650]	0.5039	

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.
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: 08SEP23

Table 301.3.2001.227.1: Summary and Results of Non-Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	116 (41.6%)	32 (11.5%)	
Number of patients censored	163 (58.4%)	246 (88.5%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [9.5, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			4.714 [3.182, 6.984]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.227.2: Summary and Results of Non-Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	65 (36.5)	NC [NC, NC]	177	26 (14.7)	NC [NC, NC]	3.012 [1.910, 4.750]	<.0001	0.0069
>65 years	101	51 (50.5)	6.4 [1.6, NC]	101	6 (5.9)	NC [NC, NC]	11.587 [4.965, 27.042]	<.0001	
Sex									
Male	174	70 (40.2)	NC [7.4, NC]	173	20 (11.6)	NC [NC, NC]	4.365 [2.653, 7.181]	<.0001	0.7588
Female	105	46 (43.8)	NC [2.3, NC]	105	12 (11.4)	NC [NC, NC]	4.912 [2.599, 9.283]	<.0001	
Region									
Asia	87	30 (34.5)	NC [NC, NC]	88	13 (14.8)	NC [NC, NC]	2.722 [1.419, 5.221]	0.0019	0.0549
Non-Asia	192	86 (44.8)	13.5 [4.7, NC]	190	19 (10.0)	NC [NC, NC]	5.992 [3.641, 9.862]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	86 (39.8)	NC [18.4, NC]	216	28 (13.0)	NC [NC, NC]	3.792 [2.474, 5.812]	<.0001	0.0937
>=3	63	30 (47.6)	7.4 [1.6, NC]	62	4 (6.5)	NC [NC, NC]	10.340 [3.632, 29.435]	<.0001	

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.
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: 08SEP23

Table 301.3.2001.228.1: Summary and Results of Non-Severe TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	219 (78.5%)	168 (60.4%)	
Number of patients censored	60 (21.5%)	110 (39.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	0.1 [0.0, 0.2]	2.1 [1.0, 3.3]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.962 [1.598, 2.408]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.228.2: Summary and Results of Non-Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	137 (77.0)	0.1 [0.0, 0.2]	177	117 (66.1)	1.1 [0.7, 2.4]	1.674 [1.306, 2.145]	0.0002	0.0369
>65 years	101	82 (81.2)	0.1 [0.0, 0.5]	101	51 (50.5)	5.0 [1.6, NC]	2.671 [1.876, 3.802]	<.0001	
Sex									
Male	174	134 (77.0)	0.2 [0.1, 0.5]	173	105 (60.7)	2.1 [1.0, 3.5]	1.790 [1.385, 2.314]	<.0001	0.3060
Female	105	85 (81.0)	0.0 [0.0, 0.1]	105	63 (60.0)	2.1 [0.7, 5.0]	2.325 [1.673, 3.232]	<.0001	
Region									
Asia	87	75 (86.2)	0.1 [0.0, 0.2]	88	59 (67.0)	1.5 [0.6, 2.5]	2.048 [1.453, 2.889]	<.0001	0.9819
Non-Asia	192	144 (75.0)	0.1 [0.0, 0.5]	190	109 (57.4)	2.5 [1.0, 7.4]	1.949 [1.518, 2.503]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	174 (80.6)	0.1 [0.0, 0.2]	216	131 (60.6)	2.1 [1.0, 3.5]	2.079 [1.654, 2.611]	<.0001	0.3866
>=3	63	45 (71.4)	0.2 [0.0, 0.7]	62	37 (59.7)	2.2 [0.6, NC]	1.629 [1.052, 2.521]	0.0468	

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.
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: 08SEP23

Table 301.3.2001.229.1: Summary and Results of Non-Severe TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	134 (48.0%)	136 (48.9%)	
Number of patients censored	145 (52.0%)	142 (51.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	5.7 [4.3, NC]	5.7 [3.7, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.953 [0.749, 1.212]
Log-rank test			
Two-sided stratified log-rank p-value			0.6944

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.229.2: Summary and Results of Non-Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	88 (49.4)	4.7 [3.4, NC]	177	90 (50.8)	5.5 [3.3, NC]	0.950 [0.708, 1.274]	0.7329	0.8675
>65 years	101	46 (45.5)	7.8 [4.4, NC]	101	46 (45.5)	6.6 [3.6, NC]	0.999 [0.664, 1.504]	0.9950	
Sex									
Male	174	82 (47.1)	5.4 [3.9, NC]	173	77 (44.5)	NC [5.1, NC]	1.094 [0.801, 1.493]	0.5684	0.2396
Female	105	52 (49.5)	5.7 [2.7, 36.1]	105	59 (56.2)	3.5 [2.3, 5.8]	0.794 [0.545, 1.155]	0.2324	
Region									
Asia	87	52 (59.8)	4.6 [2.3, 7.4]	88	48 (54.5)	4.6 [2.1, 9.7]	1.000 [0.674, 1.484]	0.9935	0.7709
Non-Asia	192	82 (42.7)	8.4 [4.4, NC]	190	88 (46.3)	6.3 [4.0, NC]	0.939 [0.695, 1.269]	0.6821	
Number of Organs with Metastatic Sites									
0-2	216	102 (47.2)	6.3 [4.3, NC]	216	111 (51.4)	5.1 [3.2, 9.7]	0.862 [0.658, 1.128]	0.2817	0.0847
>=3	63	32 (50.8)	4.6 [2.5, NC]	62	25 (40.3)	NC [4.0, NC]	1.479 [0.875, 2.500]	0.1397	

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.
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: 08SEP23

Table 301.3.2001.230.1: Summary and Results of Non-Severe TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	175 (62.7%)	99 (35.6%)	
Number of patients censored	104 (37.3%)	179 (64.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	1.2 [0.7, 2.4]	NC [16.6, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.611 [2.033, 3.354]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.230.2: Summary and Results of Non-Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	116 (65.2)	0.9 [0.5, 2.7]	177	72 (40.7)	25.9 [9.7, NC]	2.339 [1.741, 3.142]	<.0001	0.3094
>65 years	101	59 (58.4)	2.0 [0.7, 12.2]	101	27 (26.7)	NC [NC, NC]	3.060 [1.937, 4.832]	<.0001	
Sex									
Male	174	105 (60.3)	1.6 [0.7, 3.5]	173	57 (32.9)	NC [16.6, NC]	2.621 [1.896, 3.623]	<.0001	0.7350
Female	105	70 (66.7)	0.9 [0.1, 2.5]	105	42 (40.0)	NC [5.5, NC]	2.421 [1.650, 3.554]	<.0001	
Region									
Asia	87	52 (59.8)	1.4 [0.4, 12.2]	88	29 (33.0)	16.6 [13.2, NC]	2.349 [1.485, 3.714]	0.0003	0.8486
Non-Asia	192	123 (64.1)	1.1 [0.7, 2.5]	190	70 (36.8)	NC [25.9, NC]	2.614 [1.946, 3.512]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	137 (63.4)	1.1 [0.7, 2.4]	216	76 (35.2)	25.9 [16.6, NC]	2.632 [1.986, 3.488]	<.0001	0.5223
>=3	63	38 (60.3)	1.6 [0.6, 12.0]	62	23 (37.1)	NC [4.7, NC]	2.192 [1.304, 3.683]	0.0031	

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.
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: 08SEP23

Table 301.3.2001.231.1: Summary and Results of Severe TEAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	7 (2.5%)	
Number of patients censored	261 (93.5%)	271 (97.5%)	
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			2.816 [1.174, 6.754]
Log-rank test			
Two-sided stratified log-rank p-value			0.0154

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.231.2: Summary and Results of Severe TEAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	15 (8.4)	NC [NC, NC]	177	7 (4.0)	NC [NC, NC]	2.183 [0.890, 5.355]	0.0805	0.9885
>65 years	101	3 (3.0)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	2.82E7 [0.000, NC]	0.0911	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	5 (2.9)	NC [NC, NC]	1.953 [0.666, 5.722]	0.2141	0.4525
Female	105	8 (7.6)	NC [NC, NC]	105	2 (1.9)	NC [NC, NC]	4.065 [0.863, 19.151]	0.0546	
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	0.000 [0.000, NC]	0.3173	0.9886
Non-Asia	192	18 (9.4)	NC [NC, NC]	190	6 (3.2)	NC [NC, NC]	3.228 [1.281, 8.136]	0.0086	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	4 (1.9)	NC [NC, NC]	3.747 [1.243, 11.294]	0.0118	0.1844
>=3	63	3 (4.8)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	1.127 [0.227, 5.590]	0.8839	

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.
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: 08SEP23

Table 301.3.2001.232.1: Summary and Results of Severe TEAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	25 (9.0%)	26 (9.4%)	
Number of patients censored	254 (91.0%)	252 (90.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.952 [0.549, 1.651]
Log-rank test			
Two-sided stratified log-rank p-value			0.8604

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.232.2: Summary and Results of Severe TEAEs by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	19 (10.7)	NC [NC, NC]	177	19 (10.7)	NC [NC, NC]	0.994 [0.526, 1.878]	0.9837	0.7635
>65 years	101	6 (5.9)	NC [NC, NC]	101	7 (6.9)	NC [NC, NC]	0.857 [0.288, 2.549]	0.7804	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	15 (8.7)	NC [NC, NC]	0.660 [0.296, 1.471]	0.3062	0.2073
Female	105	15 (14.3)	NC [28.3, NC]	105	11 (10.5)	NC [NC, NC]	1.345 [0.617, 2.934]	0.4546	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	6 (6.8)	NC [NC, NC]	1.252 [0.441, 3.555]	0.6717	0.4306
Non-Asia	192	16 (8.3)	NC [NC, NC]	190	20 (10.5)	NC [NC, NC]	0.830 [0.430, 1.602]	0.5780	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	20 (9.3)	NC [NC, NC]	0.724 [0.370, 1.415]	0.3421	0.1681
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.762 [0.640, 4.849]	0.2665	

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.
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: 08SEP23

Table 301.3.2001.233.1: Summary and Results of Severe TEAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	6 (2.2%)	3 (1.1%)	
Number of patients censored	273 (97.8%)	275 (98.9%)	
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			1.996 [0.498, 7.997]
Log-rank test			
Two-sided stratified log-rank p-value			0.3197

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.233.2: Summary and Results of Severe TEAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	3 (1.7)		177	2 (1.1)				
>65 years	101	3 (3.0)		101	1 (1.0)				
Sex									
Male	174	4 (2.3)		173	1 (0.6)				
Female	105	2 (1.9)		105	2 (1.9)				
Region									
Asia	87	1 (1.1)		88	1 (1.1)				
Non-Asia	192	5 (2.6)		190	2 (1.1)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	2 (0.9)				
>=3	63	2 (3.2)		62	1 (1.6)				

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.
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: 08SEP23

Table 301.3.2001.234.1: Summary and Results of Severe TEAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	2 (0.7%)	
Number of patients censored	259 (92.8%)	276 (99.3%)	
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			10.673 [2.494, 45.677]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.234.2: Summary and Results of Severe TEAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	14 (7.9)	NC [NC, NC]	177	0 (0.0)	NC [NC, NC]	3.13E7 [0.000, NC]	0.0001	0.9907
>65 years	101	6 (5.9)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	3.097 [0.625, 15.345]	0.1453	
Sex									
Male	174	12 (6.9)	NC [NC, NC]	173	2 (1.2)	NC [NC, NC]	6.287 [1.407, 28.088]	0.0058	0.9893
Female	105	8 (7.6)	NC [NC, NC]	105	0 (0.0)	NC [NC, NC]	3.1E7 [0.000, NC]	0.0038	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	1 (1.1)	NC [NC, NC]	2.032 [0.184, 22.403]	0.5545	0.1598
Non-Asia	192	18 (9.4)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	19.192 [2.562, 143.79]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	16 (7.4)	NC [NC, NC]	216	1 (0.5)	NC [NC, NC]	16.918 [2.245, 127.51]	0.0002	0.3485
>=3	63	4 (6.3)	NC [NC, NC]	62	1 (1.6)	NC [NC, NC]	4.116 [0.460, 36.839]	0.1701	

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.
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: 08SEP23

Table 301.3.2001.235.1: Summary and Results of Severe TEAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	19 (6.8%)	
Number of patients censored	234 (83.9%)	259 (93.2%)	
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			2.514 [1.469, 4.304]
Log-rank test			
Two-sided stratified log-rank p-value			0.0005

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.235.2: Summary and Results of Severe TEAEs by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	29 (16.3)	NC [NC, NC]	177	15 (8.5)	NC [NC, NC]	2.080 [1.115, 3.880]	0.0200	0.2807
>65 years	101	16 (15.8)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	4.159 [1.389, 12.456]	0.0057	
Sex									
Male	174	23 (13.2)	NC [NC, NC]	173	10 (5.8)	NC [NC, NC]	2.422 [1.153, 5.089]	0.0166	0.8748
Female	105	22 (21.0)	NC [NC, NC]	105	9 (8.6)	NC [NC, NC]	2.628 [1.209, 5.712]	0.0117	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	6 (6.8)	NC [NC, NC]	1.430 [0.505, 4.051]	0.5066	0.2576
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	3.047 [1.615, 5.746]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	34 (15.7)	NC [NC, NC]	216	12 (5.6)	NC [NC, NC]	3.009 [1.557, 5.813]	0.0006	0.2934
>=3	63	11 (17.5)	NC [NC, NC]	62	7 (11.3)	NC [NC, NC]	1.650 [0.639, 4.261]	0.2978	

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.
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: 08SEP23

Table 301.3.2001.236.1: Summary and Results of Severe TEAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	147 (52.7%)	131 (47.1%)	
Number of patients censored	132 (47.3%)	147 (52.9%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	3.9 [2.8, 8.5]	5.9 [3.8, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.185 [0.935, 1.500]
Log-rank test			
Two-sided stratified log-rank p-value			0.1496

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.236.2: Summary and Results of Severe TEAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	93 (52.2)	4.1 [2.3, 21.4]	177	82 (46.3)	6.8 [3.7, NC]	1.245 [0.925, 1.676]	0.1399	0.7582
>65 years	101	54 (53.5)	3.6 [2.3, NC]	101	49 (48.5)	4.8 [2.8, NC]	1.155 [0.784, 1.700]	0.4544	
Sex									
Male	174	75 (43.1)	NC [4.1, NC]	173	66 (38.2)	NC [NC, NC]	1.229 [0.883, 1.711]	0.2116	0.9096
Female	105	72 (68.6)	2.1 [1.6, 3.4]	105	65 (61.9)	2.6 [2.1, 4.2]	1.184 [0.846, 1.657]	0.3156	
Region									
Asia	87	57 (65.5)	2.5 [1.7, 4.1]	88	47 (53.4)	4.2 [2.1, NC]	1.283 [0.872, 1.889]	0.1912	0.6953
Non-Asia	192	90 (46.9)	6.3 [3.4, NC]	190	84 (44.2)	NC [3.9, NC]	1.164 [0.865, 1.568]	0.3068	
Number of Organs with Metastatic Sites									
0-2	216	113 (52.3)	4.1 [2.8, 9.1]	216	110 (50.9)	4.7 [3.4, NC]	1.069 [0.822, 1.390]	0.5976	0.0464
>=3	63	34 (54.0)	3.4 [1.4, NC]	62	21 (33.9)	NC [6.8, NC]	1.888 [1.095, 3.257]	0.0191	

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.
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: 08SEP23

Table 301.3.2001.237.1: Summary and Results of Severe TEAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	45 (16.1%)	17 (6.1%)	
Number of patients censored	234 (83.9%)	261 (93.9%)	
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			2.851 [1.629, 4.988]
Log-rank test			
Two-sided stratified log-rank p-value			0.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.237.2: Summary and Results of Severe TEAEs by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	30 (16.9)	NC [NC, NC]	177	14 (7.9)	NC [NC, NC]	2.277 [1.207, 4.296]	0.0104	0.2434
>65 years	101	15 (14.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	5.289 [1.531, 18.271]	0.0032	
Sex									
Male	174	21 (12.1)	NC [NC, NC]	173	9 (5.2)	NC [NC, NC]	2.397 [1.097, 5.235]	0.0251	0.6073
Female	105	24 (22.9)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	3.304 [1.484, 7.355]	0.0021	
Region									
Asia	87	9 (10.3)	NC [NC, NC]	88	4 (4.5)	NC [NC, NC]	2.125 [0.649, 6.954]	0.2081	0.6729
Non-Asia	192	36 (18.8)	NC [NC, NC]	190	13 (6.8)	NC [NC, NC]	3.037 [1.611, 5.728]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	35 (16.2)	NC [NC, NC]	216	11 (5.1)	NC [NC, NC]	3.381 [1.717, 6.659]	0.0002	0.2736
>=3	63	10 (15.9)	NC [NC, NC]	62	6 (9.7)	NC [NC, NC]	1.757 [0.638, 4.837]	0.2728	

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.
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: 08SEP23

Table 301.3.2001.238.1: Summary and Results of TESAEs - Abdominal Pain (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	10 (3.6%)	
Number of patients censored	274 (98.2%)	268 (96.4%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.507 [0.173, 1.487]
Log-rank test			
Two-sided stratified log-rank p-value			0.2072

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.238.2: Summary and Results of TESAEs by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	3 (1.7)	NC [NC, NC]	177	8 (4.5)	NC [NC, NC]	0.370 [0.098, 1.395]	0.1260	0.4368
>65 years	101	2 (2.0)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	0.950 [0.134, 6.749]	0.9590	
Sex									
Male	174	3 (1.7)		173	5 (2.9)				
Female	105	2 (1.9)		105	5 (4.8)				
Region									
Asia	87	0 (0.0)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	0.000 [0.000, NC]	0.1585	0.9905
Non-Asia	192	5 (2.6)	NC [NC, NC]	190	8 (4.2)	NC [NC, NC]	0.633 [0.207, 1.937]	0.4193	
Number of Organs with Metastatic Sites									
0-2	216	3 (1.4)	NC [NC, NC]	216	7 (3.2)	NC [NC, NC]	0.413 [0.107, 1.599]	0.1860	0.6960
>=3	63	2 (3.2)	NC [NC, NC]	62	3 (4.8)	NC [NC, NC]	0.699 [0.117, 4.193]	0.6941	

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.
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: 08SEP23

Table 301.3.2001.239.1: Summary and Results of TESAEs - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	4 (1.4%)	
Number of patients censored	274 (98.2%)	274 (98.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.280 [0.343, 4.769]
Log-rank test			
Two-sided stratified log-rank p-value			0.7127

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.239.2: Summary and Results of TESAEs by Subgroups - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	4 (2.2)		177	2 (1.1)				
>65 years	101	1 (1.0)		101	2 (2.0)				
Sex									
Male	174	3 (1.7)		173	4 (2.3)				
Female	105	2 (1.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)		88	0 (0.0)				
Non-Asia	192	4 (2.1)		190	4 (2.1)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)		216	3 (1.4)				
>=3	63	3 (4.8)		62	1 (1.6)				

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.
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: 08SEP23

Table 301.3.2001.240.1: Summary and Results of TESAEs - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	1 (0.4%)	
Number of patients censored	275 (98.6%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			3.994 [0.446, 35.746]
Log-rank test			
Two-sided stratified log-rank p-value			0.1803

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.240.2: Summary and Results of TESAEs by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	3 (3.0)		101	1 (1.0)				
Sex									
Male	174	4 (2.3)		173	1 (0.6)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	1 (1.1)				
Non-Asia	192	4 (2.1)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	1 (0.5)		216	1 (0.5)				
>=3	63	3 (4.8)		62	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.
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: 08SEP23

Table 301.3.2001.241.1: Summary and Results of TESAEs - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	8 (2.9%)	0 (0.0%)	
Number of patients censored	271 (97.1%)	278 (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			0.0041

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.241.2: Summary and Results of TESAEs by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	6 (3.4)		177	0 (0.0)				
>65 years	101	2 (2.0)		101	0 (0.0)				
Sex									
Male	174	6 (3.4)		173	0 (0.0)				
Female	105	2 (1.9)		105	0 (0.0)				
Region									
Asia	87	1 (1.1)		88	0 (0.0)				
Non-Asia	192	7 (3.6)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	0 (0.0)				
>=3	63	4 (6.3)		62	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.
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: 08SEP23

Table 301.3.2001.242.1: Summary and Results of TESAEs - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	19 (6.8%)	12 (4.3%)	
Number of patients censored	260 (93.2%)	266 (95.7%)	
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			1.619 [0.784, 3.344]
Log-rank test			
Two-sided stratified log-rank p-value			0.1893

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.242.2: Summary and Results of TESAEs by Subgroups - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [NC, NC]	177	8 (4.5)	NC [NC, NC]	1.673 [0.693, 4.036]	0.2478	0.8888
>65 years	101	6 (5.9)	NC [NC, NC]	101	4 (4.0)	NC [NC, NC]	1.435 [0.403, 5.116]	0.5764	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	5 (2.9)	NC [NC, NC]	1.831 [0.614, 5.466]	0.2709	0.7566
Female	105	10 (9.5)	NC [NC, NC]	105	7 (6.7)	NC [NC, NC]	1.420 [0.539, 3.739]	0.4797	
Region									
Asia	87	4 (4.6)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	1.140 [0.248, 5.233]	0.8658	0.7229
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	9 (4.7)	NC [NC, NC]	1.748 [0.765, 3.994]	0.1808	
Number of Organs with Metastatic Sites									
0-2	216	12 (5.6)	NC [NC, NC]	216	7 (3.2)	NC [NC, NC]	1.716 [0.675, 4.365]	0.2526	0.7778
>=3	63	7 (11.1)	NC [NC, NC]	62	5 (8.1)	NC [NC, NC]	1.417 [0.449, 4.467]	0.5513	

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.
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: 08SEP23

Table 301.3.2001.243.1: Summary and Results of TESAEs - Neutropenia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	16 (5.7%)	8 (2.9%)	
Number of patients censored	263 (94.3%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.047 [0.876, 4.787]
Log-rank test			
Two-sided stratified log-rank p-value			0.0912

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.243.2: Summary and Results of TESAEs by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	11 (6.2)	NC [NC, NC]	177	6 (3.4)	NC [NC, NC]	1.891 [0.699, 5.114]	0.2014	0.7735
>65 years	101	5 (5.0)	NC [NC, NC]	101	2 (2.0)	NC [NC, NC]	2.512 [0.487, 12.948]	0.2544	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	4 (2.3)	NC [NC, NC]	2.583 [0.810, 8.236]	0.0959	0.5639
Female	105	6 (5.7)	NC [NC, NC]	105	4 (3.8)	NC [NC, NC]	1.531 [0.432, 5.424]	0.5065	
Region									
Asia	87	3 (3.4)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	1.413 [0.236, 8.476]	0.7039	0.6823
Non-Asia	192	13 (6.8)	NC [NC, NC]	190	6 (3.2)	NC [NC, NC]	2.261 [0.859, 5.949]	0.0893	
Number of Organs with Metastatic Sites									
0-2	216	9 (4.2)	NC [NC, NC]	216	8 (3.7)	NC [NC, NC]	1.140 [0.440, 2.954]	0.7878	0.9903
>=3	63	7 (11.1)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	3.06E7 [0.000, NC]	0.0072	

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.
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: 08SEP23

Table 301.3.2001.244.1: Summary and Results of TESAEs - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	24 (8.6%)	15 (5.4%)	
Number of patients censored	255 (91.4%)	263 (94.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			1.713 [0.898, 3.266]
Log-rank test			
Two-sided stratified log-rank p-value			0.1004

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.244.2: Summary and Results of TESAEs by Subgroups - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	17 (9.6)	NC [NC, NC]	177	12 (6.8)	NC [NC, NC]	1.452 [0.693, 3.041]	0.3247	0.5359
>65 years	101	7 (6.9)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	2.379 [0.615, 9.200]	0.1956	
Sex									
Male	174	10 (5.7)	NC [NC, NC]	173	7 (4.0)	NC [NC, NC]	1.426 [0.543, 3.748]	0.4705	0.7159
Female	105	14 (13.3)	NC [NC, NC]	105	8 (7.6)	NC [NC, NC]	1.845 [0.774, 4.397]	0.1641	
Region									
Asia	87	1 (1.1)	NC [NC, NC]	88	3 (3.4)	NC [NC, NC]	0.336 [0.035, 3.232]	0.3215	0.1262
Non-Asia	192	23 (12.0)	NC [NC, NC]	190	12 (6.3)	NC [NC, NC]	2.029 [1.010, 4.078]	0.0435	
Number of Organs with Metastatic Sites									
0-2	216	16 (7.4)	NC [NC, NC]	216	10 (4.6)	NC [NC, NC]	1.635 [0.742, 3.603]	0.2212	0.9882
>=3	63	8 (12.7)	NC [NC, NC]	62	5 (8.1)	NC [NC, NC]	1.622 [0.530, 4.960]	0.3946	

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.
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: 08SEP23

Table 301.3.2001.245.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	2 (0.7%)	1 (0.4%)	
Number of patients censored	277 (99.3%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			2.148 [0.195, 23.689]
Log-rank test			
Two-sided stratified log-rank p-value			0.5224

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.245.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	1 (1.0)		101	1 (1.0)				
Sex									
Male	174	2 (1.1)		173	1 (0.6)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	2 (1.0)		190	1 (0.5)				
Number of Organs with Metastatic Sites									
0-2	216	2 (0.9)		216	1 (0.5)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.246.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	4 (1.4%)	3 (1.1%)	
Number of patients censored	275 (98.6%)	275 (98.9%)	
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			1.368 [0.306, 6.127]
Log-rank test			
Two-sided stratified log-rank p-value			0.6805

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.246.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)		177	2 (1.1)				
>65 years	101	2 (2.0)		101	1 (1.0)				
Sex									
Male	174	3 (1.7)		173	3 (1.7)				
Female	105	1 (1.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	4 (2.1)		190	3 (1.6)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)		216	1 (0.5)				
>=3	63	0 (0.0)		62	2 (3.2)				

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.
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: 08SEP23

Table 301.3.2001.247.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	5 (1.8%)	8 (2.9%)	
Number of patients censored	274 (98.2%)	270 (97.1%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			0.565 [0.184, 1.733]
Log-rank test			
Two-sided stratified log-rank p-value			0.3116

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.247.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	2 (1.1)		177	5 (2.8)				
>65 years	101	3 (3.0)		101	3 (3.0)				
Sex									
Male	174	3 (1.7)		173	6 (3.5)				
Female	105	2 (1.9)		105	2 (1.9)				
Region									
Asia	87	2 (2.3)		88	7 (8.0)				
Non-Asia	192	3 (1.6)		190	1 (0.5)				
Number of Organs with Metastatic Sites									
0-2	216	4 (1.9)	NC [NC, NC]	216	6 (2.8)	NC [NC, NC]	0.673 [0.190, 2.385]	0.5363	0.8629
>=3	63	1 (1.6)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	0.549 [0.050, 6.059]	0.6195	

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.
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: 08SEP23

Table 301.3.2001.248.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	**Placebo + mFOLFOX6 (N= 278)**	**Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6**
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	17 (6.1%)	11 (4.0%)	
Number of patients censored	262 (93.9%)	267 (96.0%)	
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			1.571 [0.735, 3.357]
Log-rank test			
Two-sided stratified log-rank p-value			0.2414

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.248.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	13 (7.3)	NC [NC, NC]	177	8 (4.5)	NC [NC, NC]	1.673 [0.694, 4.038]	0.2483	0.8074
>65 years	101	4 (4.0)	NC [NC, NC]	101	3 (3.0)	NC [NC, NC]	1.353 [0.303, 6.048]	0.6909	
Sex									
Male	174	8 (4.6)	NC [NC, NC]	173	8 (4.6)	NC [NC, NC]	1.012 [0.380, 2.698]	0.9809	0.1784
Female	105	9 (8.6)	NC [NC, NC]	105	3 (2.9)	NC [NC, NC]	3.147 [0.852, 11.626]	0.0698	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	5 (5.7)	NC [NC, NC]	0.378 [0.073, 1.951]	0.2272	0.0455
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	6 (3.2)	NC [NC, NC]	2.624 [1.018, 6.764]	0.0382	
Number of Organs with Metastatic Sites									
0-2	216	15 (6.9)	NC [NC, NC]	216	7 (3.2)	NC [NC, NC]	2.209 [0.901, 5.418]	0.0757	0.1337
>=3	63	2 (3.2)	NC [NC, NC]	62	4 (6.5)	NC [NC, NC]	0.524 [0.096, 2.863]	0.4482	

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.
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: 08SEP23

Table 301.3.2001.249.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	18 (6.5%)	3 (1.1%)	
Number of patients censored	261 (93.5%)	275 (98.9%)	
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			5.949 [1.749, 20.234]
Log-rank test			
Two-sided stratified log-rank p-value			0.0012

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.249.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	11 (6.2)	NC [NC, NC]	177	2 (1.1)	NC [NC, NC]	5.637 [1.249, 25.429]	0.0110	0.8755
>65 years	101	7 (6.9)	NC [NC, NC]	101	1 (1.0)	NC [NC, NC]	6.595 [0.808, 53.804]	0.0423	
Sex									
Male	174	8 (4.6)	NC [NC, NC]	173	1 (0.6)	NC [NC, NC]	8.148 [1.019, 65.156]	0.0183	0.7188
Female	105	10 (9.5)	NC [NC, NC]	105	2 (1.9)	NC [NC, NC]	4.924 [1.077, 22.519]	0.0228	
Region									
Asia	87	3 (3.4)	NC [NC, NC]	88	2 (2.3)	NC [NC, NC]	1.140 [0.183, 7.096]	0.8884	0.0751
Non-Asia	192	15 (7.8)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	15.752 [2.081, 119.22]	0.0003	
Number of Organs with Metastatic Sites									
0-2	216	14 (6.5)	NC [NC, NC]	216	3 (1.4)	NC [NC, NC]	4.611 [1.324, 16.063]	0.0083	0.9916
>=3	63	4 (6.3)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	2.96E7 [0.000, NC]	0.0454	

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.
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: 08SEP23

Table 301.3.2001.250.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	34 (12.2%)	28 (10.1%)	
Number of patients censored	245 (87.8%)	250 (89.9%)	
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			1.174 [0.710, 1.942]
Log-rank test			
Two-sided stratified log-rank p-value			0.5299

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.250.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	18 (10.1)	NC [NC, NC]	177	16 (9.0)	NC [NC, NC]	1.107 [0.564, 2.172]	0.7664	0.7245
>65 years	101	16 (15.8)	NC [NC, NC]	101	12 (11.9)	NC [NC, NC]	1.368 [0.647, 2.893]	0.4111	
Sex									
Male	174	21 (12.1)	NC [NC, NC]	173	15 (8.7)	NC [NC, NC]	1.424 [0.734, 2.764]	0.2931	0.4722
Female	105	13 (12.4)	NC [NC, NC]	105	13 (12.4)	NC [NC, NC]	0.974 [0.452, 2.102]	0.9477	
Region									
Asia	87	14 (16.1)	NC [NC, NC]	88	11 (12.5)	NC [NC, NC]	1.185 [0.534, 2.626]	0.6756	0.9987
Non-Asia	192	20 (10.4)	NC [NC, NC]	190	17 (8.9)	NC [NC, NC]	1.219 [0.638, 2.327]	0.5469	
Number of Organs with Metastatic Sites									
0-2	216	25 (11.6)	NC [NC, NC]	216	26 (12.0)	NC [NC, NC]	0.952 [0.550, 1.649]	0.8603	0.0553
>=3	63	9 (14.3)	NC [NC, NC]	62	2 (3.2)	NC [NC, NC]	4.778 [1.031, 22.138]	0.0271	

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.
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: 08SEP23

Table 301.3.2001.251.1: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	20 (7.2%)	1 (0.4%)	
Number of patients censored	259 (92.8%)	277 (99.6%)	
Kaplan-Meier estimates of time to event (months)			
Quartiles, 95% CI [a]			
50%	NC [NC, NC]	NC [NC, NC]	
Cox proportional hazards model			
Stratified HR, 95% CI			20.963 [2.813, 156.24]
Log-rank test			
Two-sided stratified log-rank p-value			<.0001

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.251.2: Summary and Results of TEAEs leading to Permanent Treatment Discontinuation by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	12 (6.7)	NC [NC, NC]	177	1 (0.6)	NC [NC, NC]	12.281 [1.597, 94.447]	0.0020	0.9905
>65 years	101	8 (7.9)	NC [NC, NC]	101	0 (0.0)	NC [NC, NC]	3.03E7 [0.000, NC]	0.0042	
Sex									
Male	174	9 (5.2)	NC [NC, NC]	173	1 (0.6)	NC [NC, NC]	9.140 [1.158, 72.146]	0.0106	0.9911
Female	105	11 (10.5)	NC [NC, NC]	105	0 (0.0)	NC [NC, NC]	3.1E7 [0.000, NC]	0.0007	
Region									
Asia	87	2 (2.3)	NC [NC, NC]	88	0 (0.0)	NC [NC, NC]	2.56E7 [0.000, NC]	0.1922	0.9931
Non-Asia	192	18 (9.4)	NC [NC, NC]	190	1 (0.5)	NC [NC, NC]	18.867 [2.518, 141.35]	<.0001	
Number of Organs with Metastatic Sites									
0-2	216	14 (6.5)	NC [NC, NC]	216	1 (0.5)	NC [NC, NC]	14.455 [1.901, 109.91]	0.0006	0.9889
>=3	63	6 (9.5)	NC [NC, NC]	62	0 (0.0)	NC [NC, NC]	2.98E7 [0.000, NC]	0.0140	

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.
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: 08SEP23

Table 301.3.2001.273.1: Summary and Results of TEAEs leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.273.2: Summary and Results of TEAEs leading to Death by Subgroups - Abdominal Pain (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.274.1: Summary and Results of TEAEs leading to Death - Anemia (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.274.2: Summary and Results of TEAEs leading to Death by Subgroups - Anemia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.275.1: Summary and Results of TEAEs leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.275.2: Summary and Results of TEAEs leading to Death by Subgroups - Hypersensitivity Reactions (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.276.1: Summary and Results of TEAEs leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.276.2: Summary and Results of TEAEs leading to Death by Subgroups - Infusion Related Reaction (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.277.1: Summary and Results of TEAEs leading to Death - Nausea (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.277.2: Summary and Results of TEAEs leading to Death by Subgroups - Nausea (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	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.
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: 08SEP23

Table 301.3.2001.278.1: Summary and Results of TEAEs leading to Death - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	1 (0.4%)	0 (0.0%)	
Number of patients censored	278 (99.6%)	278 (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			0.3362

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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.278.2: Summary and Results of TEAEs leading to Death by Subgroups - Neutropenia (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	1 (0.6)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	1 (0.6)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	1 (0.5)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	1 (1.6)		62	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.
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: 08SEP23

Table 301.3.2001.279.1: Summary and Results of TEAEs leading to Death - Vomiting (AESI)
- Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N= 279)	Placebo + mFOLFOX6 (N= 278)	Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6
Number of patients at risk	279 (100.0%)	278 (100.0%)	
Number of patients with events	0 (0.0%)	0 (0.0%)	
Number of patients censored	279 (100.0%)	278 (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 region (Asia vs. Non-Asia), the number of organs with metastatic sites (0 to 2 vs. ≥ 3) and prior gastrectomy (Yes or No).
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: 08SEP23

Table 301.3.2001.279.2: Summary and Results of TEAEs leading to Death by Subgroups - Vomiting (AESI) - Safety Analysis Set

	Zolbetuximab + mFOLFOX6			Placebo + mFOLFOX6			Zolbetuximab + mFOLFOX6 vs. Placebo + mFOLFOX6		
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	178	0 (0.0)		177	0 (0.0)				
>65 years	101	0 (0.0)		101	0 (0.0)				
Sex									
Male	174	0 (0.0)		173	0 (0.0)				
Female	105	0 (0.0)		105	0 (0.0)				
Region									
Asia	87	0 (0.0)		88	0 (0.0)				
Non-Asia	192	0 (0.0)		190	0 (0.0)				
Number of Organs with Metastatic Sites									
0-2	216	0 (0.0)		216	0 (0.0)				
>=3	63	0 (0.0)		62	0 (0.0)				

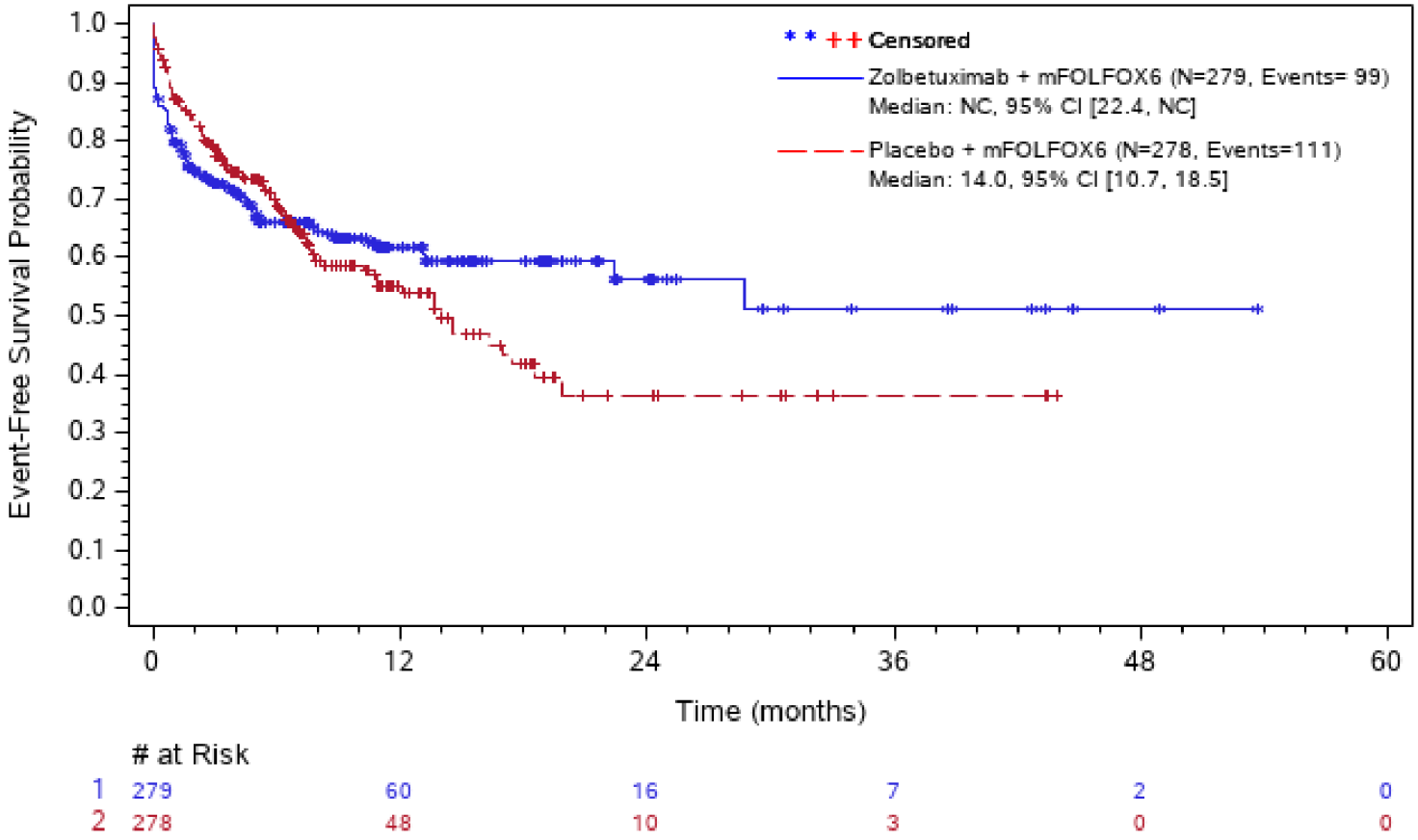
Abbreviations: AESI=adverse event of special interest; CI=confidence interval; HR=hazard ratio; KME=Kaplan-Meier Estimate of time to event (months); N=number of patients; n=number of patients with event; NC=not calculated; PT=preferred term; SOC=system organ class; TE(S)AE=treatment-emergent (serious) 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.
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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Sicherheit
Anhang 4-G4 Unerwünschte Ereignisse von besonderem Interesse

2. Kaplan-Meier-Plots

The SAS System

Figure 301.3.2001.217: Kaplan-Meier Plot of Time to first TEAE - Abdominal Pain (AESI) - Safety Analysis Set

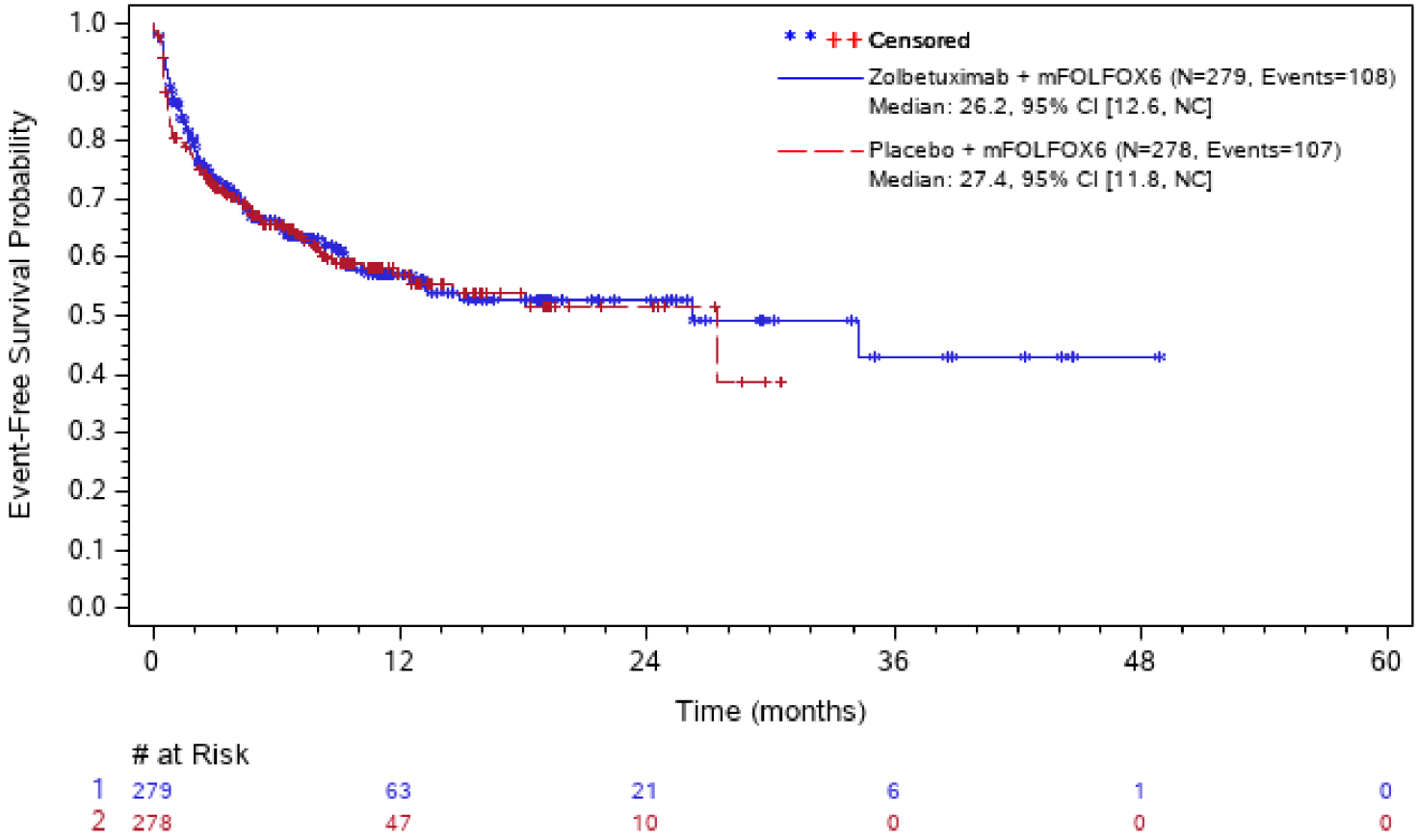


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.218: Kaplan-Meier Plot of Time to first TEAE - Anemia (AESI) - Safety Analysis Set

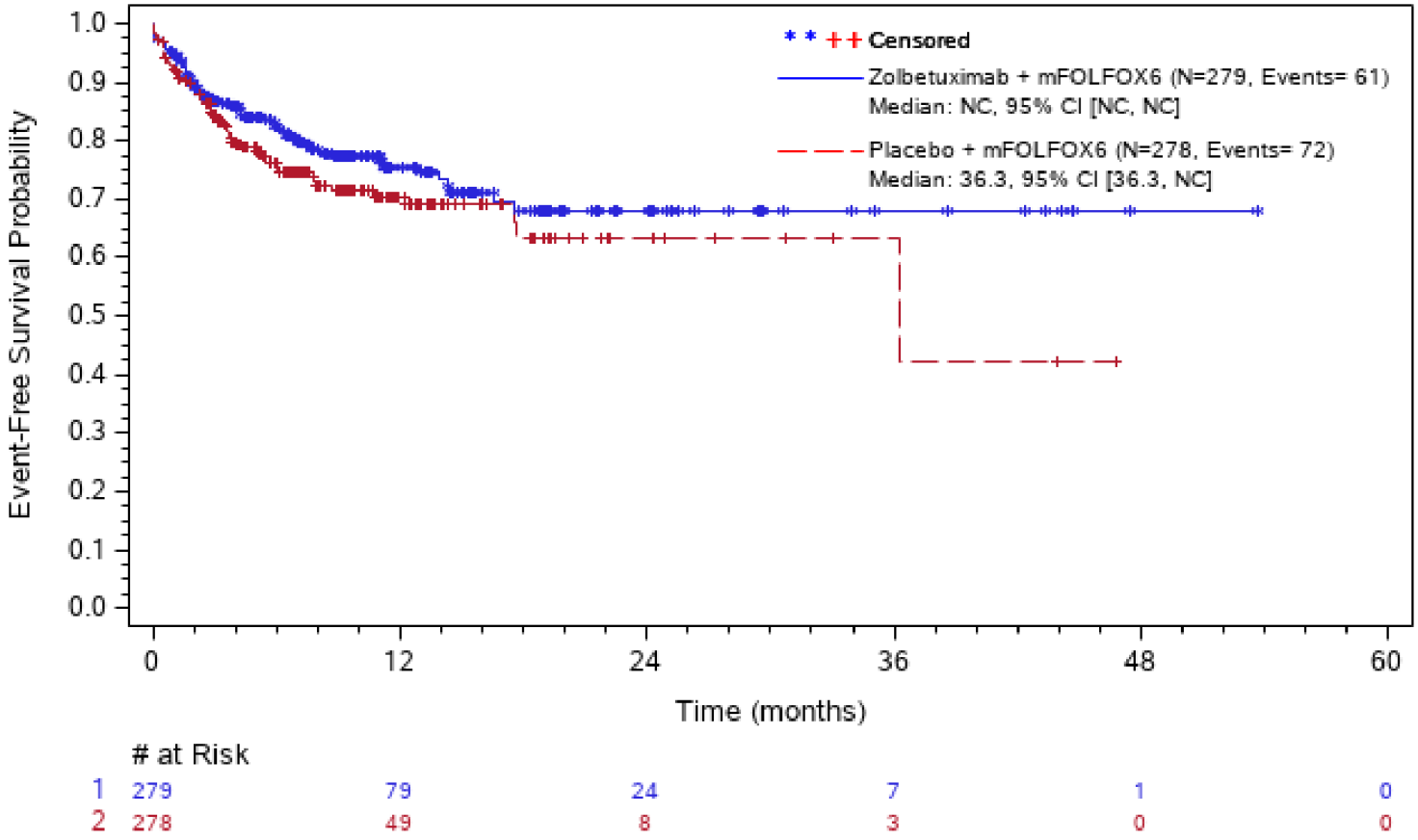


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.219: Kaplan-Meier Plot of Time to first TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set

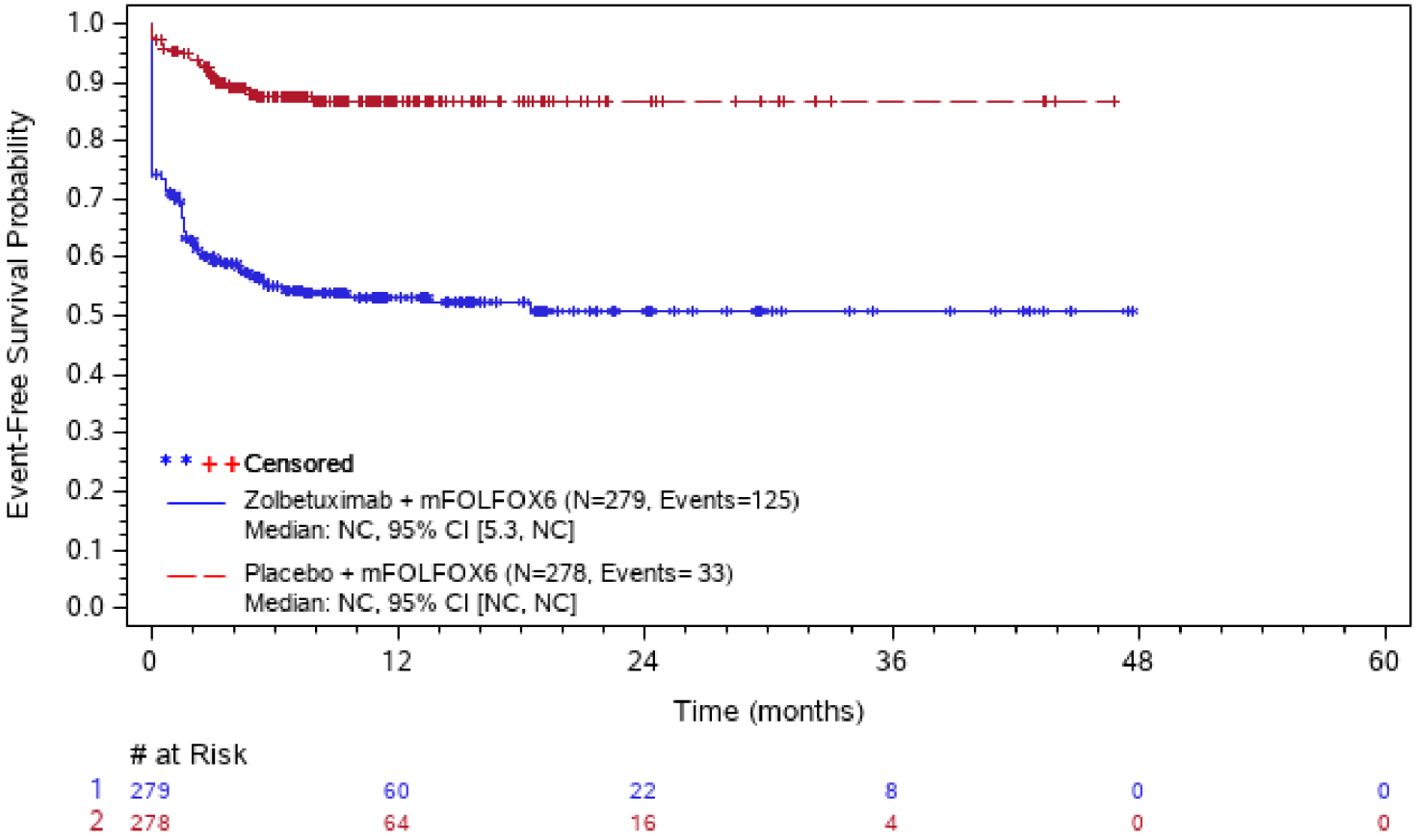


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.220: Kaplan-Meier Plot of Time to first TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set



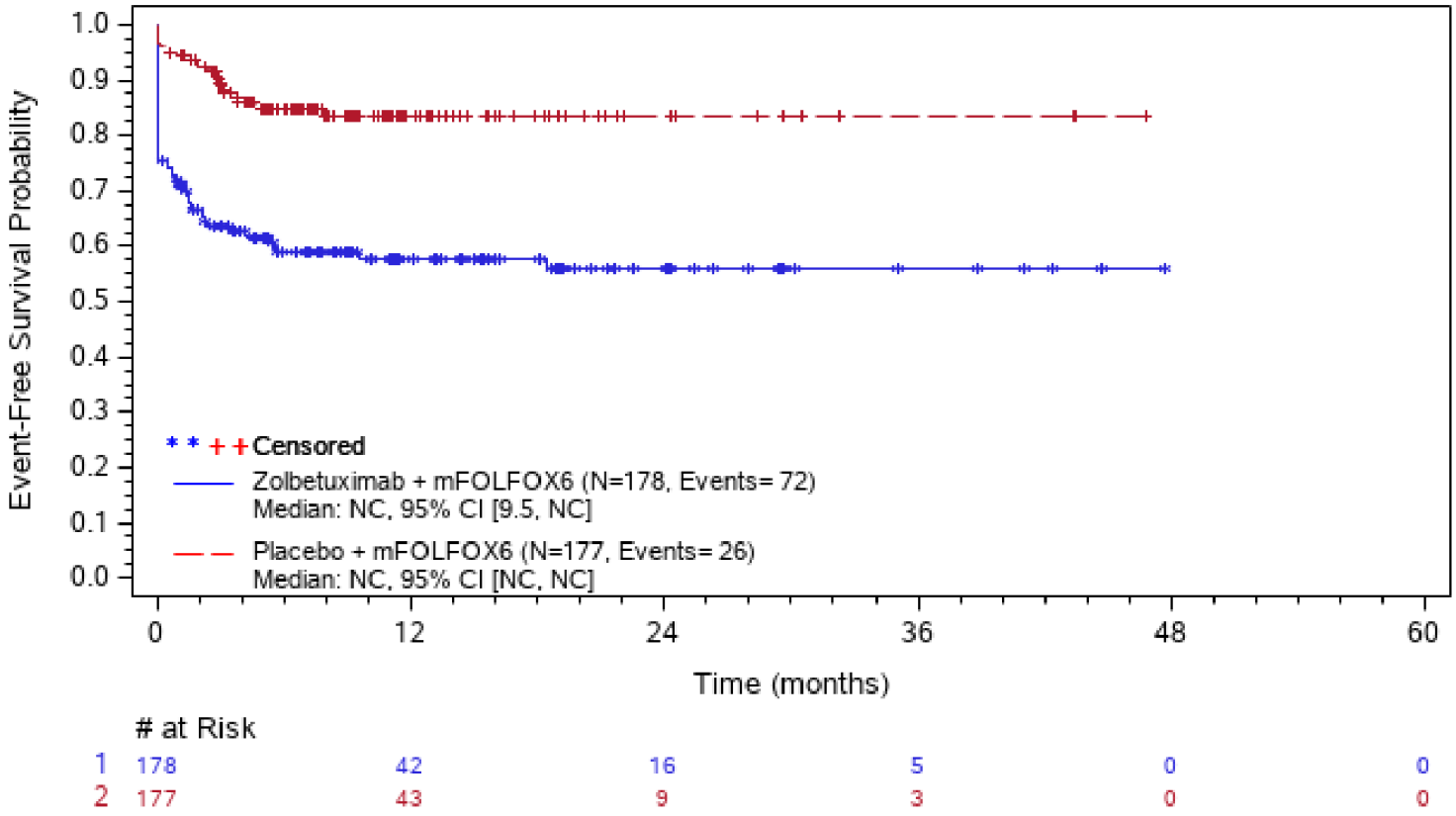
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.220.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set

Pooled Age Group 1: <=65 years



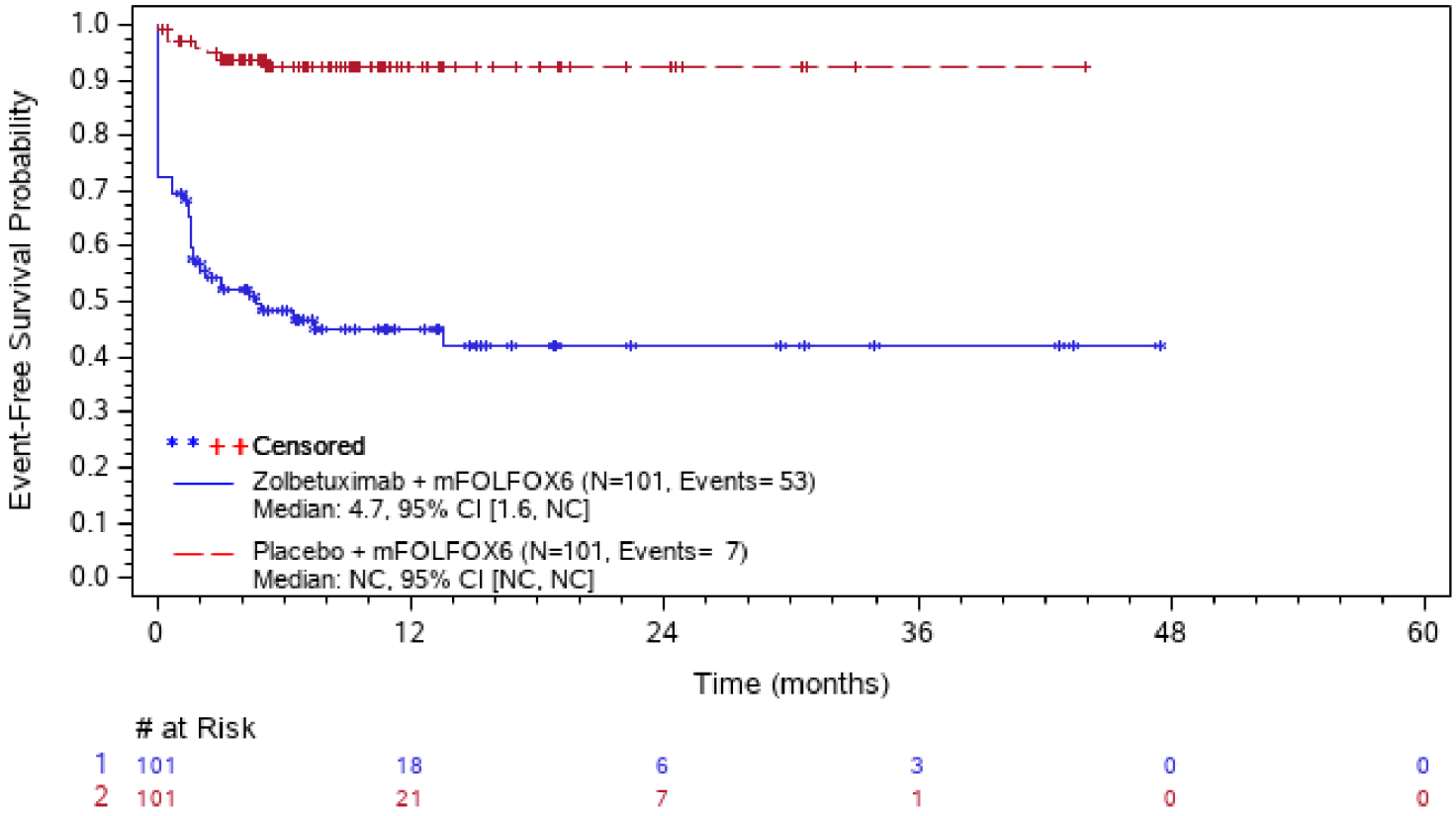
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.220.1: Kaplan-Meier Plot of Time to first TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set

Pooled Age Group 1: >65 years

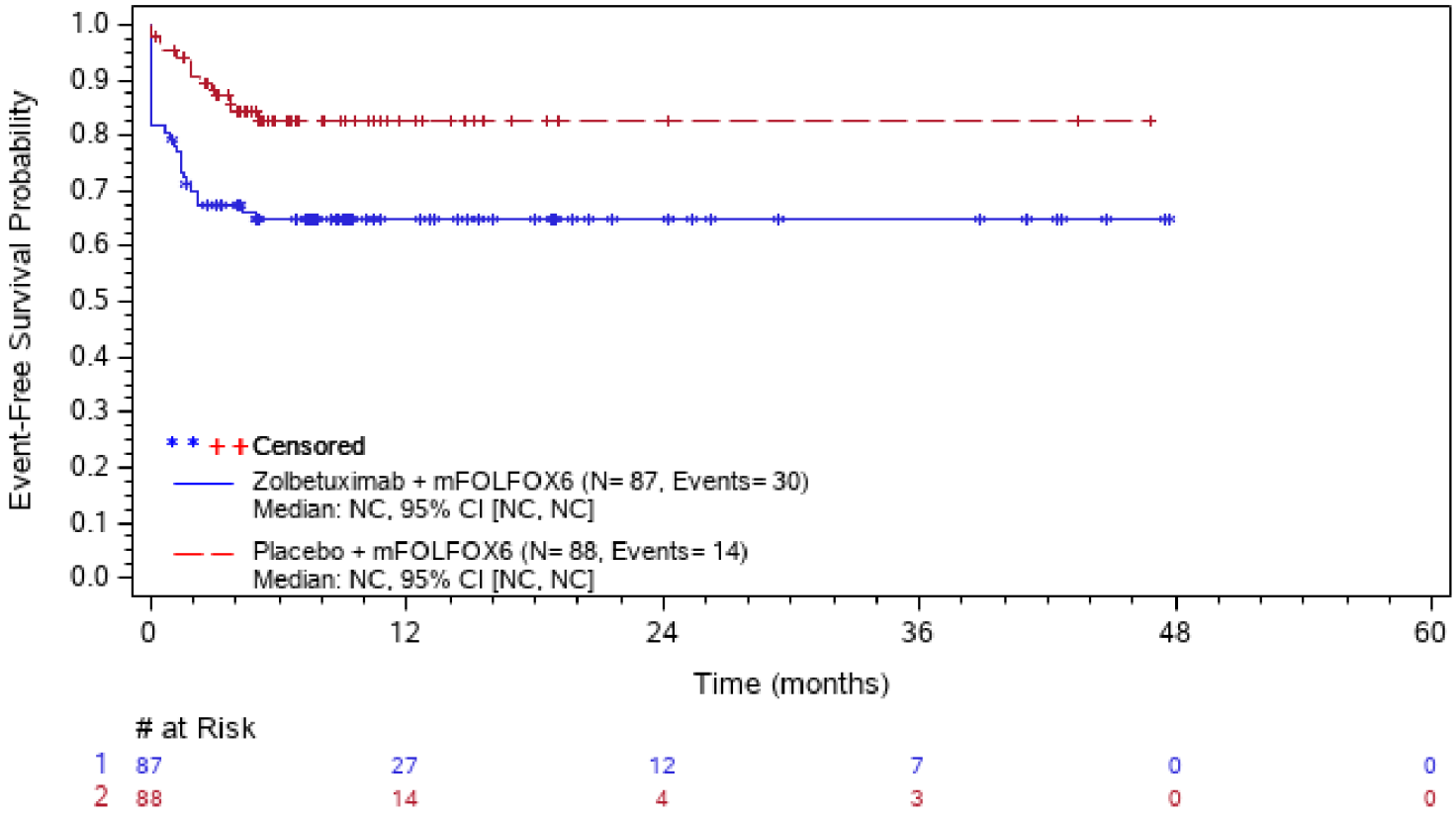


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

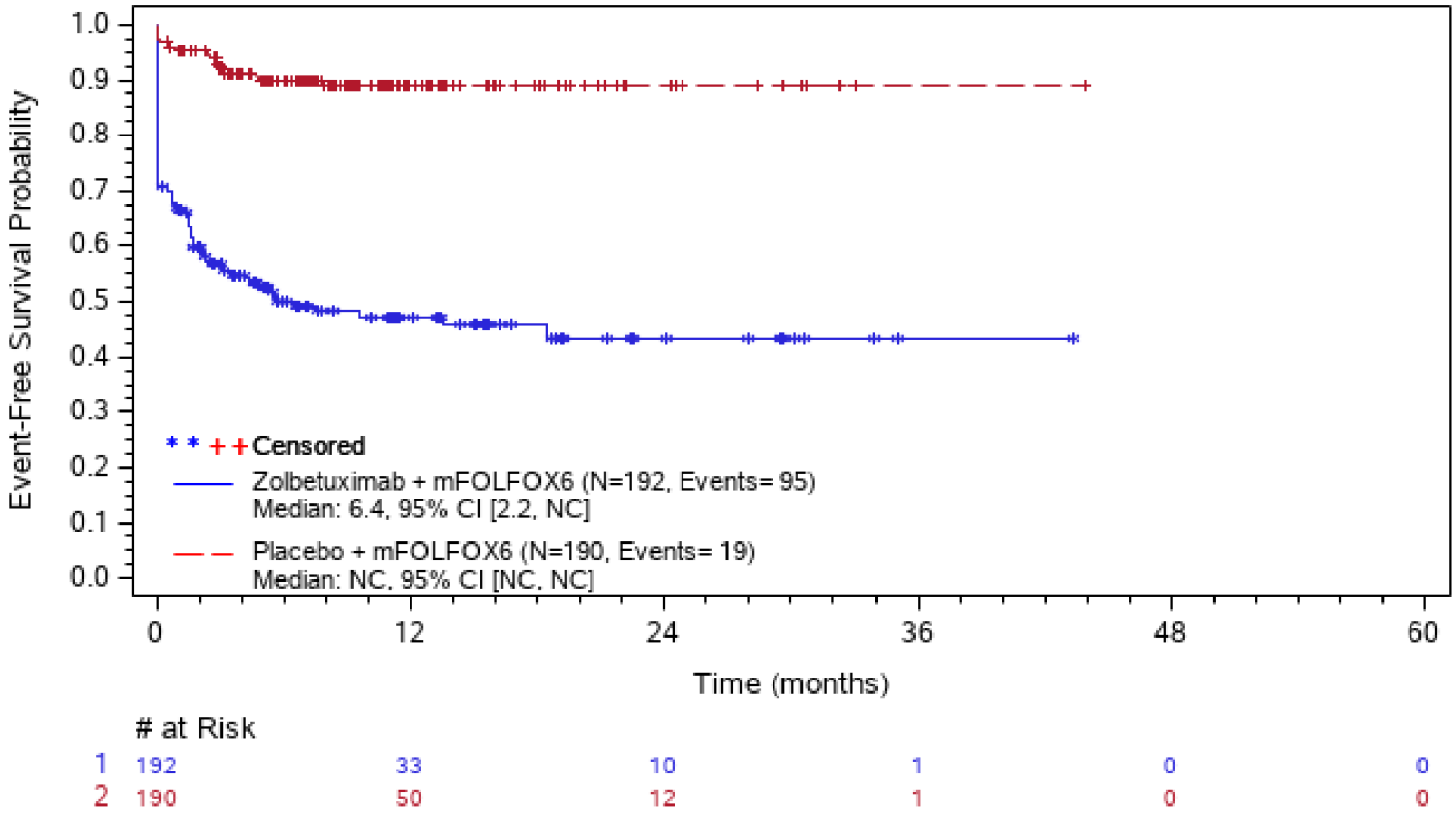
Figure 301.3.2001.220.3: Kaplan-Meier Plot of Time to first TEAE by Region - Infusion Related Reaction (AESI) - Safety Analysis Set
IRT- Region Subject is Enrolling In: Asia



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: 08SEP23

The SAS System

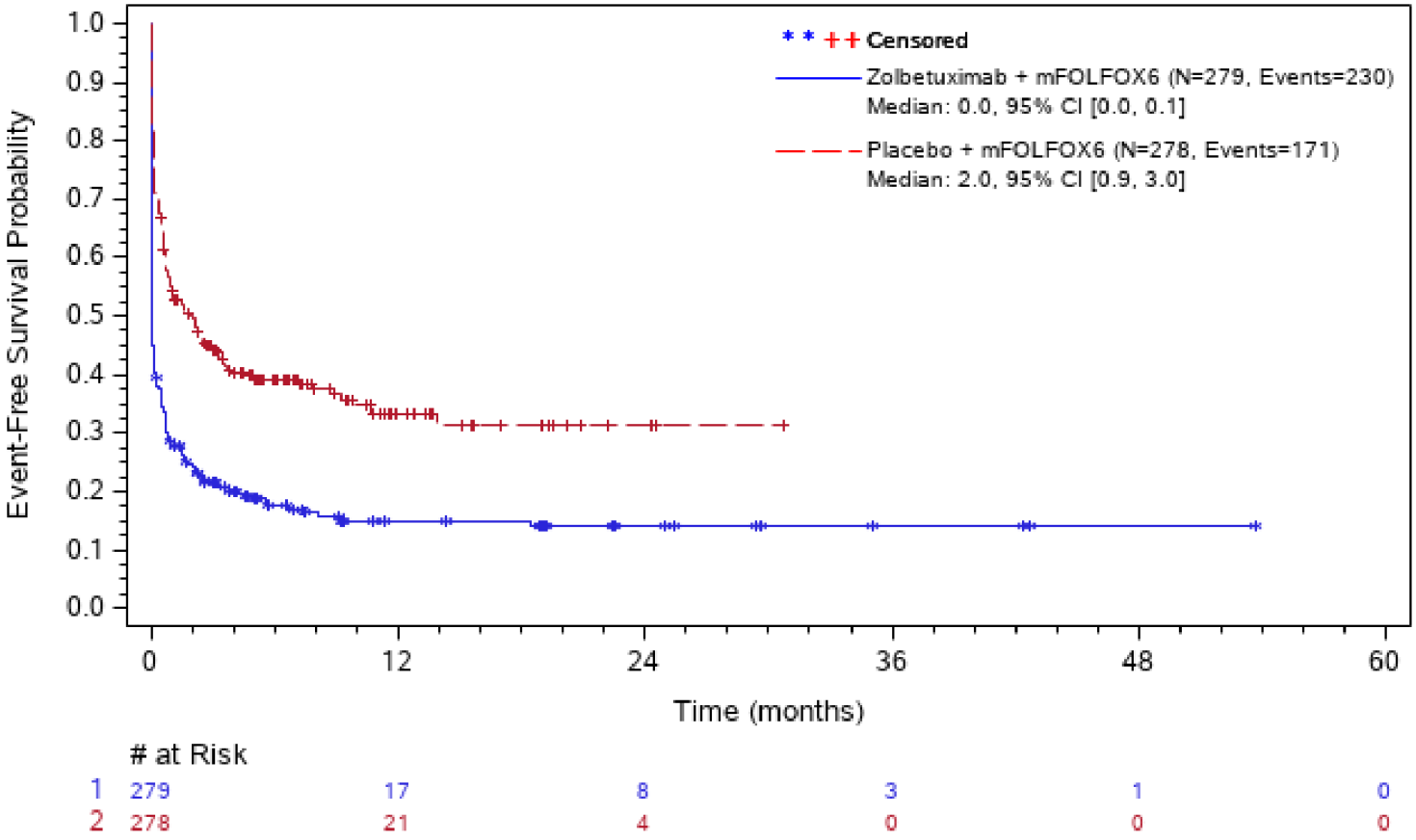
Figure 301.3.2001.220.3: Kaplan-Meier Plot of Time to first TEAE by Region - Infusion Related Reaction (AESI) - Safety Analysis Set
IRT- Region Subject is Enrolling In: Non-Asia



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: 08SEP23

The SAS System

Figure 301.3.2001.221: Kaplan-Meier Plot of Time to first TEAE - Nausea (AESI) - Safety Analysis Set

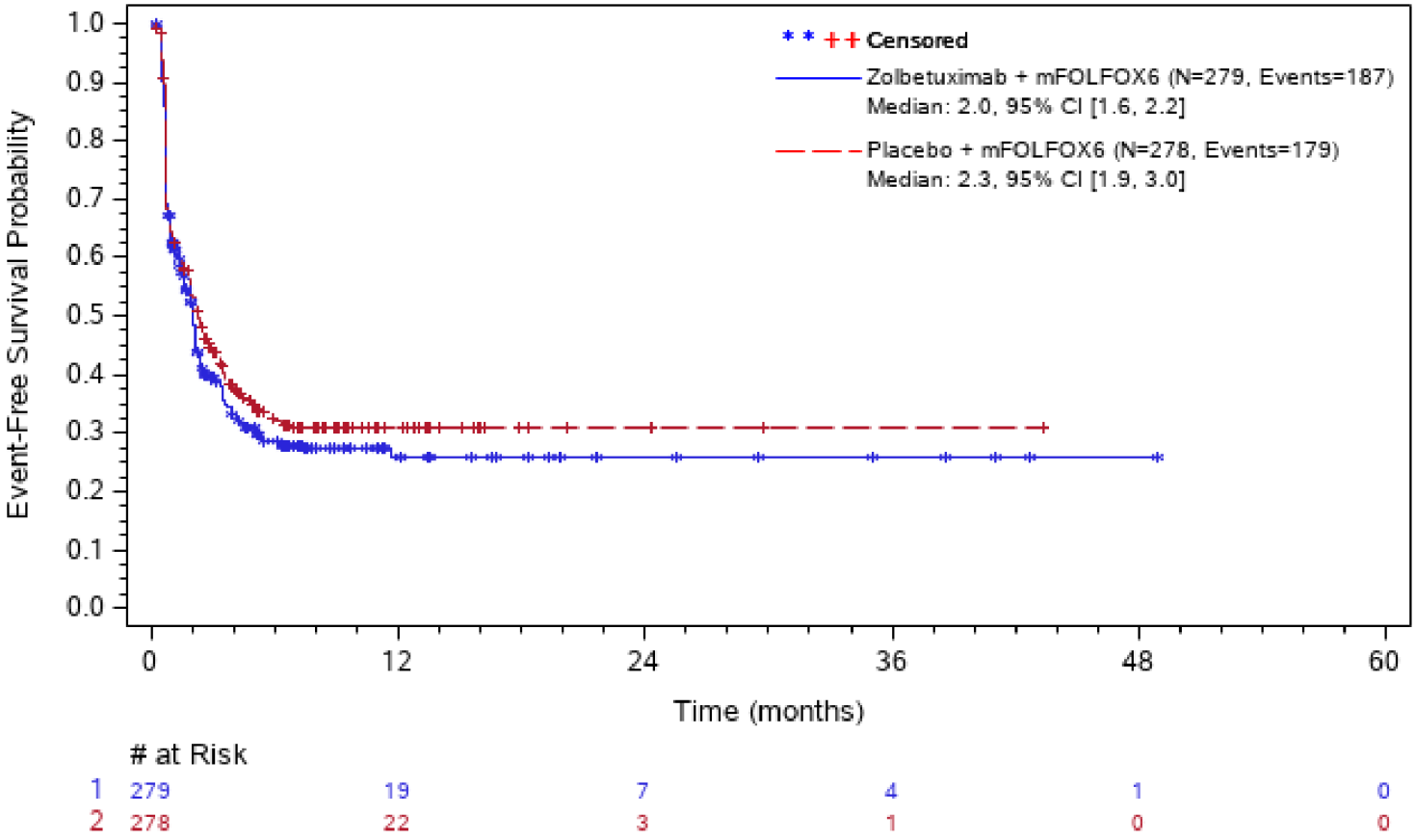


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.222: Kaplan-Meier Plot of Time to first TEAE - Neutropenia (AESI) - Safety Analysis Set

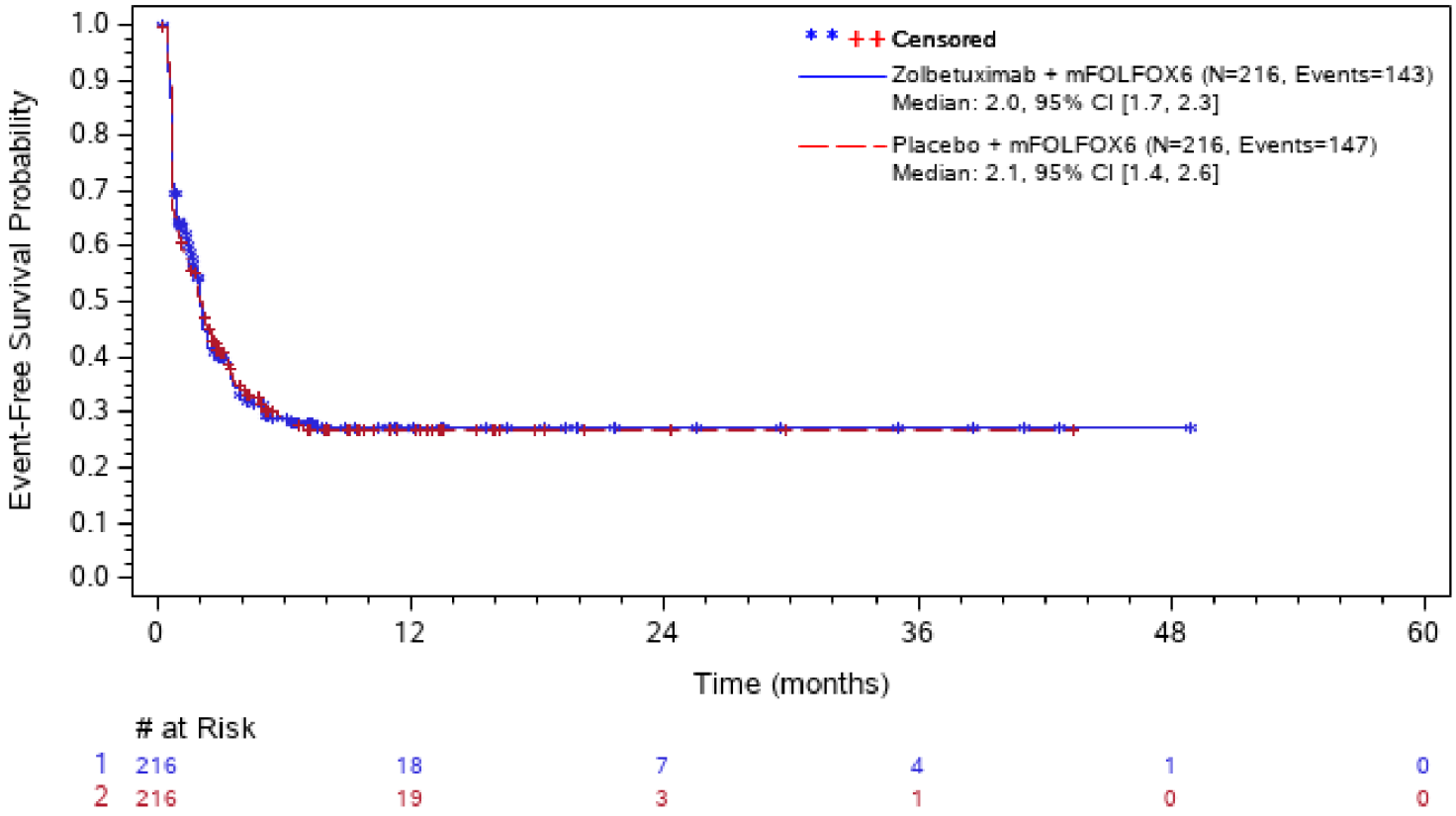


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

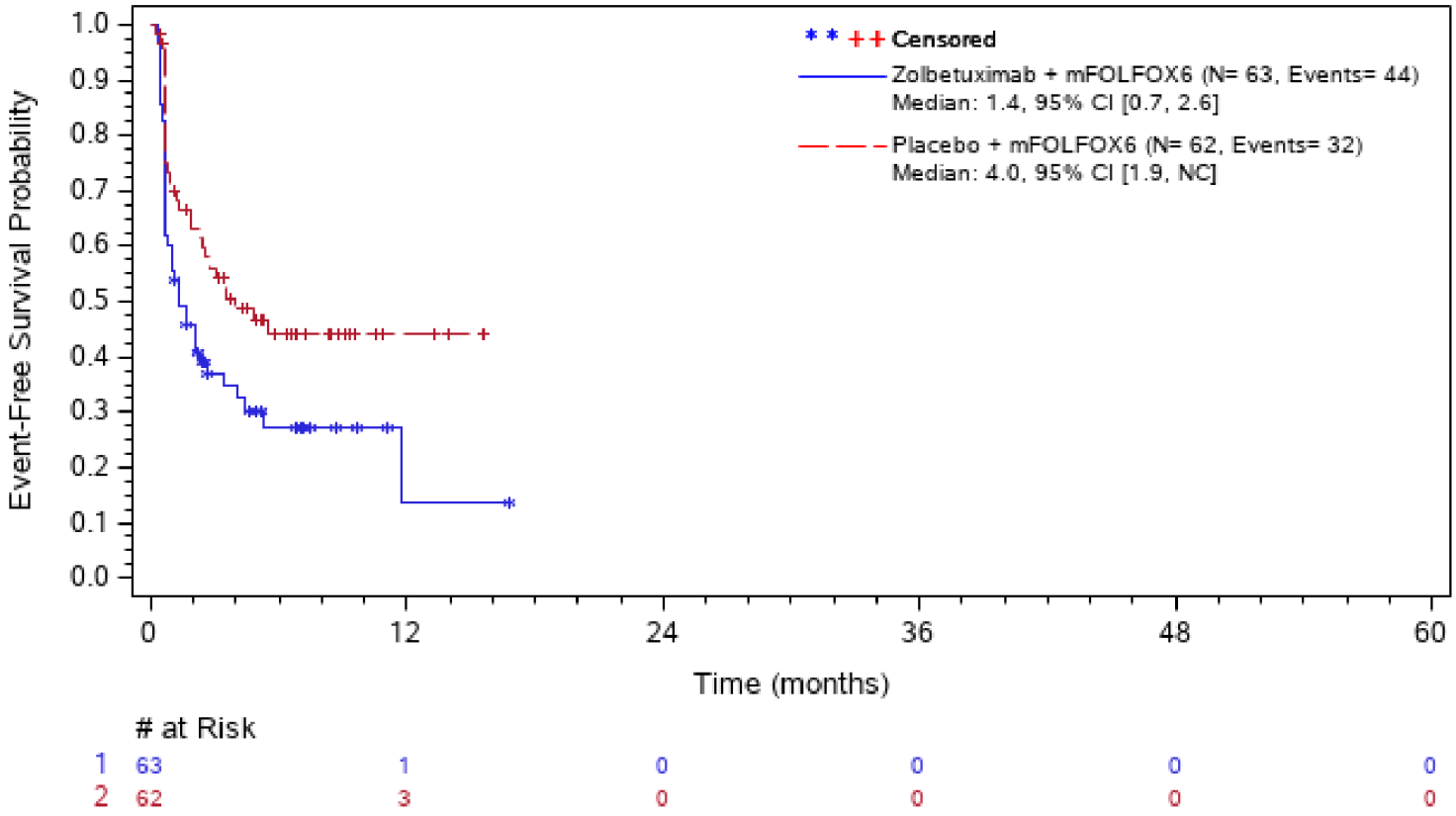
Figure 301.3.2001.222.4: Kaplan-Meier Plot of Time to first TEAE by Number of Organs with Metastatic Sites - Neutropenia (AESI) - Safety Analysis Set
IRT- Number of Metastatic Site: 0-2



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: 08SEP23

The SAS System

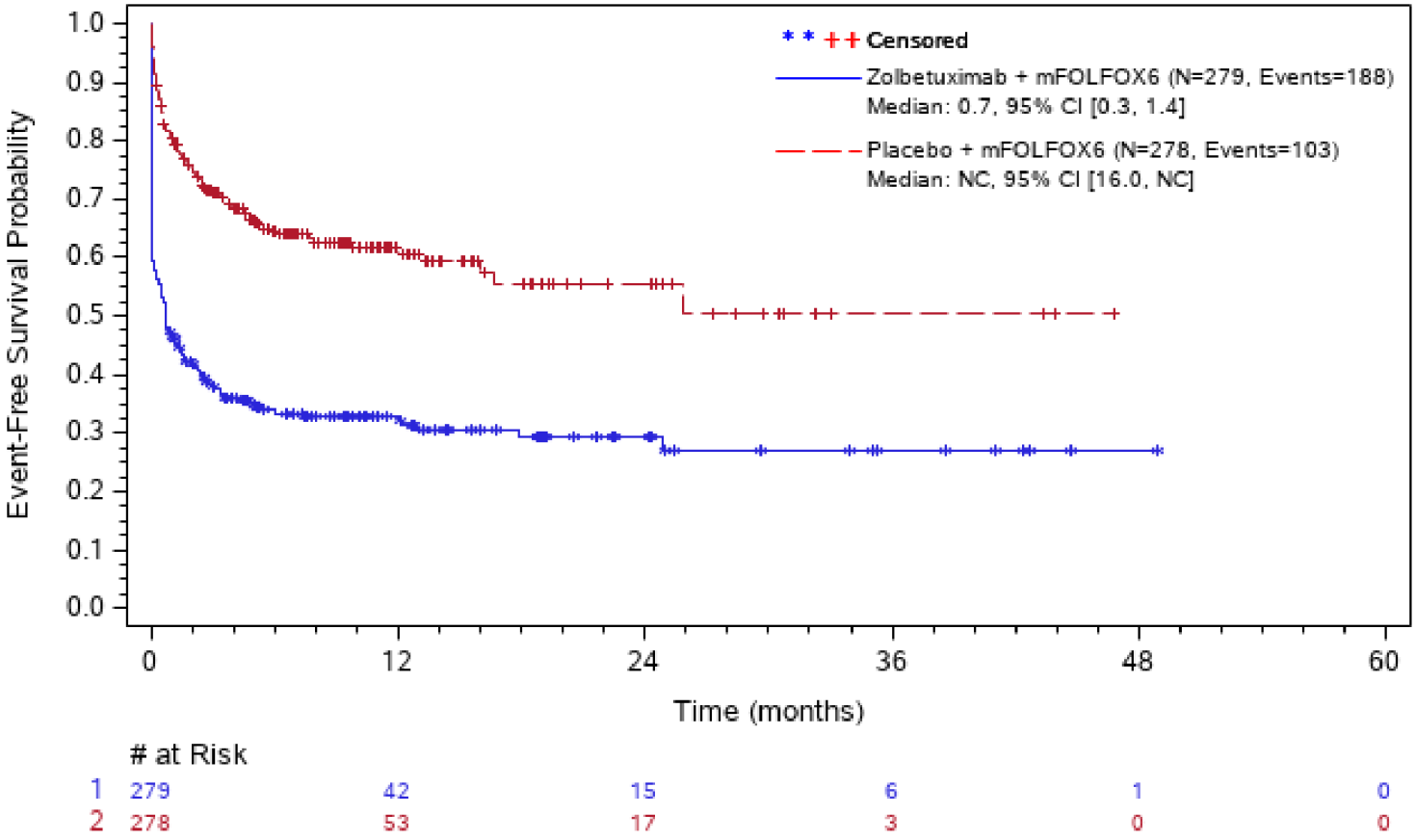
Figure 301.3.2001.222.4: Kaplan-Meier Plot of Time to first TEAE by Number of Organs with Metastatic Sites - Neutropenia (AESI) - Safety Analysis Set
IRT- Number of Metastatic Site: >=3



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: 08SEP23

The SAS System

Figure 301.3.2001.223: Kaplan-Meier Plot of Time to first TEAE - Vomiting (AESI) - Safety Analysis Set

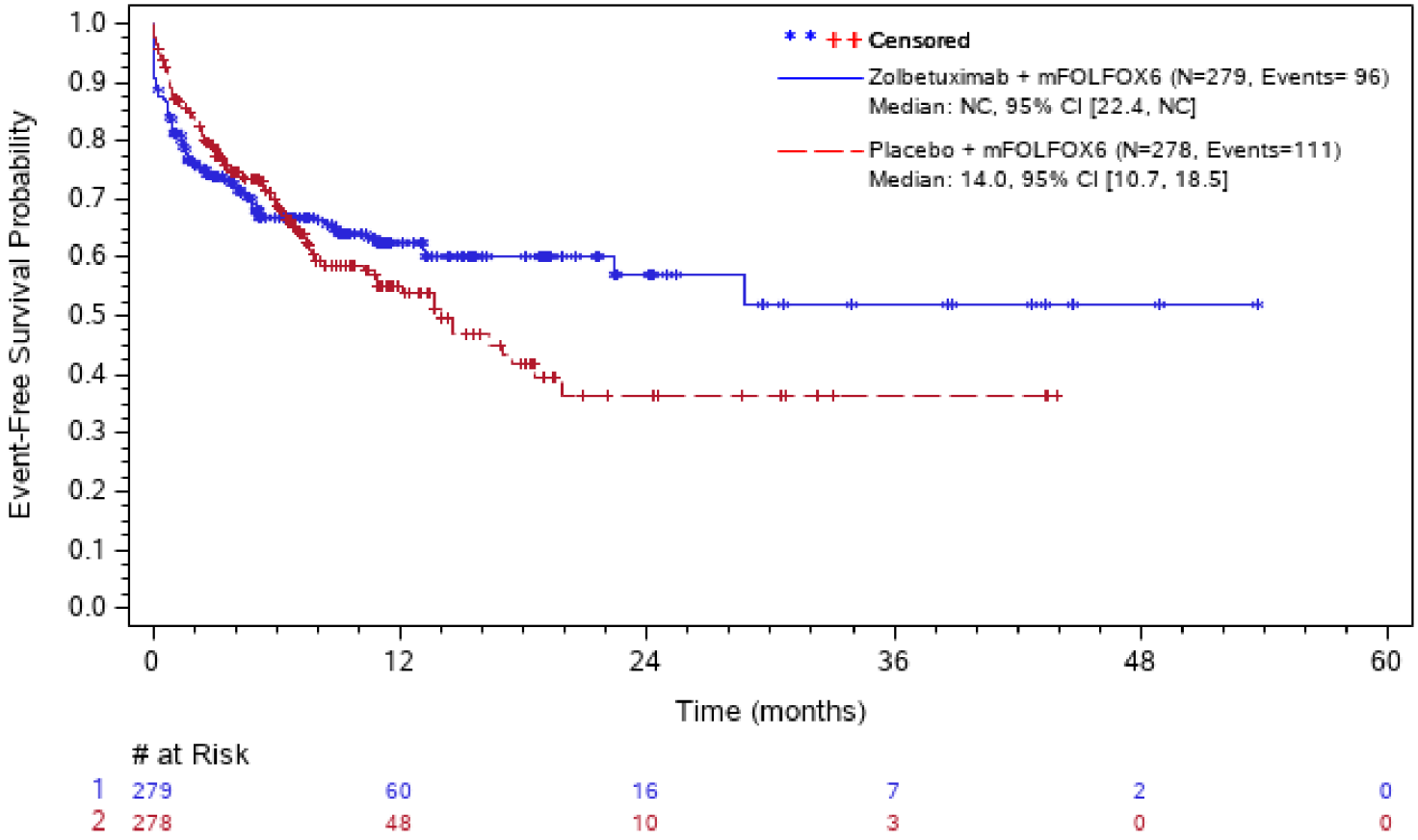


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.224: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set

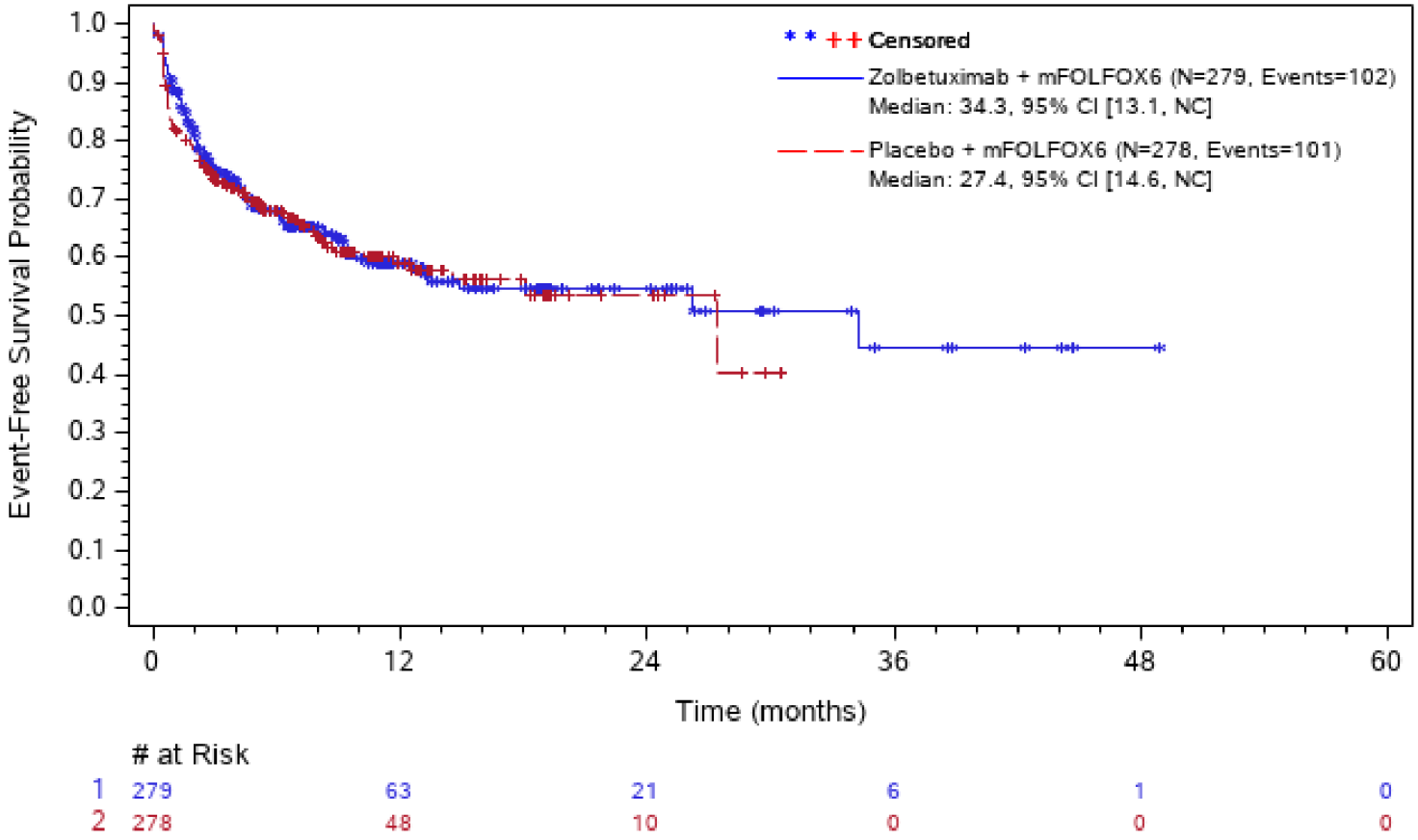


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.225: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Anemia (AESI) - Safety Analysis Set



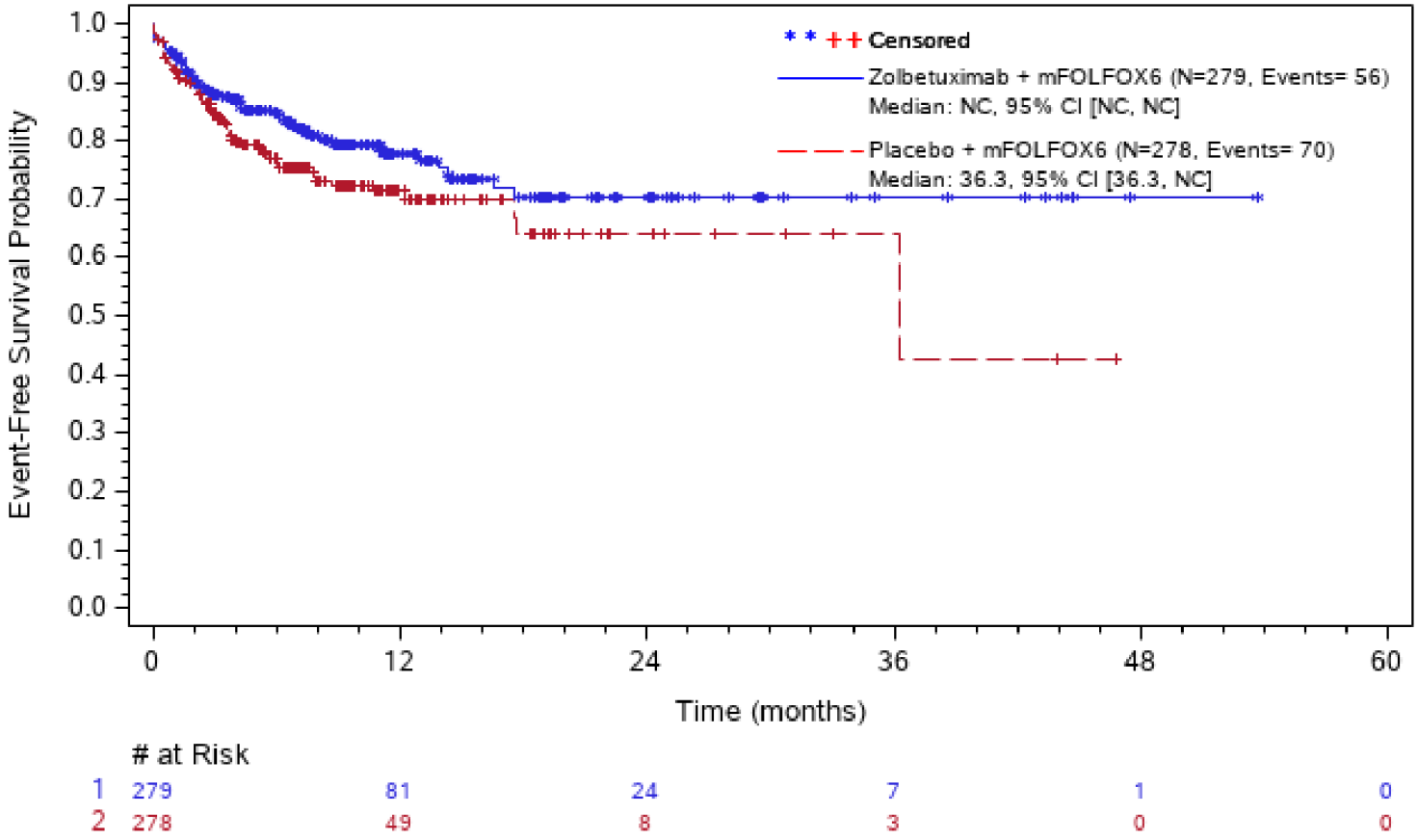
	# at Risk					
1	279	63	21	6	1	0
2	278	48	10	0	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.226: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set



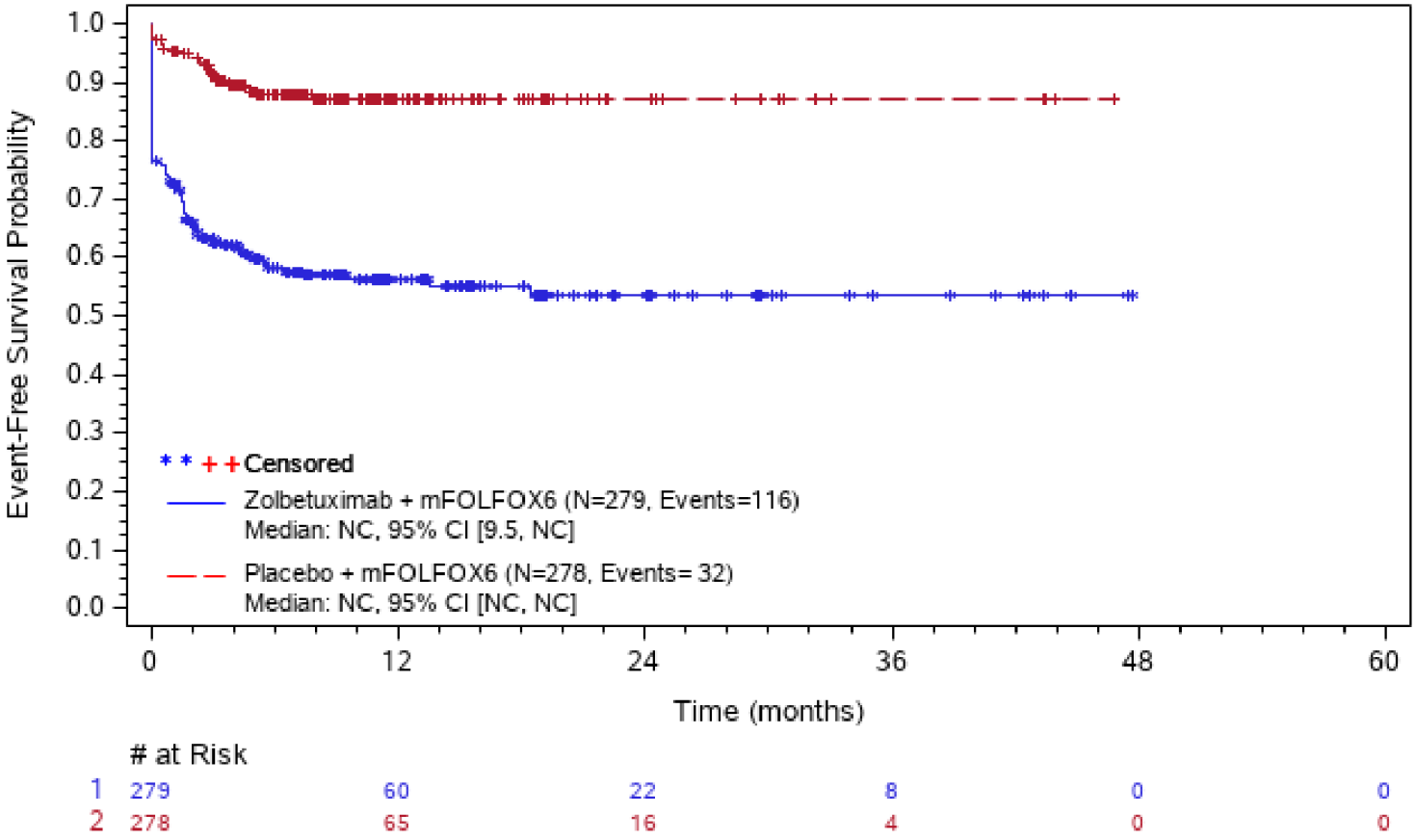
	# at Risk					
1	279	81	24	7	1	0
2	278	49	8	3	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.227: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set

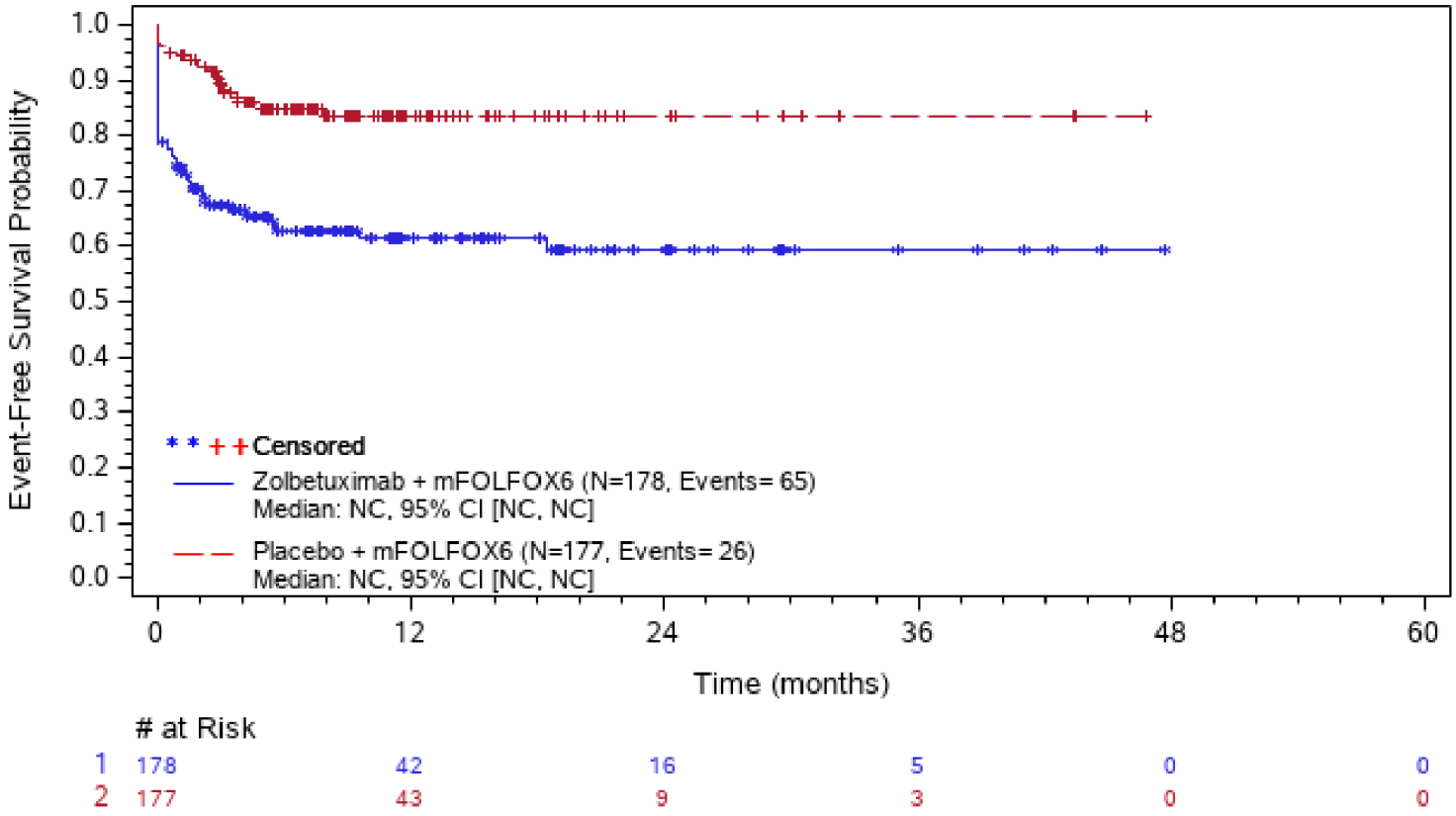


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

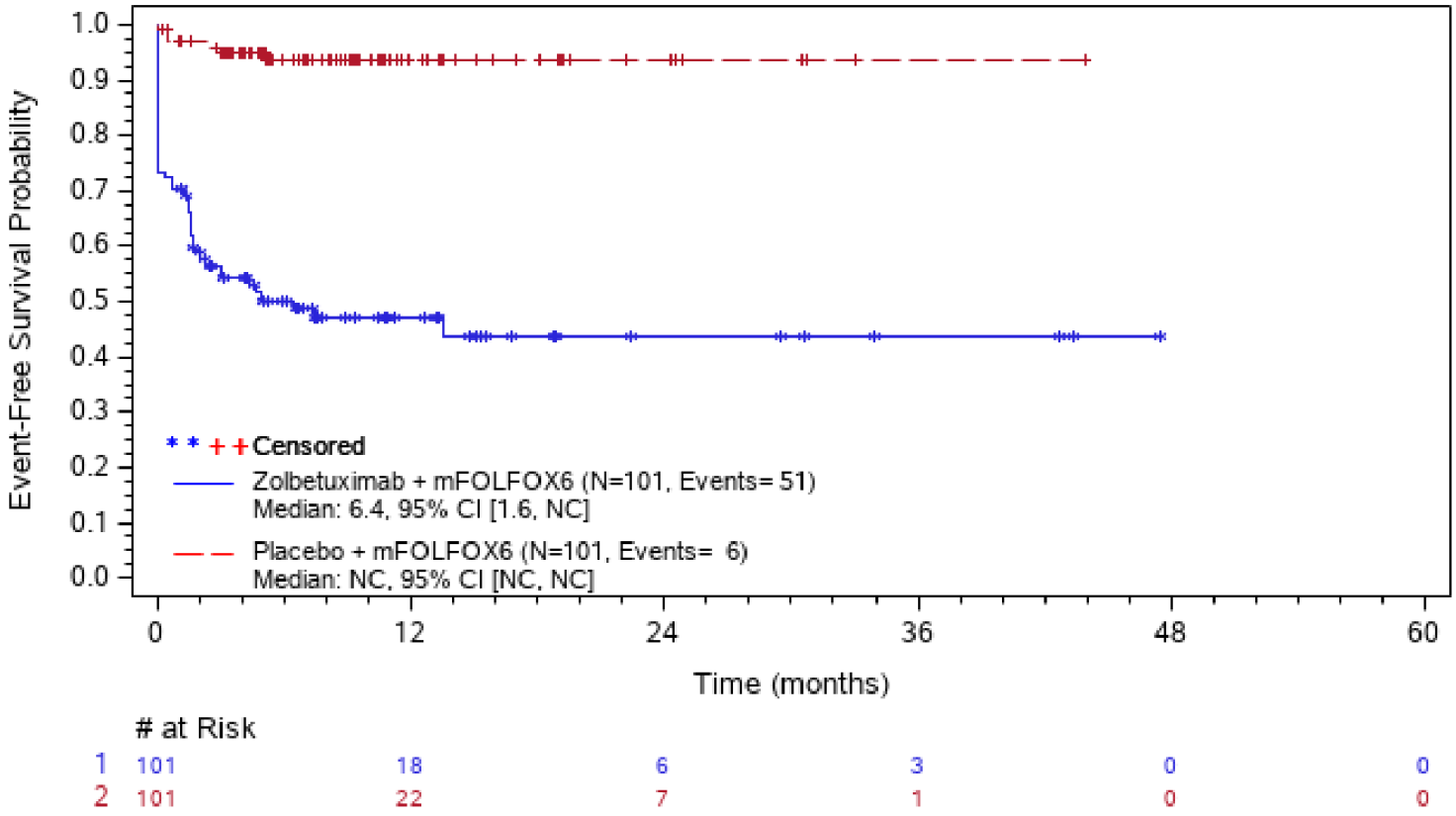
Figure 301.3.2001.227.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set
Pooled Age Group 1: <=65 years



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: 08SEP23

The SAS System

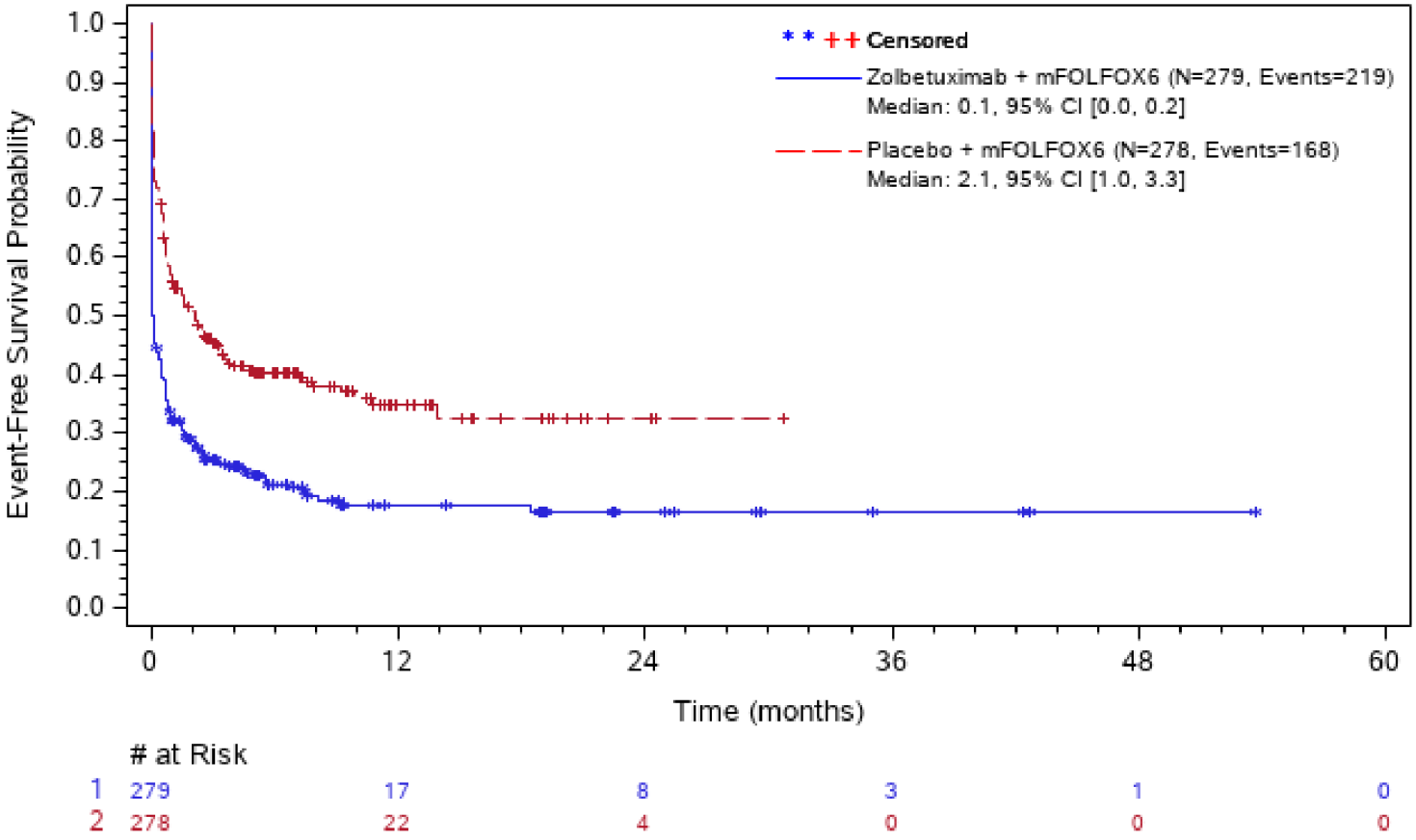
Figure 301.3.2001.227.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Infusion Related Reaction (AESI) - Safety Analysis Set
Pooled Age Group 1: >65 years



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: 08SEP23

The SAS System

Figure 301.3.2001.228: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Nausea (AESI) - Safety Analysis Set

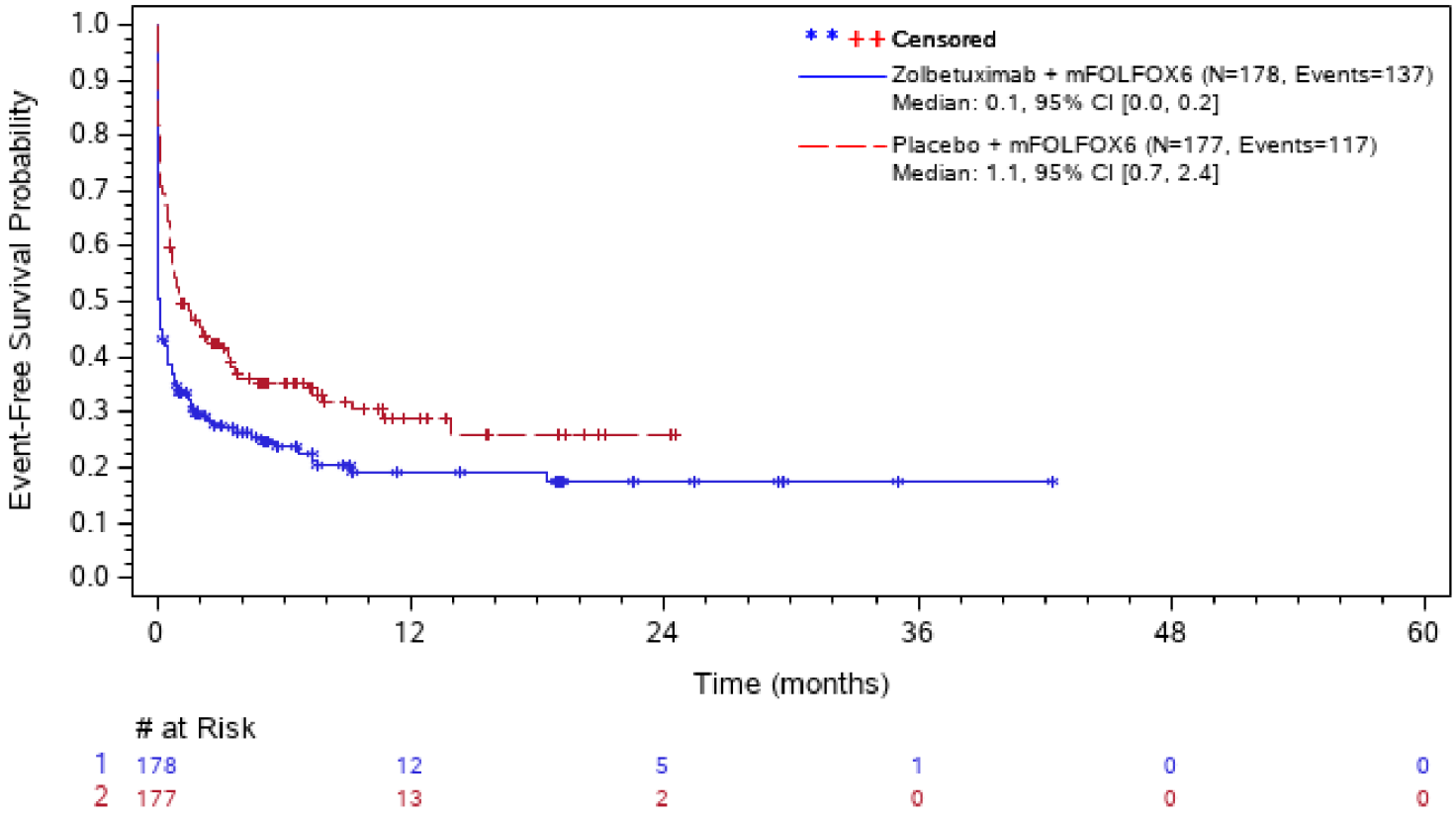


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

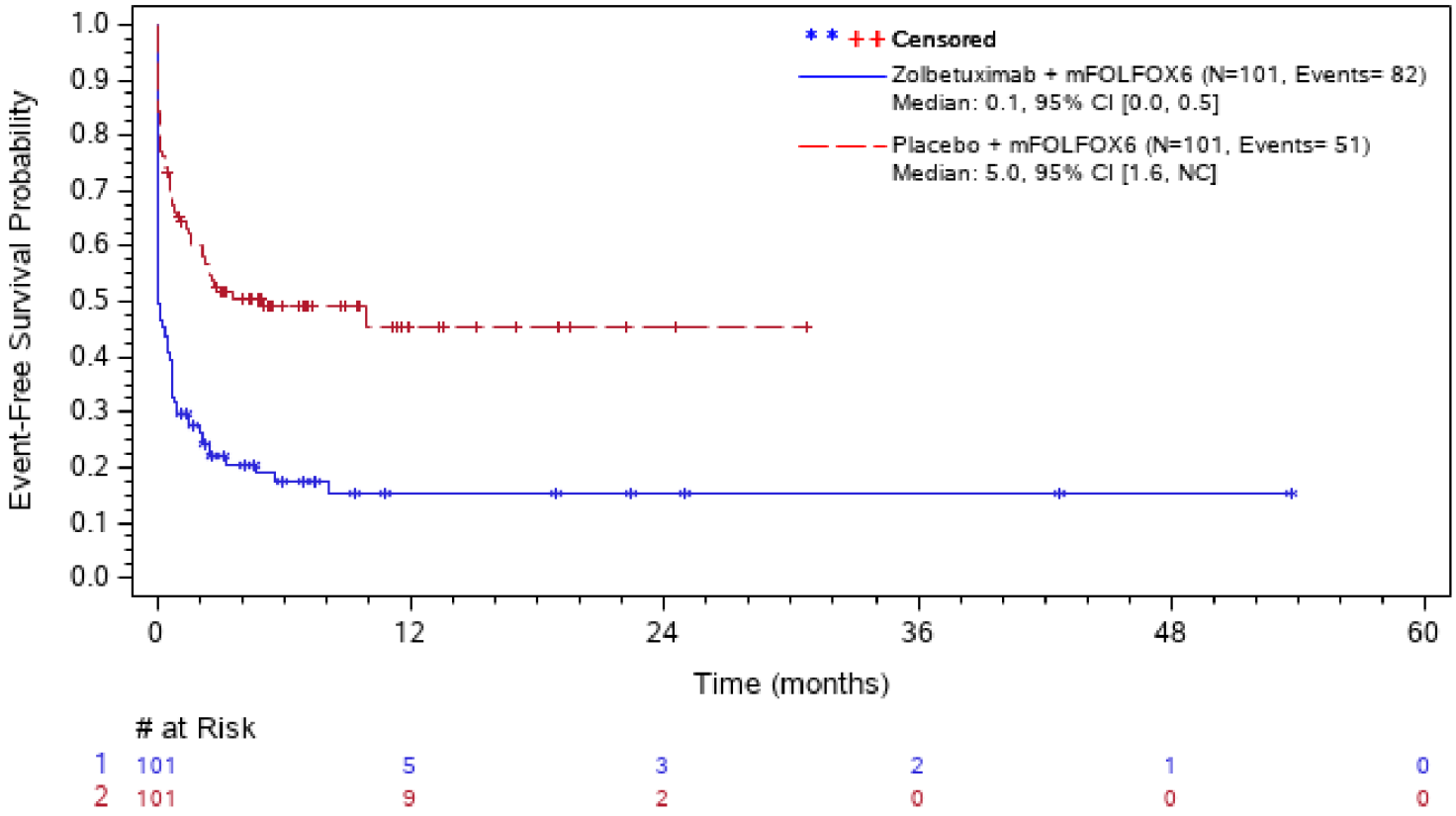
Figure 301.3.2001.228.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set
Pooled Age Group 1: <=65 years



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: 08SEP23

The SAS System

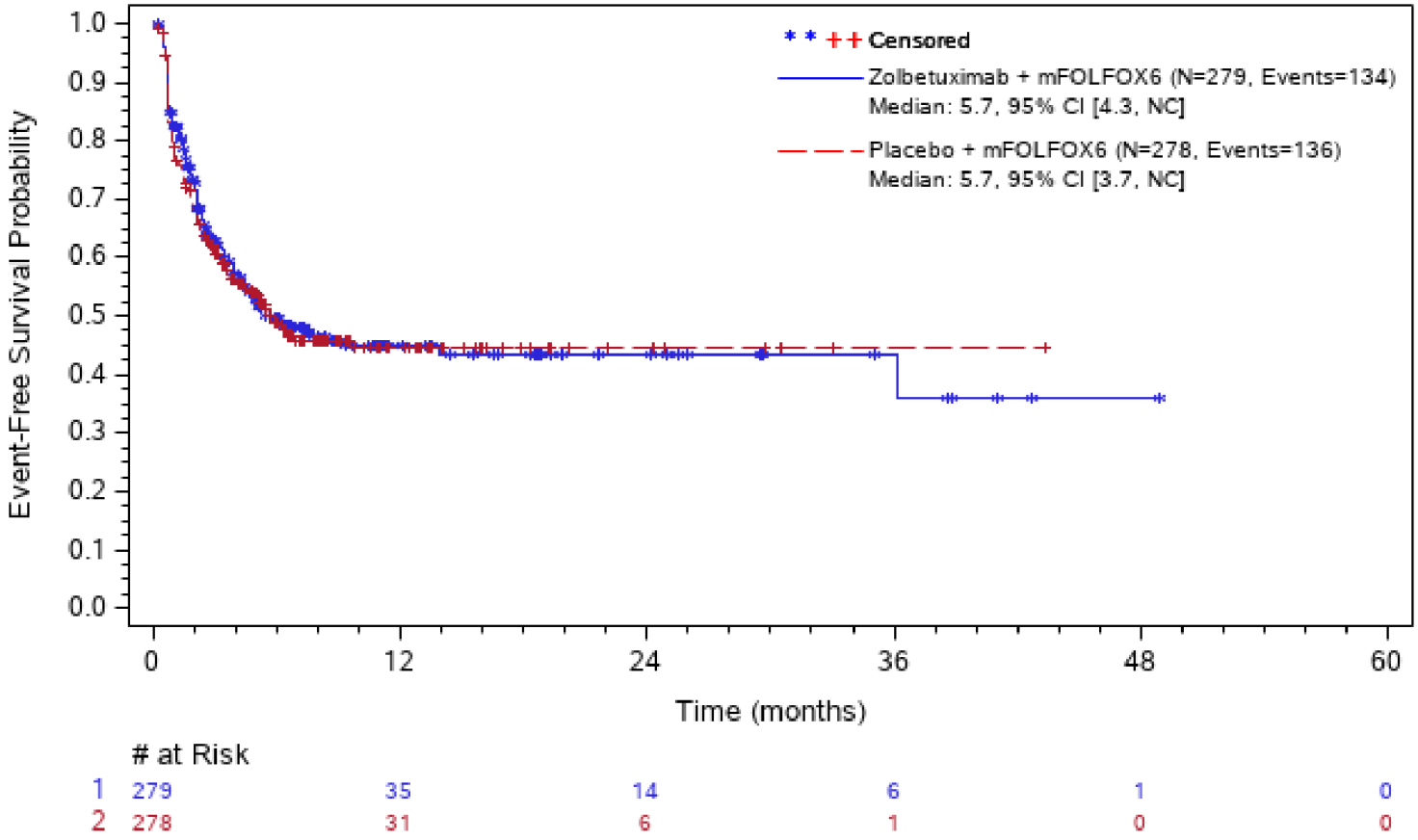
Figure 301.3.2001.228.1: Kaplan-Meier Plot of Time to first Non-Severe TEAE by Age Group 1 - Nausea (AESI) - Safety Analysis Set
Pooled Age Group 1: >65 years



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: 08SEP23

The SAS System

Figure 301.3.2001.229: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Neutropenia (AESI) - Safety Analysis Set

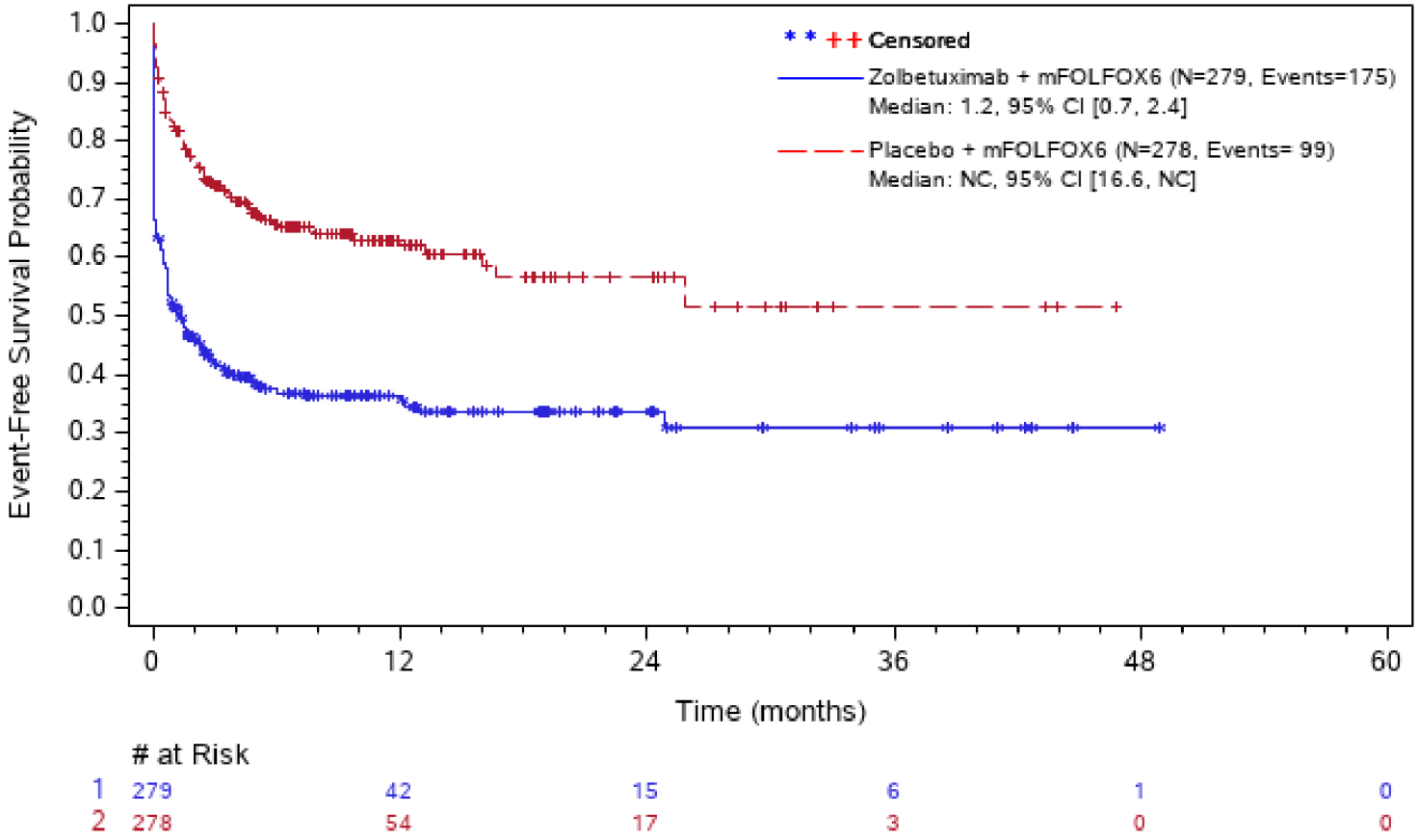


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.230: Kaplan-Meier Plot of Time to first Non-Severe TEAE - Vomiting (AESI) - Safety Analysis Set

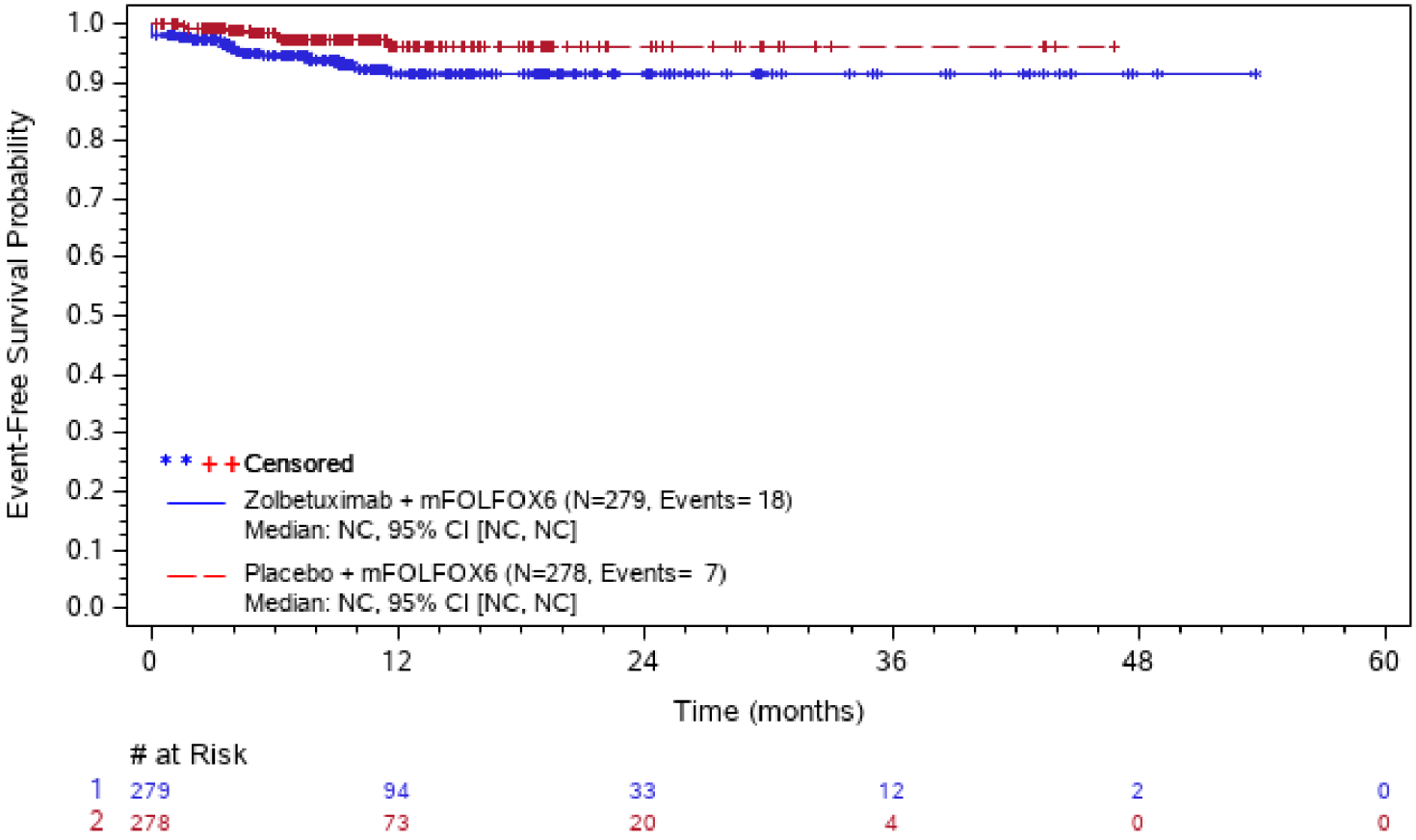


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.231: Kaplan-Meier Plot of Time to first Severe TEAE - Abdominal Pain (AESI) - Safety Analysis Set

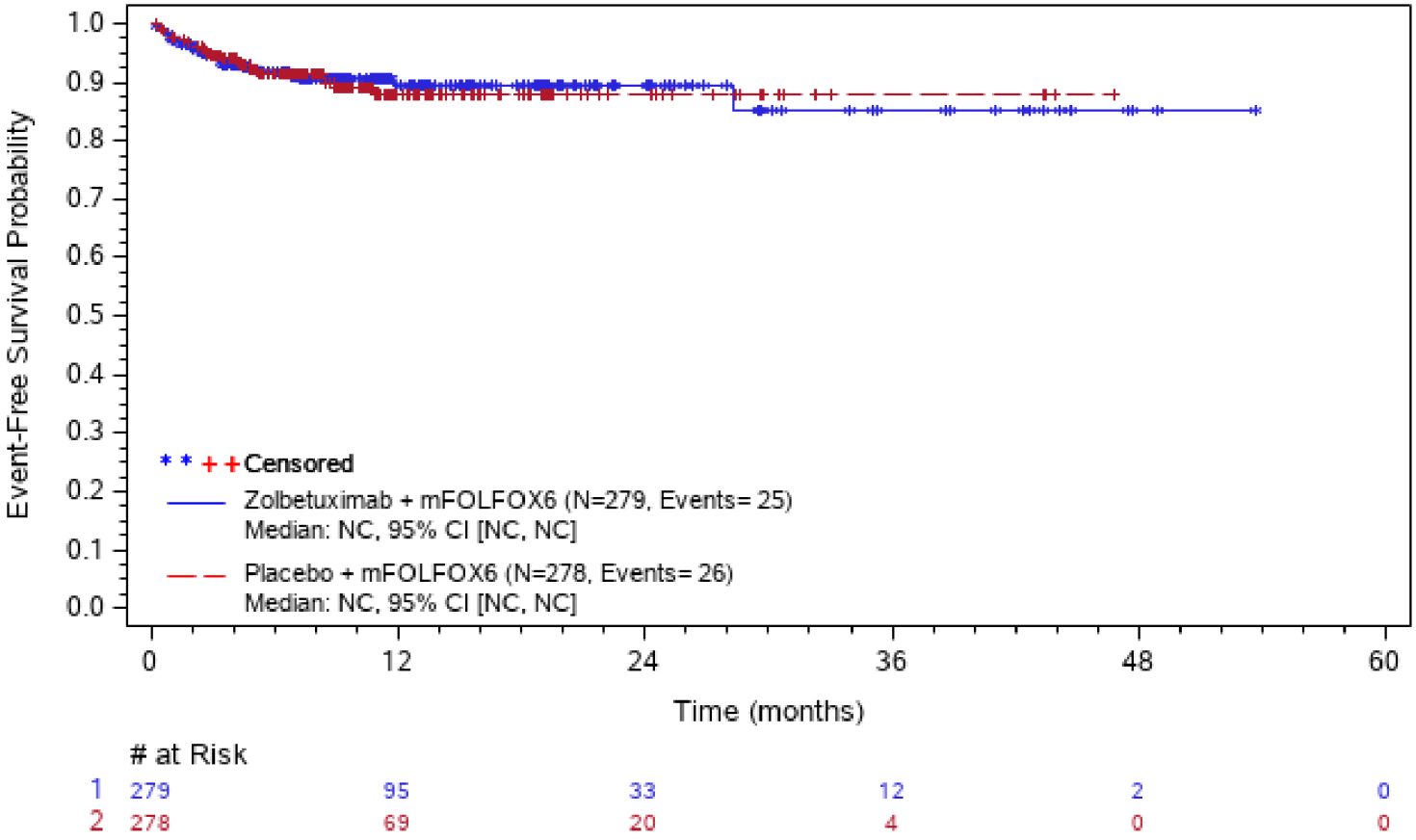


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.232: Kaplan-Meier Plot of Time to first Severe TEAE - Anemia (AESI) - Safety Analysis Set



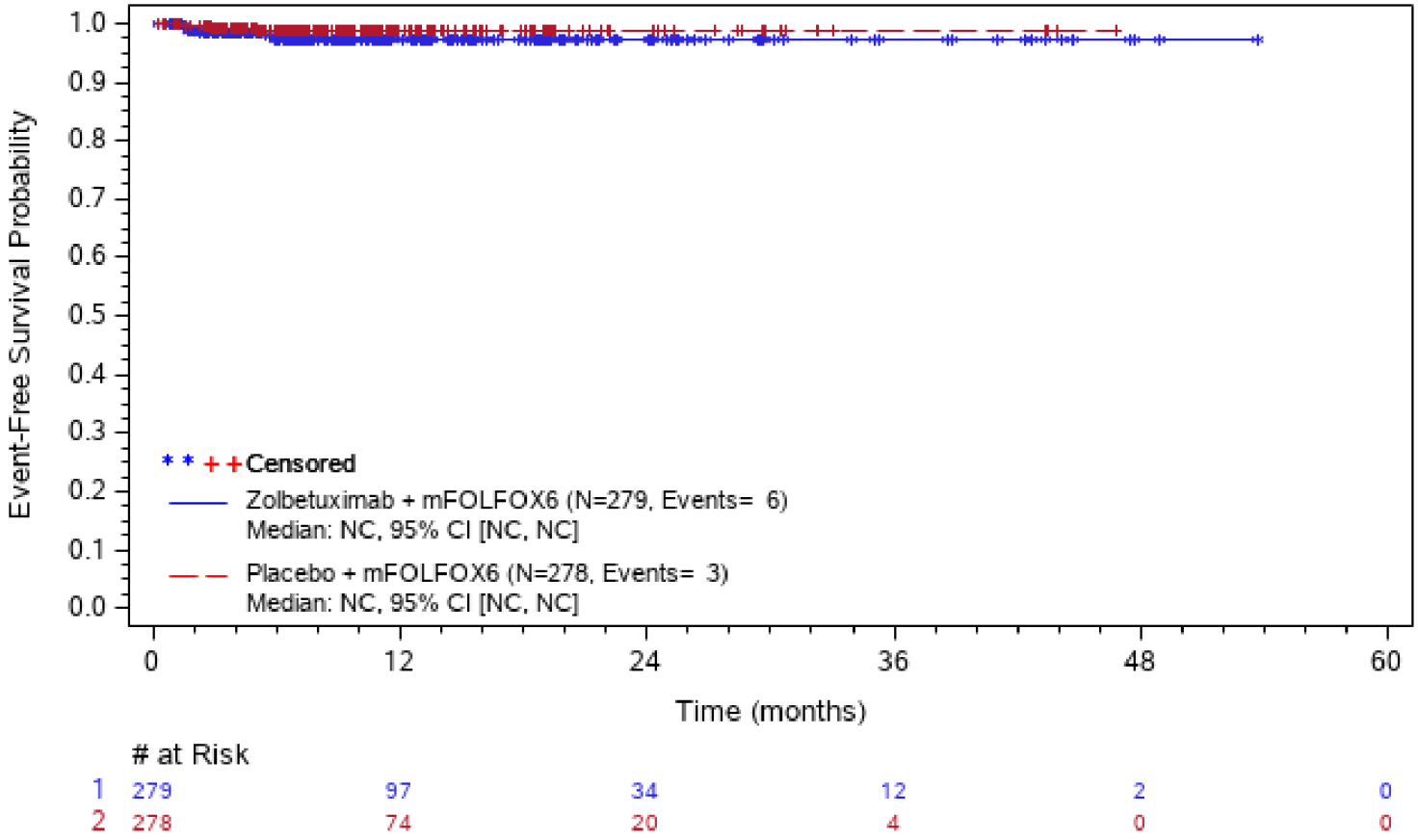
# at Risk						
1	279	95	33	12	2	0
2	278	69	20	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.233: Kaplan-Meier Plot of Time to first Severe TEAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set

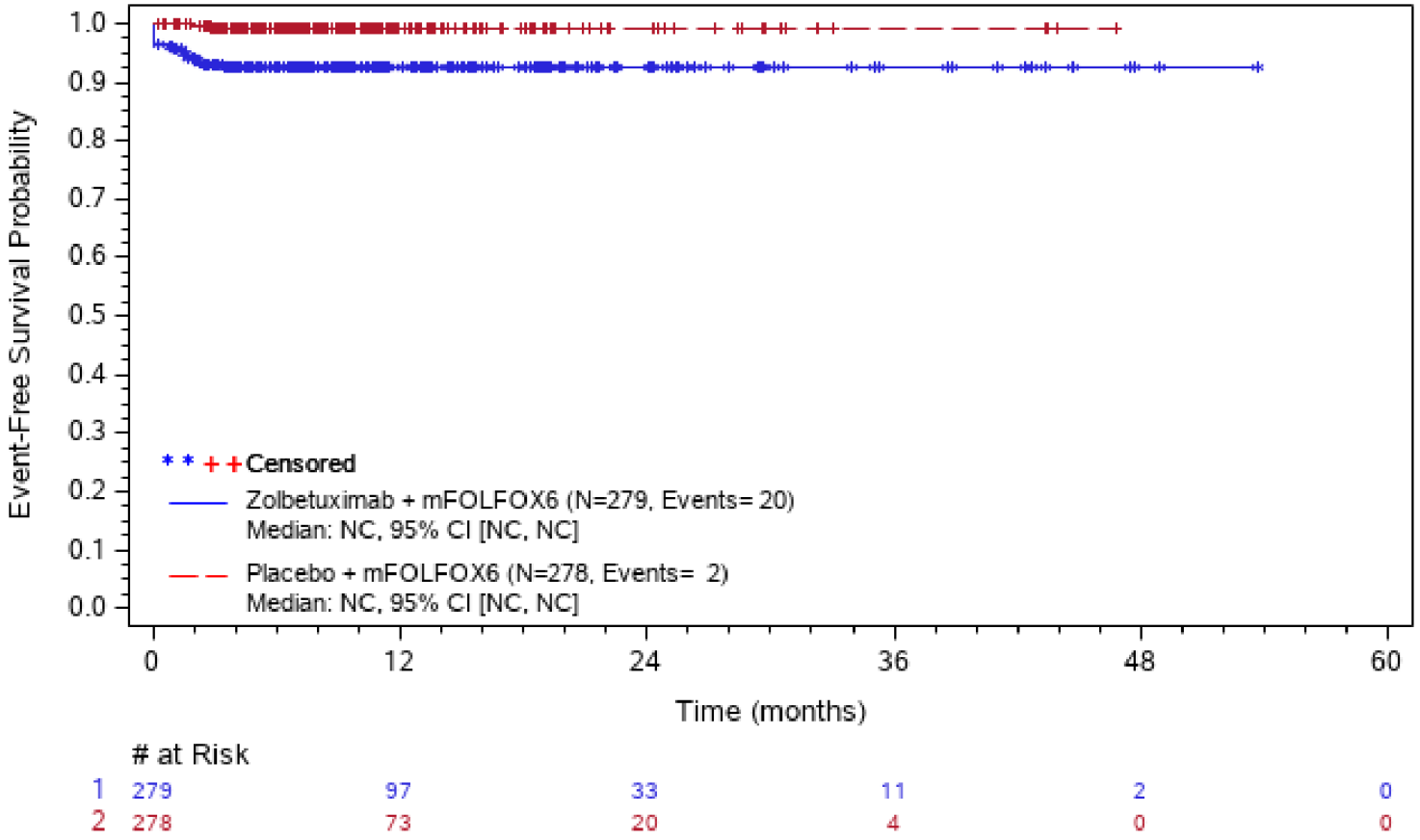


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.234: Kaplan-Meier Plot of Time to first Severe TEAE - Infusion Related Reaction (AESI) - Safety Analysis Set

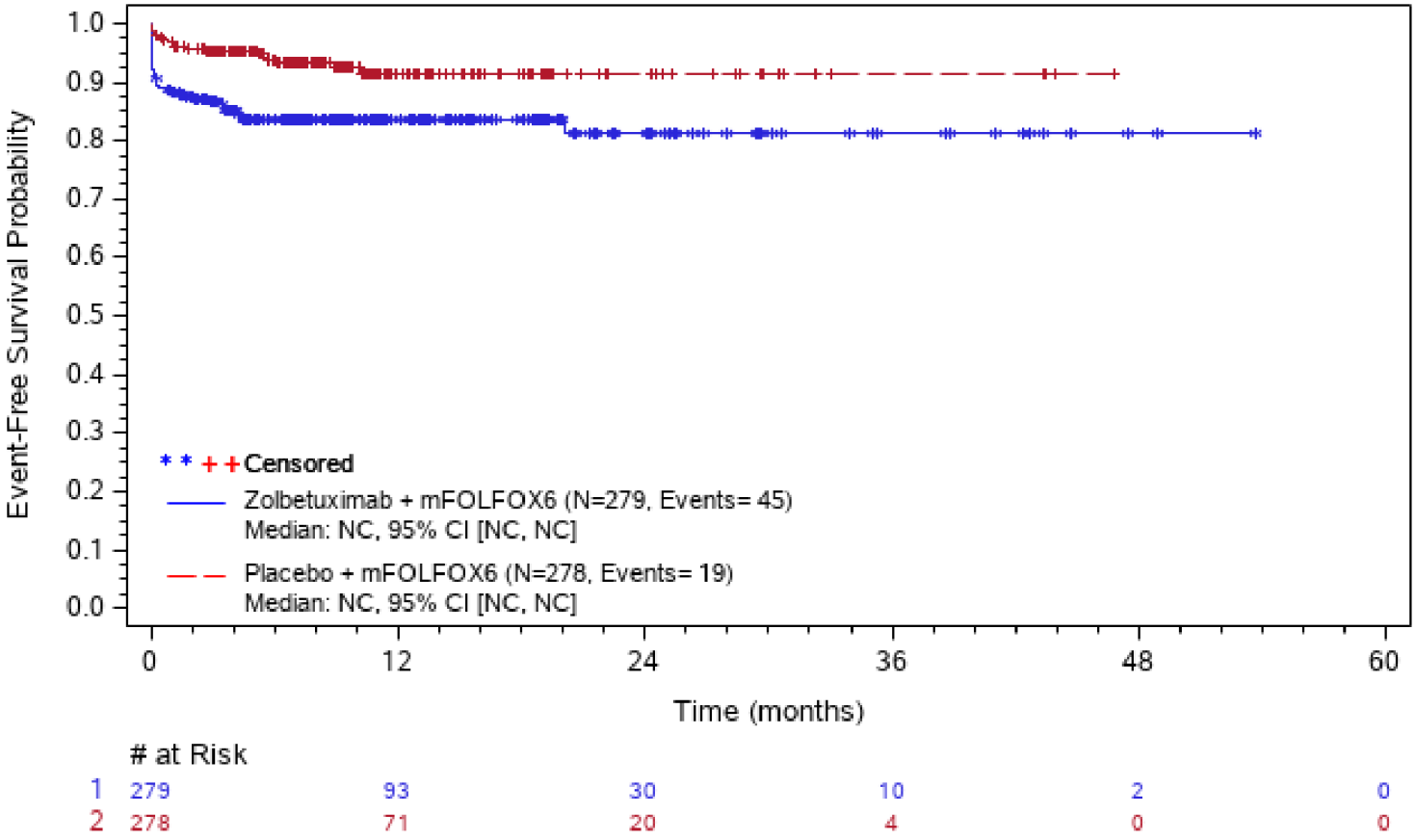


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.235: Kaplan-Meier Plot of Time to first Severe TEAE - Nausea (AESI) - Safety Analysis Set



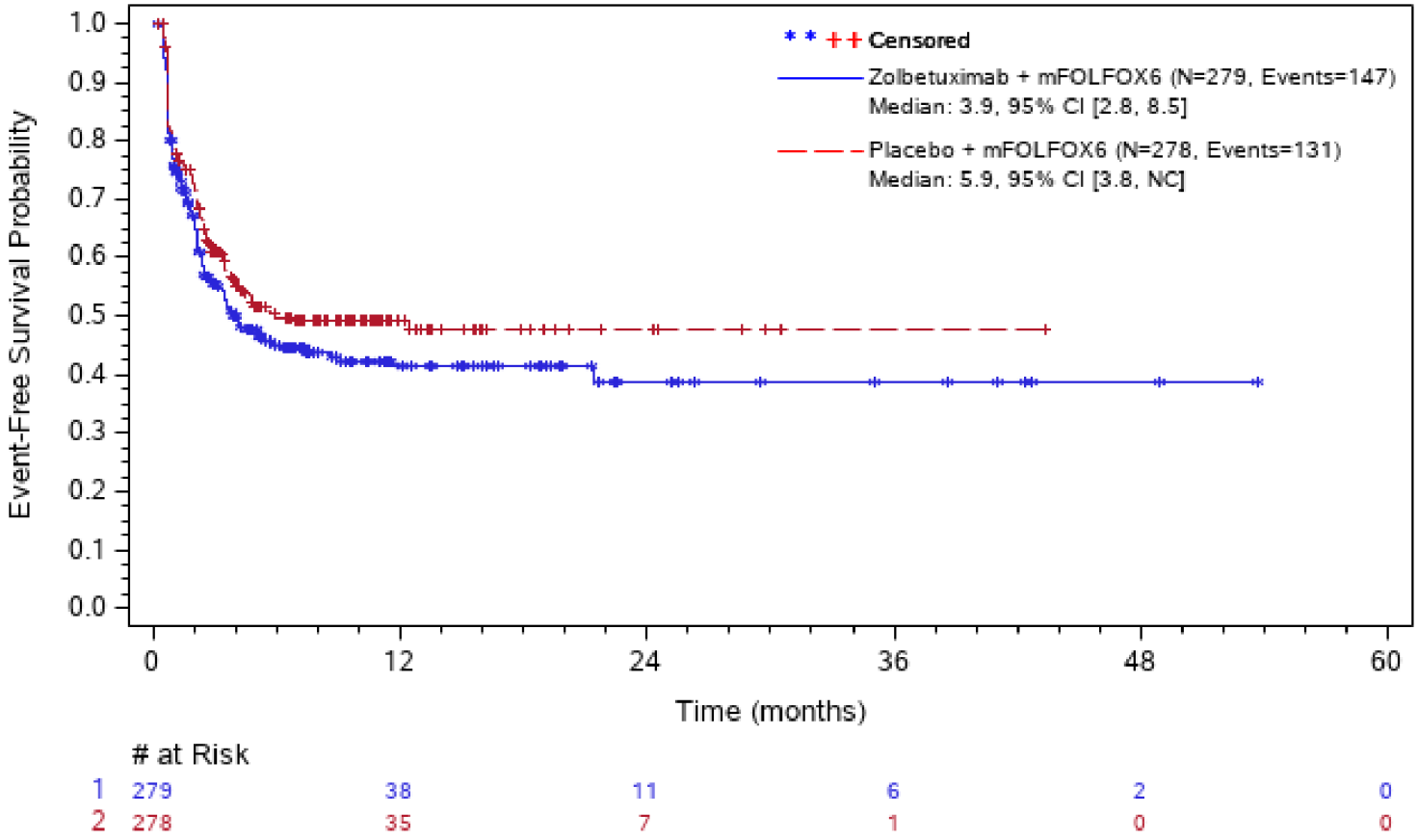
# at Risk						
1	279	93	30	10	2	0
2	278	71	20	4	0	0

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: 08SEP23

The SAS System

Figure 301.3.2001.236: Kaplan-Meier Plot of Time to first Severe TEAE - Neutropenia (AESI) - Safety Analysis Set

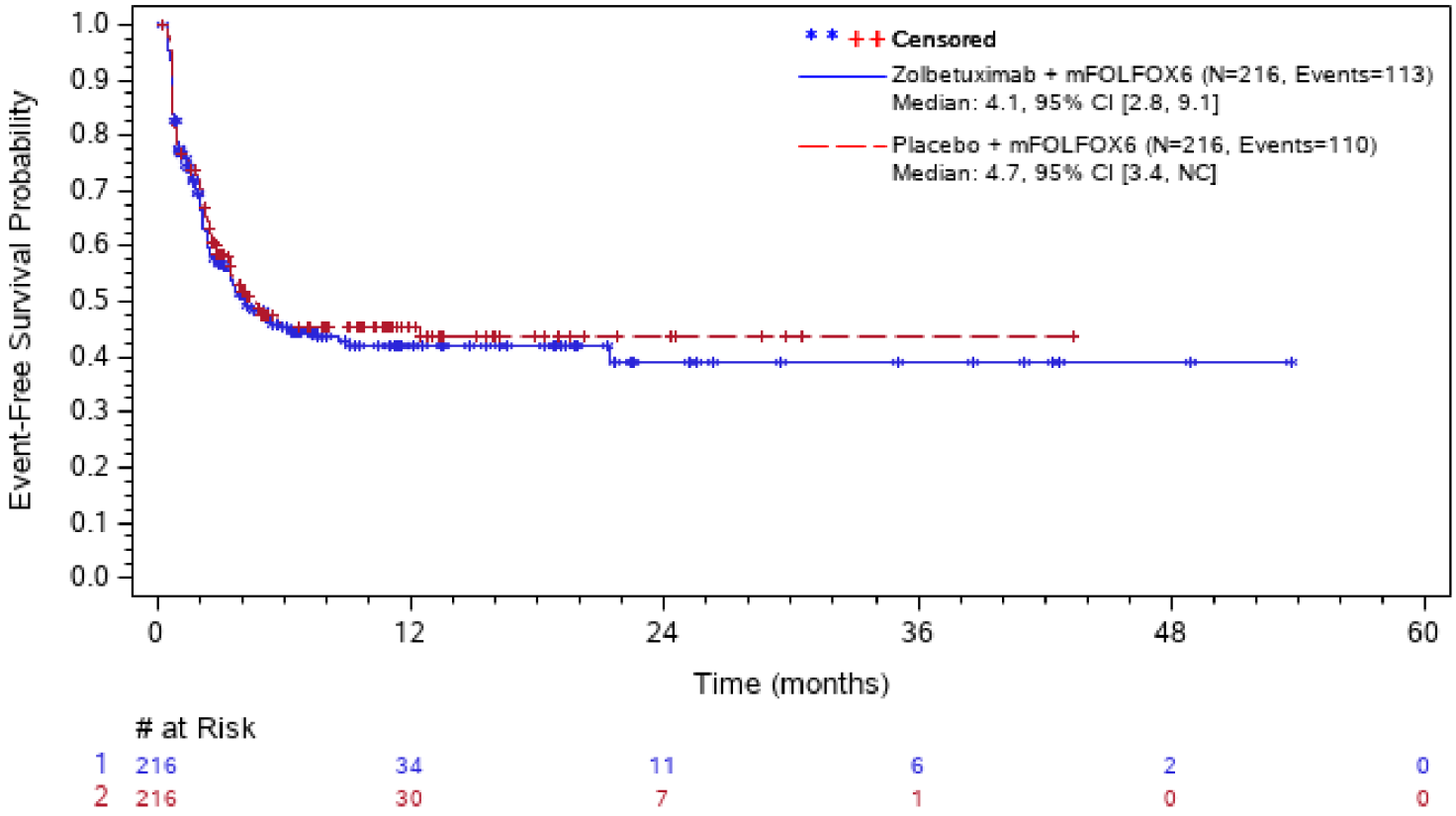


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

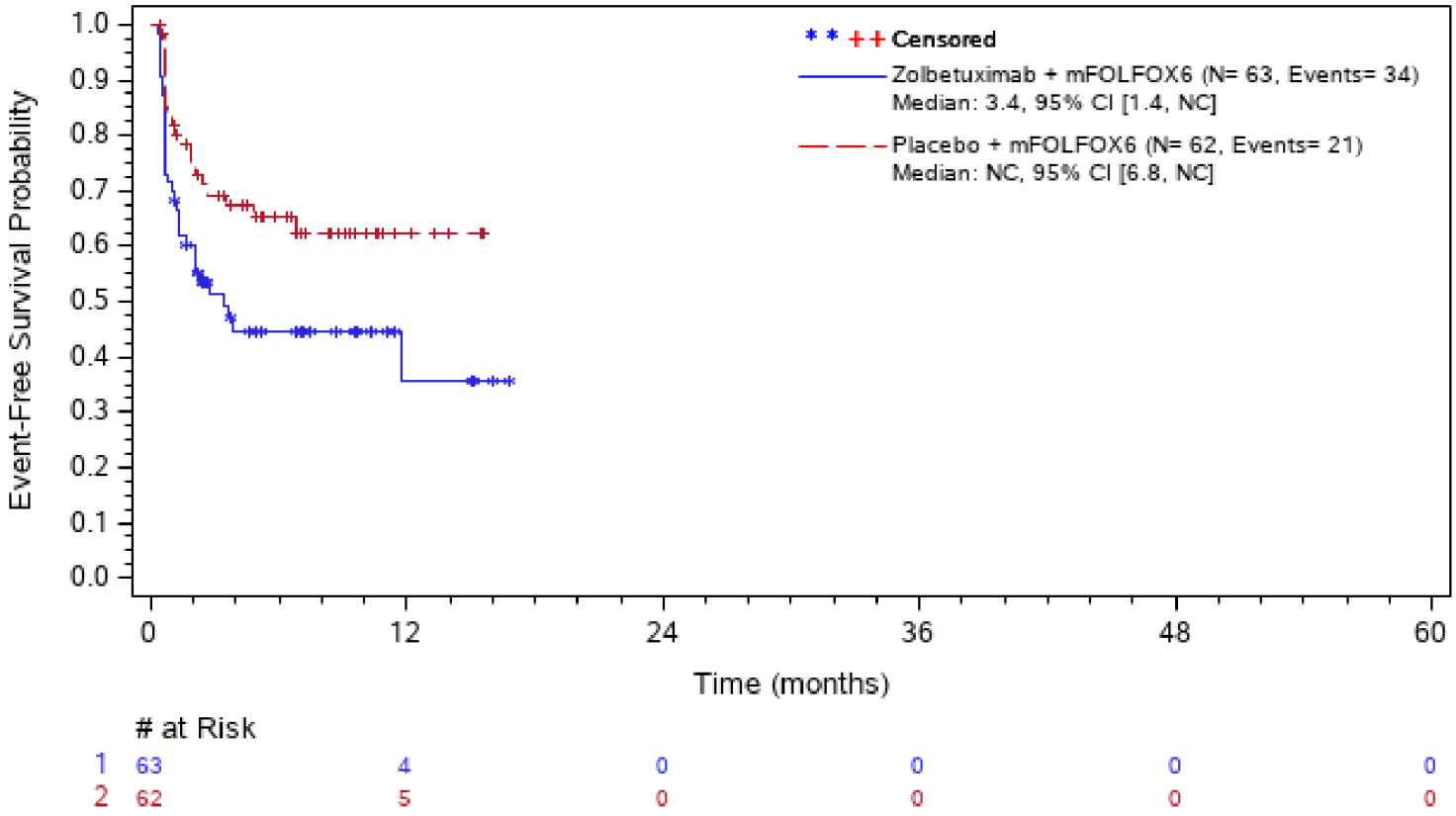
Figure 301.3.2001.236.4: Kaplan-Meier Plot of Time to first Severe TEAE by Number of Organs with Metastatic Sites - Neutropenia (AESI) - Safety Analysis Set
IRT- Number of Metastatic Site: 0-2



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: 08SEP23

The SAS System

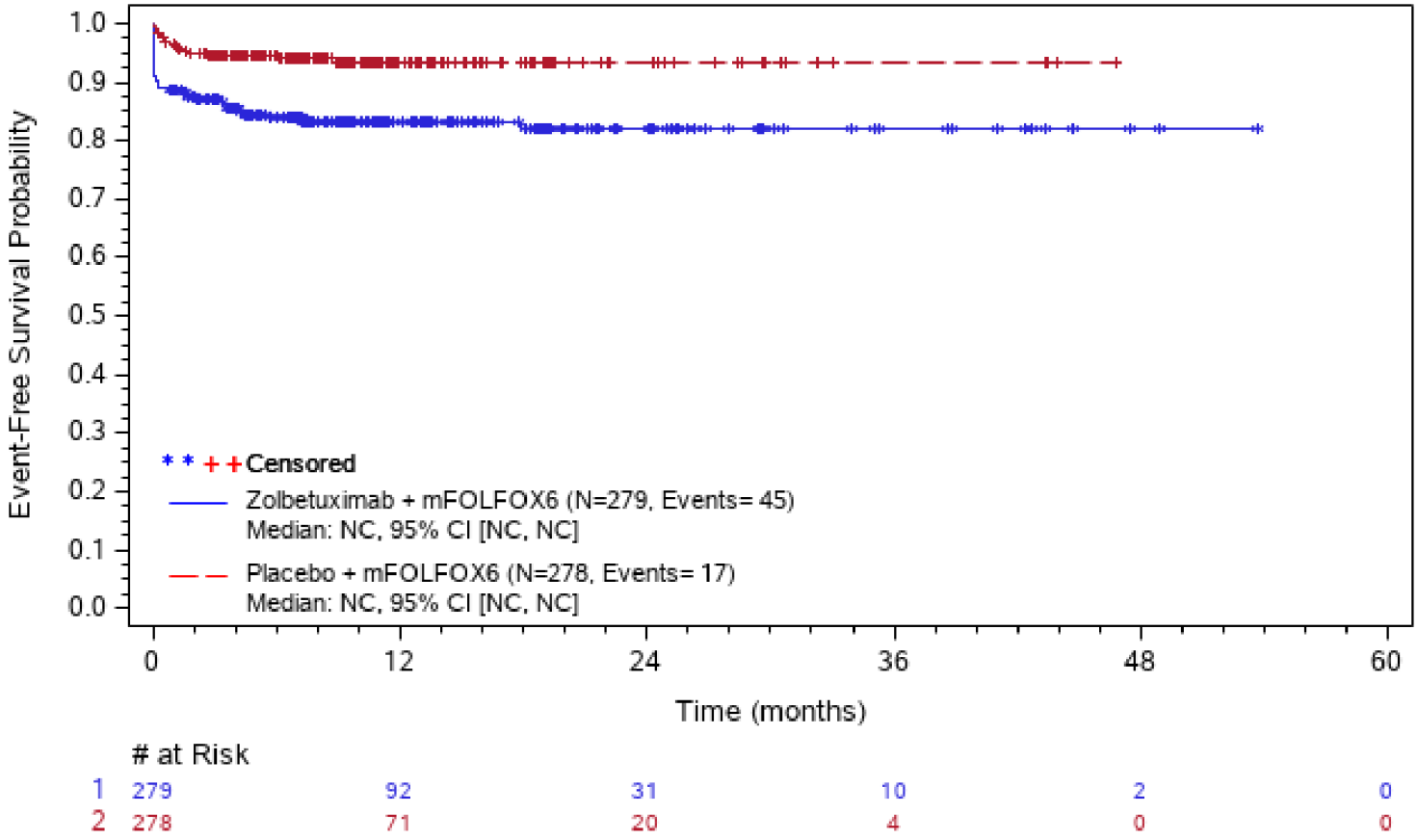
Figure 301.3.2001.236.4: Kaplan-Meier Plot of Time to first Severe TEAE by Number of Organs with Metastatic Sites - Neutropenia (AESI) - Safety Analysis Set
IRT- Number of Metastatic Site: >=3



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: 08SEP23

The SAS System

Figure 301.3.2001.237: Kaplan-Meier Plot of Time to first Severe TEAE - Vomiting (AESI) - Safety Analysis Set

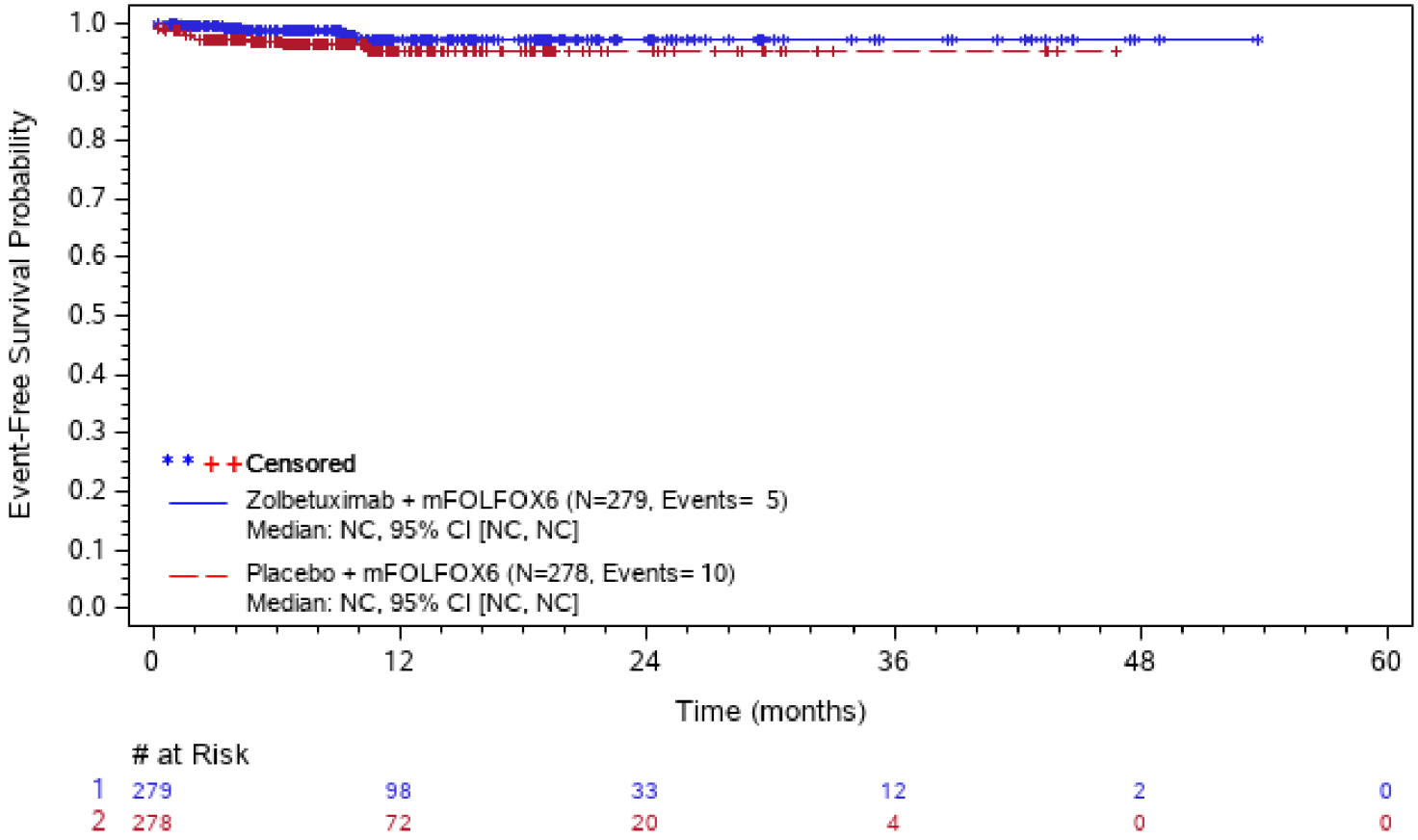


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.238: Kaplan-Meier Plot of Time to first TESAE - Abdominal Pain (AESI) - Safety Analysis Set

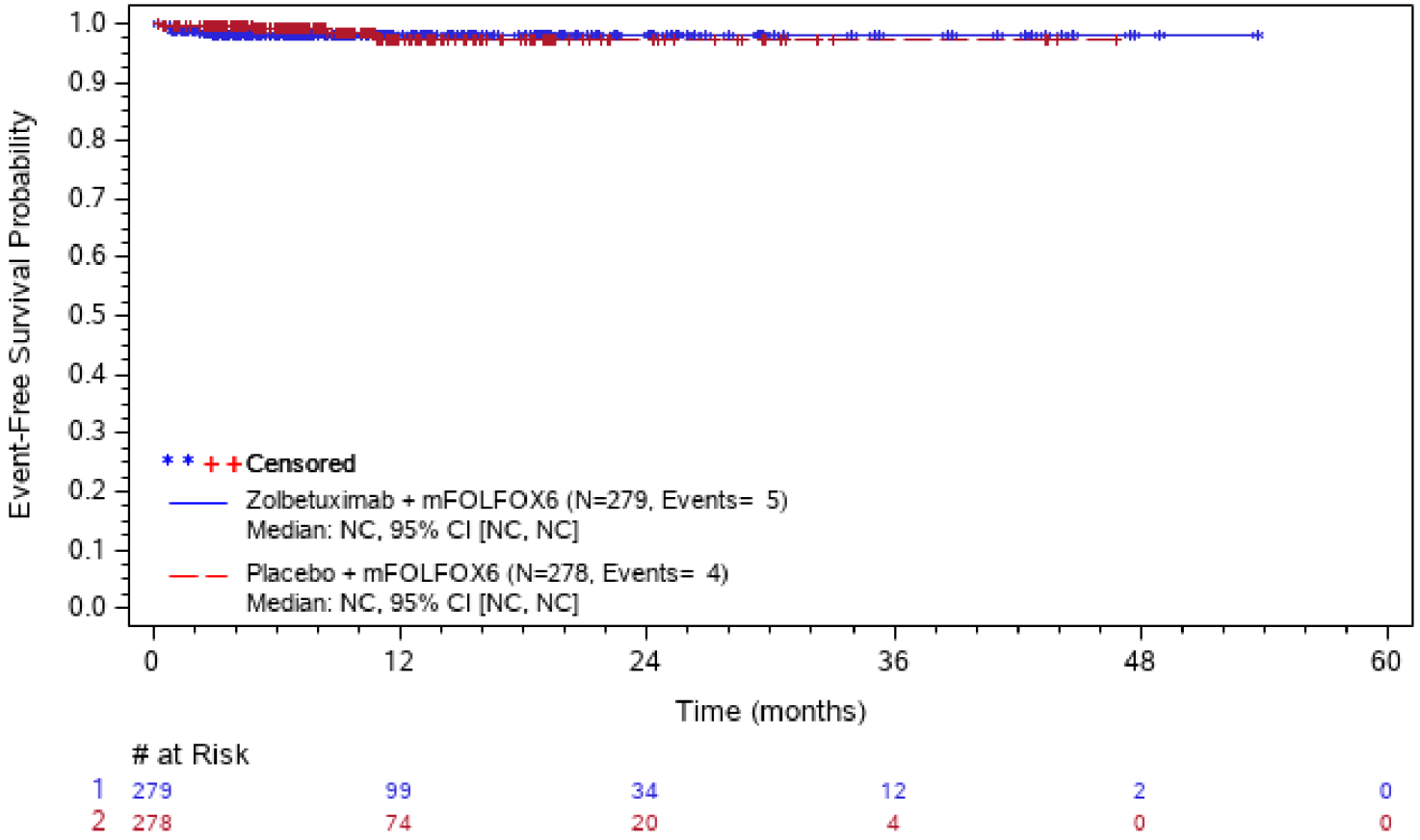


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.239: Kaplan-Meier Plot of Time to first TESAE - Anemia (AESI) - Safety Analysis Set

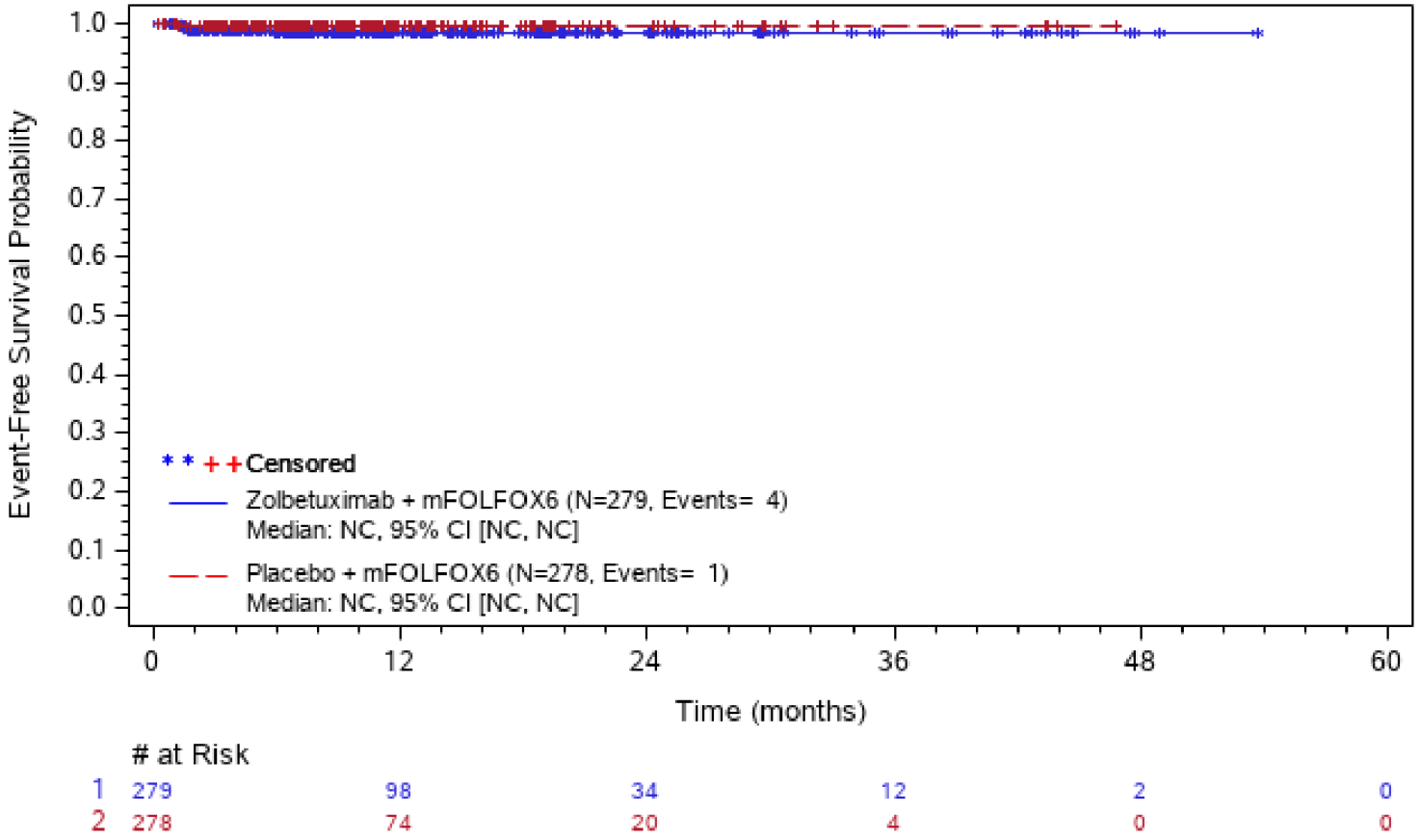


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.240: Kaplan-Meier Plot of Time to first TESAE - Hypersensitivity Reactions (AESI) - Safety Analysis Set

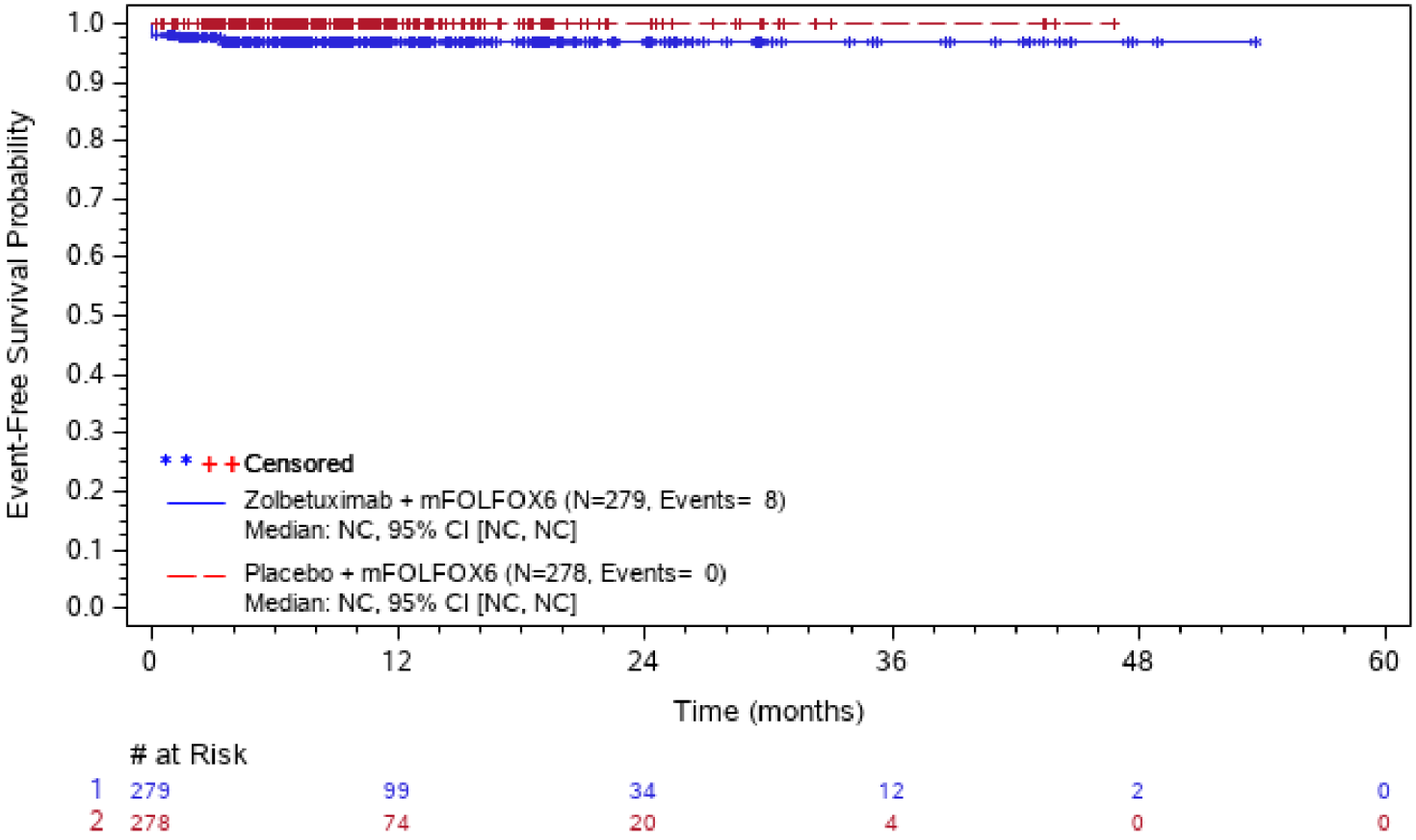


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.241: Kaplan-Meier Plot of Time to first TESAE - Infusion Related Reaction (AESI) - Safety Analysis Set

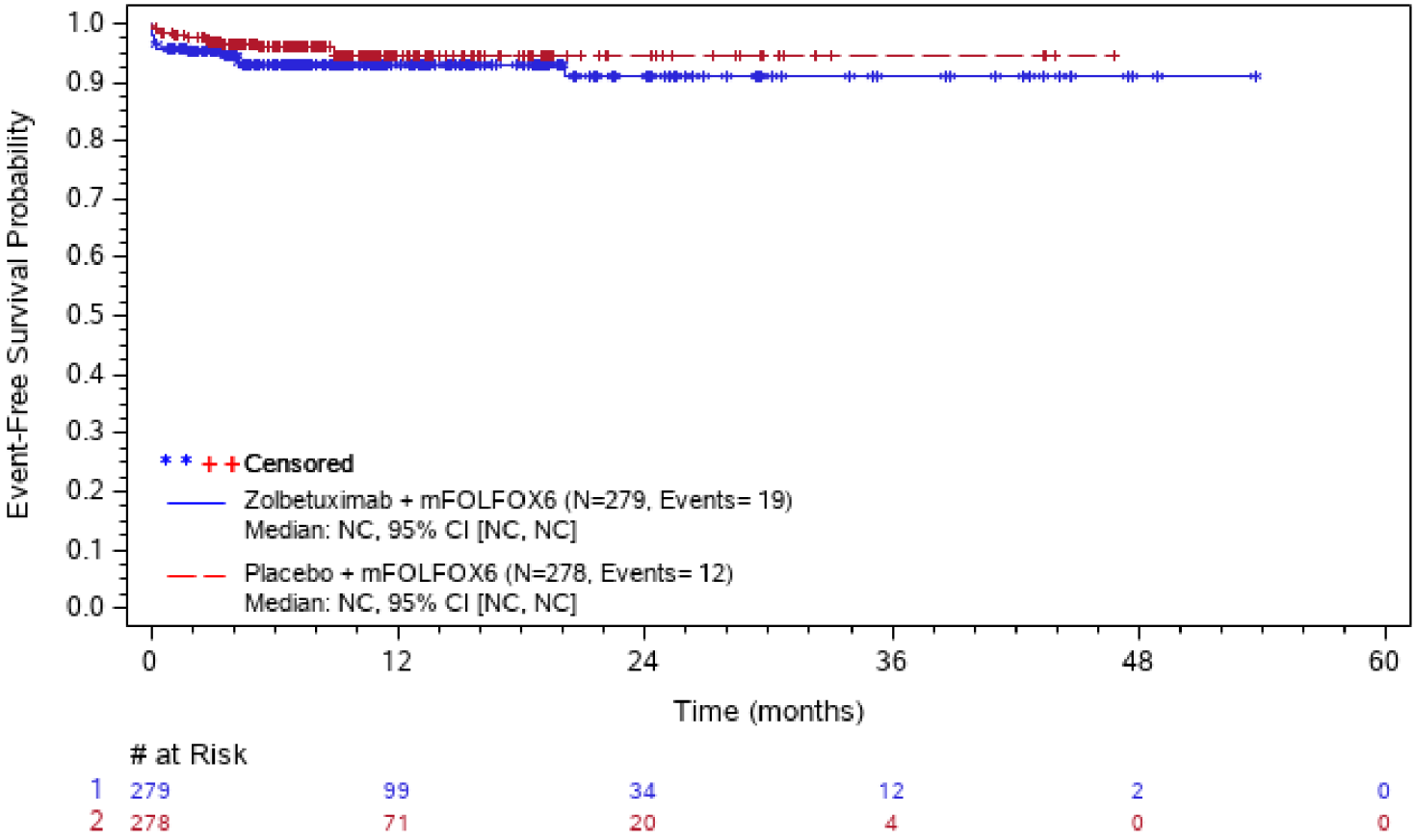


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.242: Kaplan-Meier Plot of Time to first TESAE - Nausea (AESI) - Safety Analysis Set

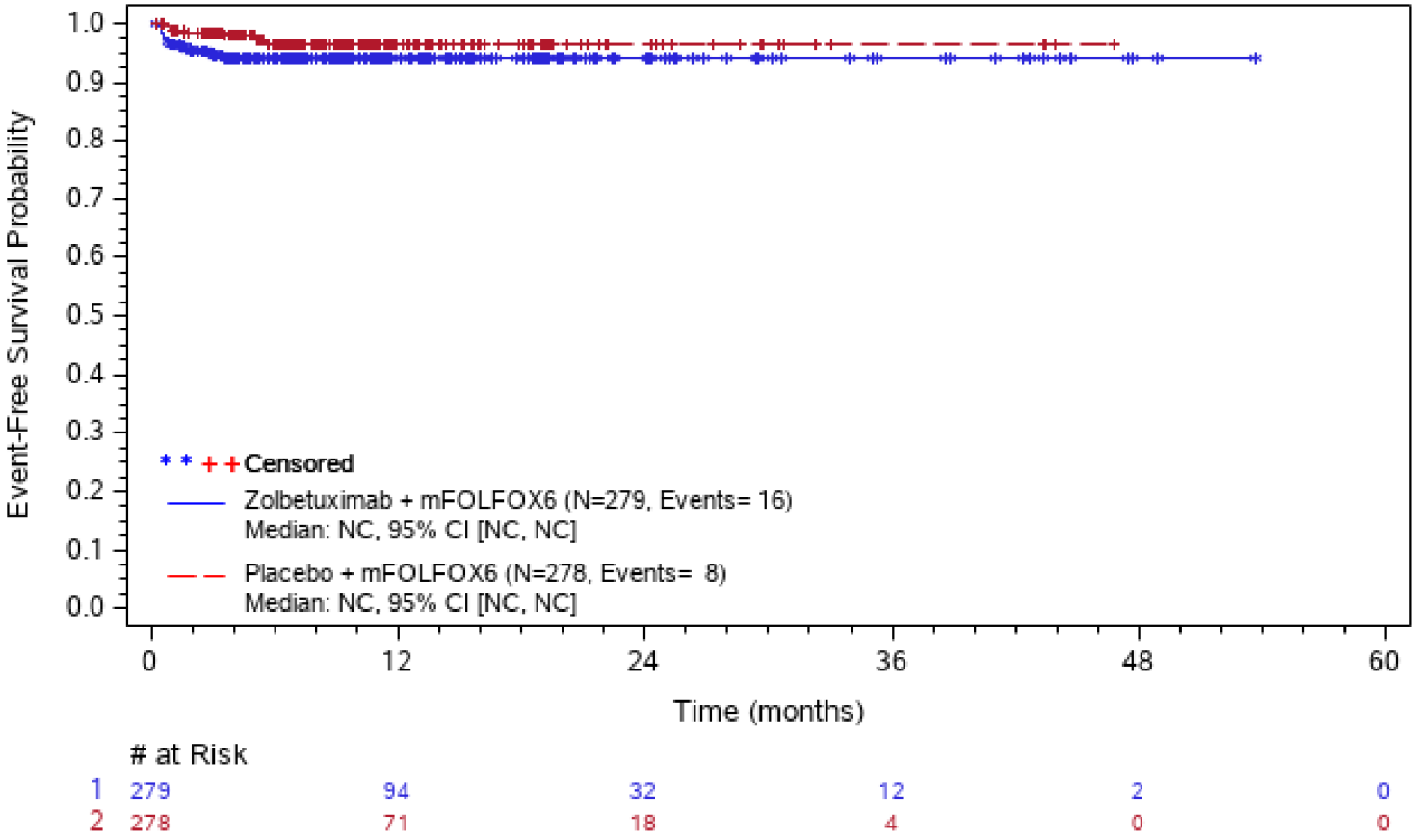


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.243: Kaplan-Meier Plot of Time to first TESAE - Neutropenia (AESI) - Safety Analysis Set

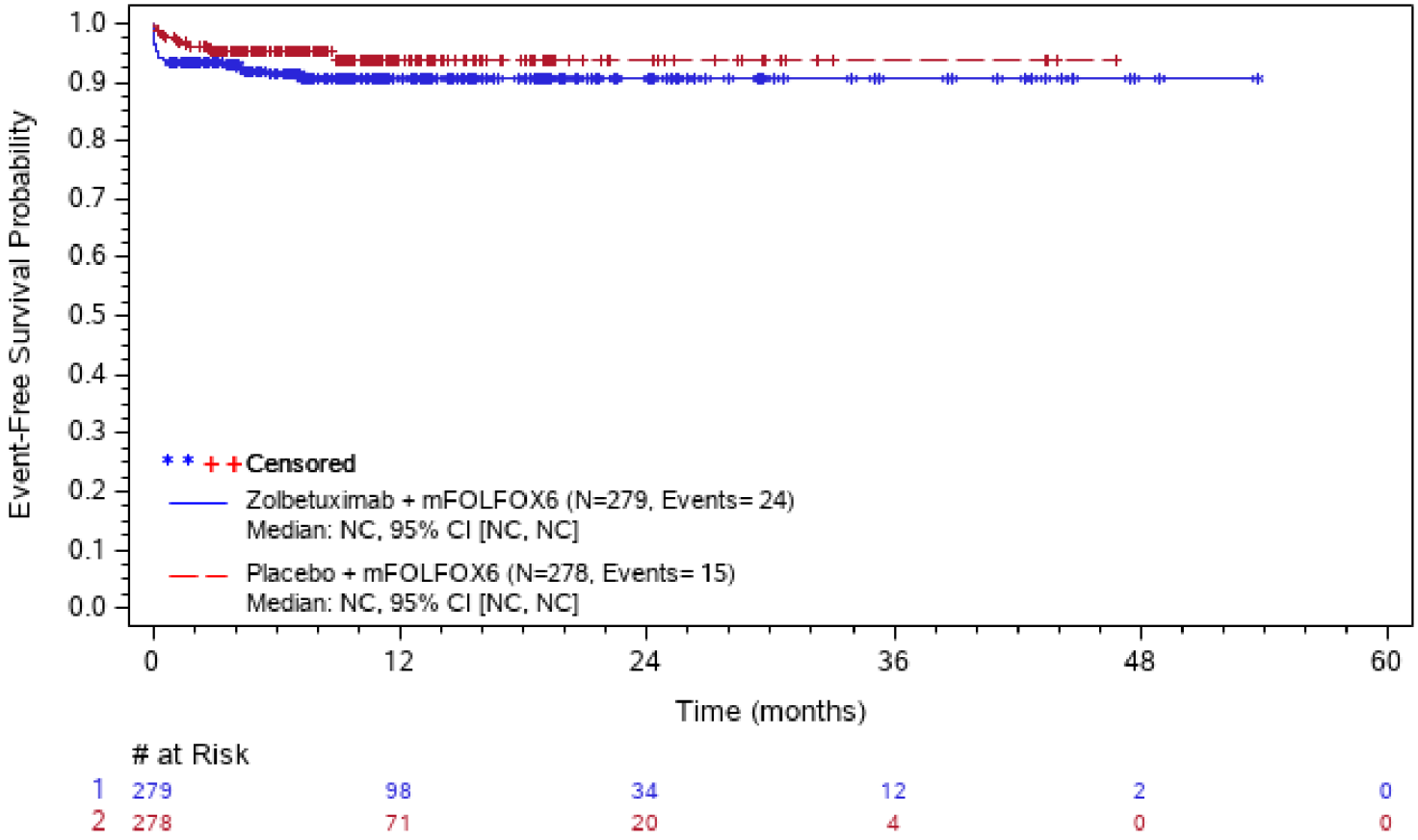


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.244: Kaplan-Meier Plot of Time to first TESAE - Vomiting (AESI) - Safety Analysis Set

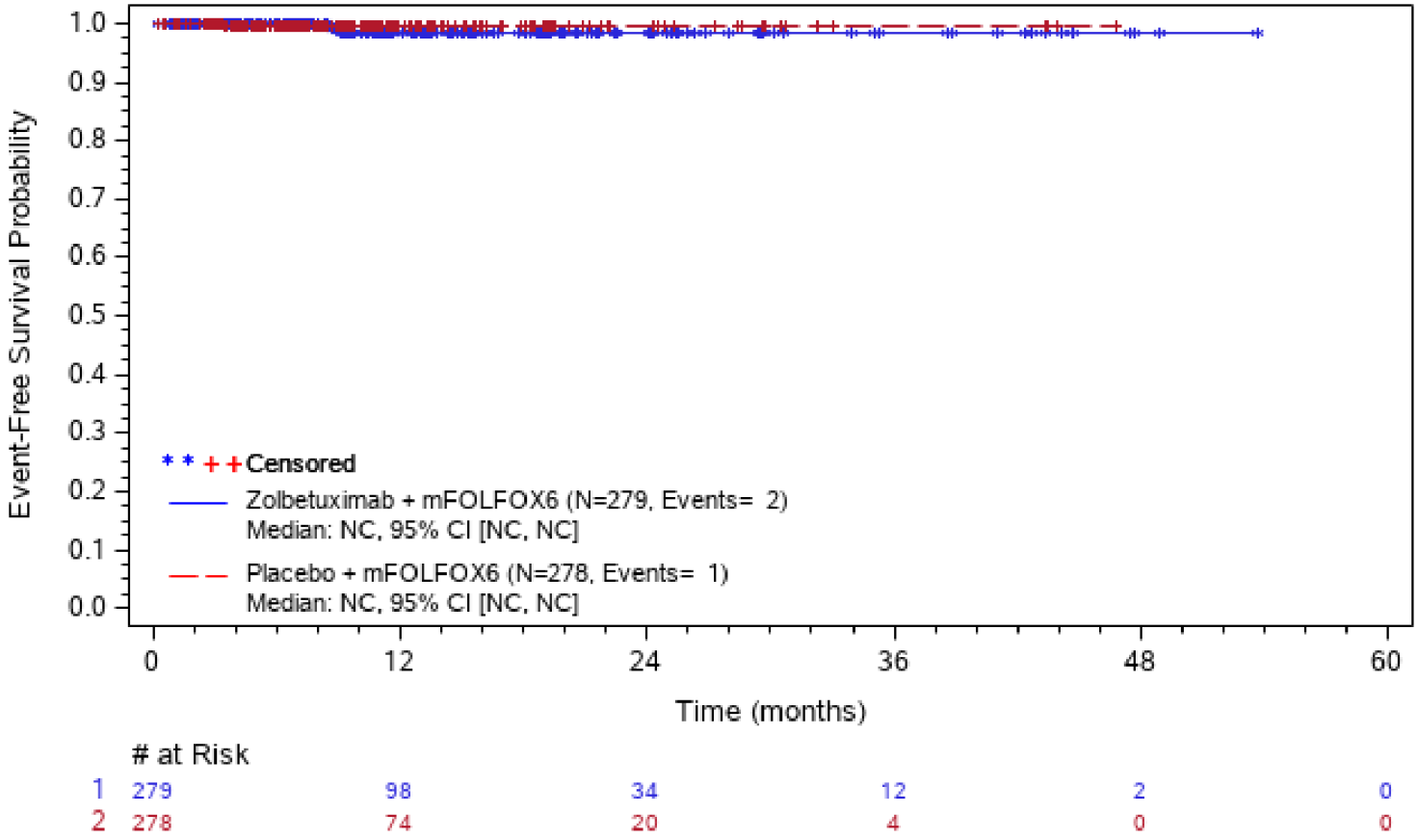


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.245: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Abdominal Pain (AESI) - Safety Analysis Set

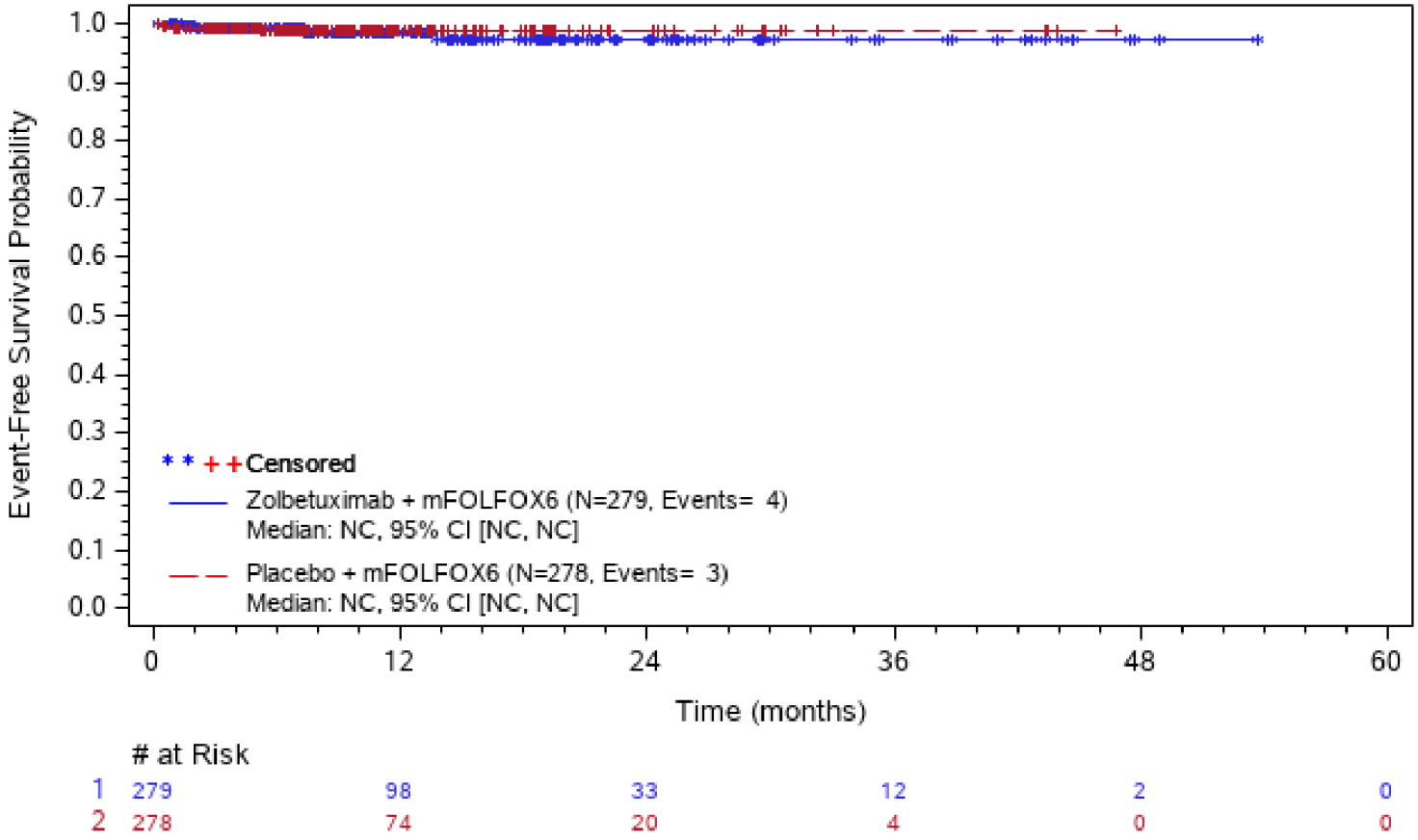


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.246: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Anemia (AESI) - Safety Analysis Set

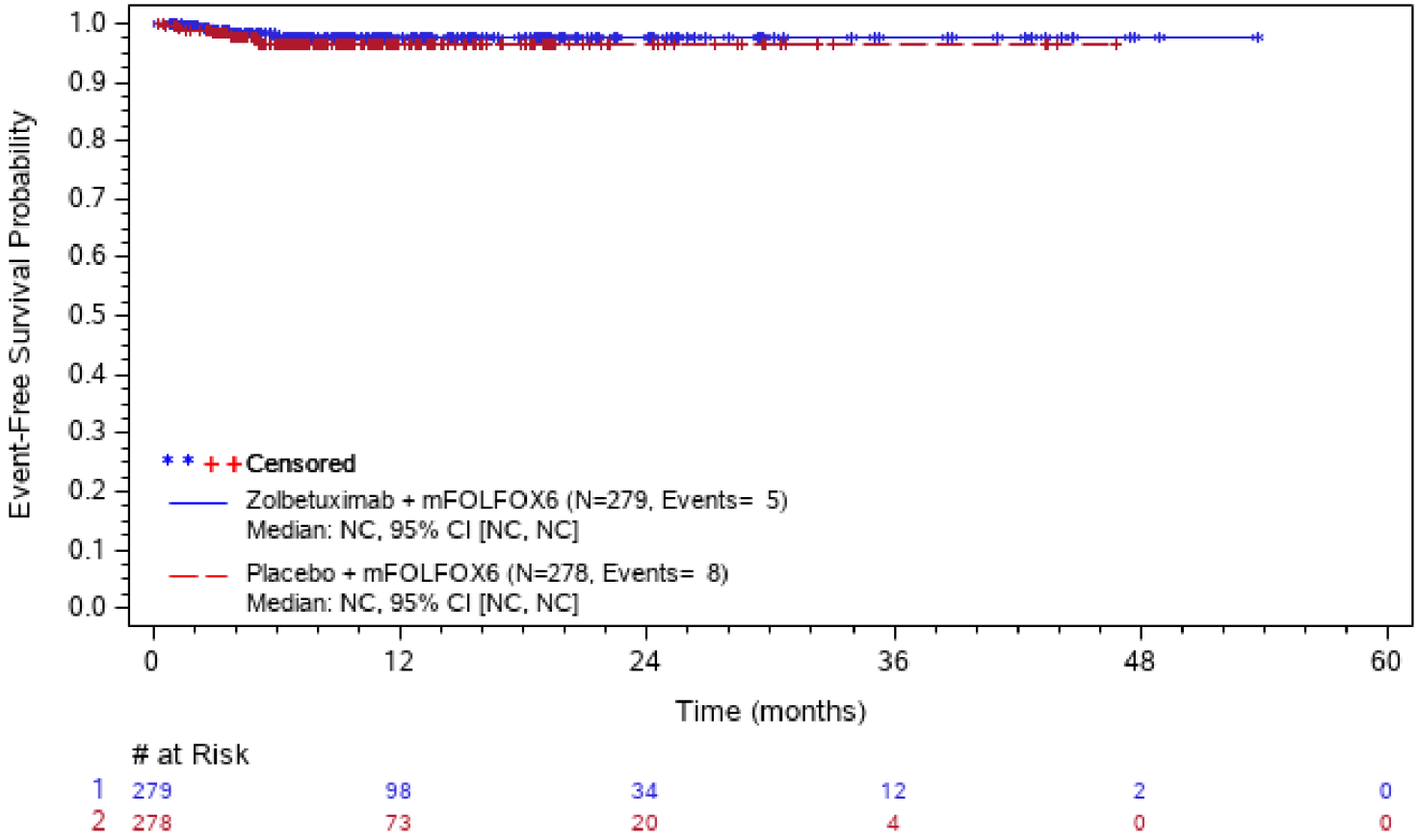


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.247: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Hypersensitivity Reactions (AESI) - Safety Analysis Set

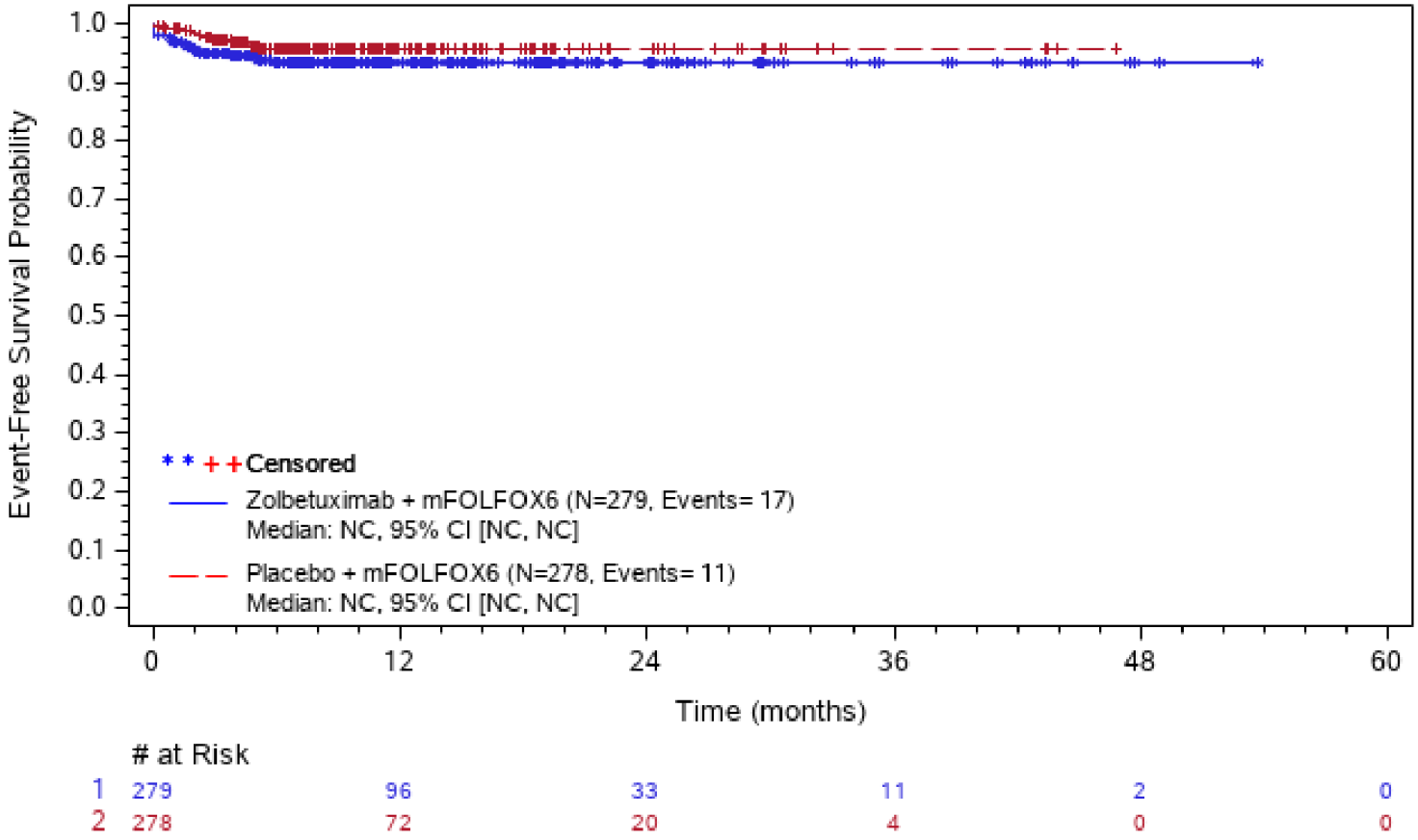


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.248: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Infusion Related Reaction (AESI) - Safety Analysis Set



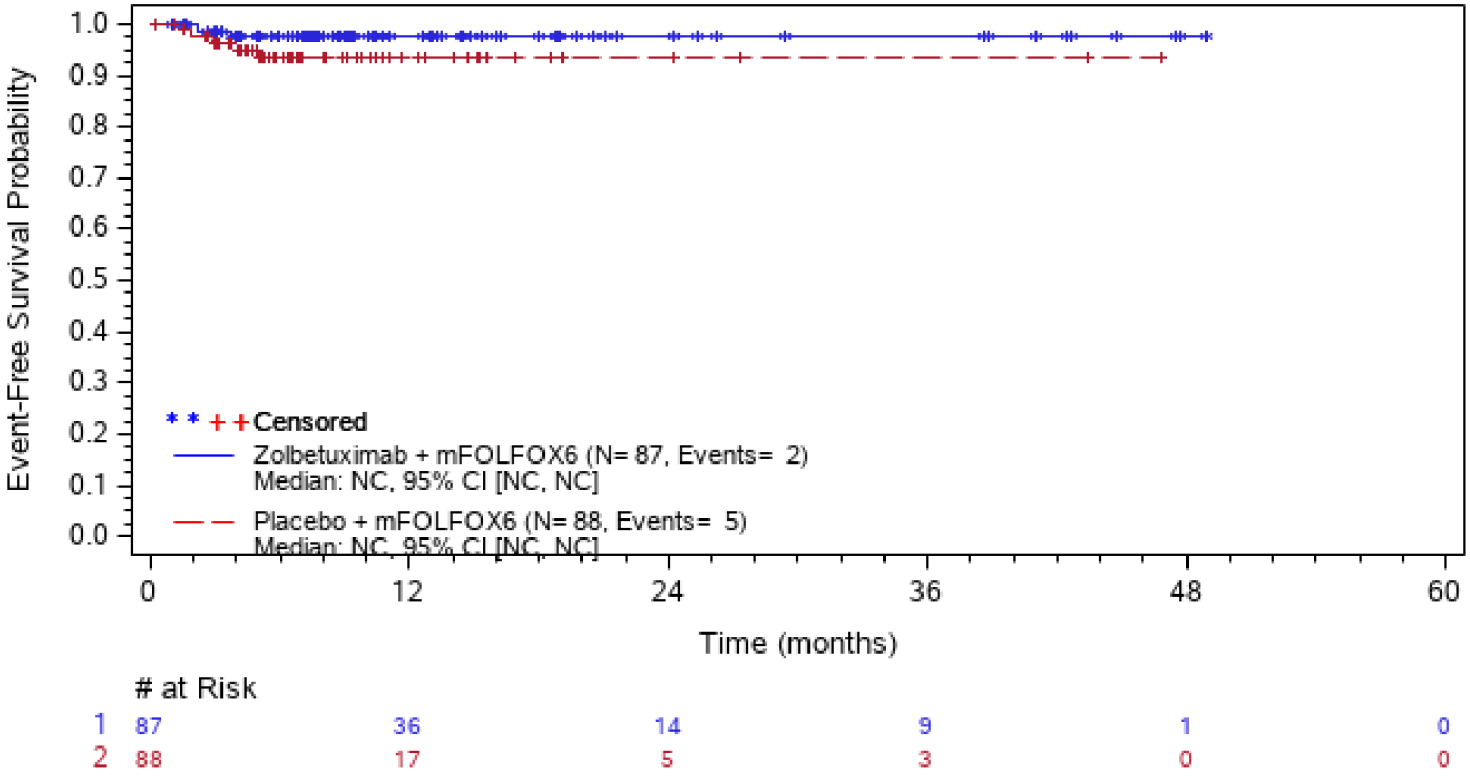
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.248.3: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation by Region - Infusion Related Reaction (AESI) - Safety Analysis Set

IRT- Region Subject is Enrolling In: Asia



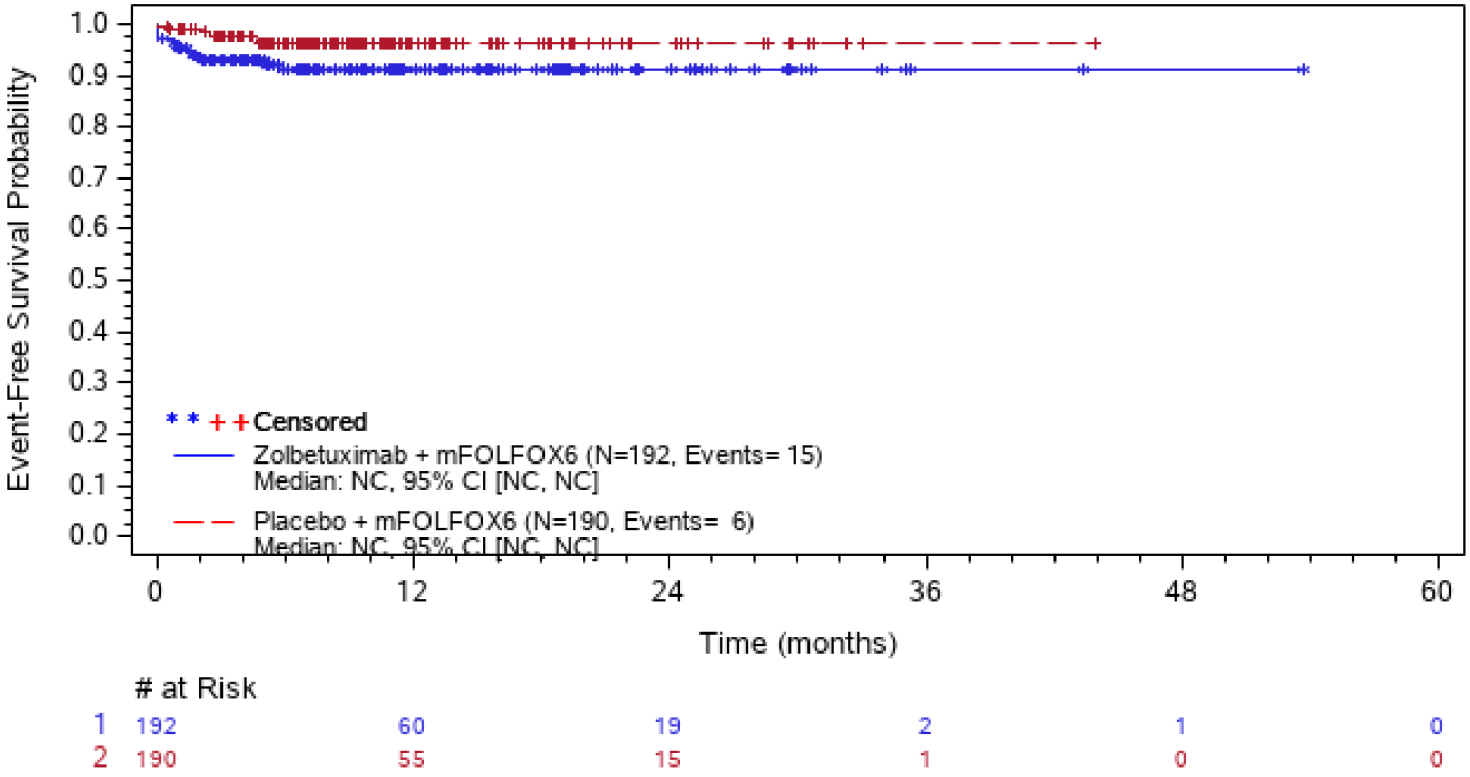
Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.248.3: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation by Region - Infusion Related Reaction (AESI) - Safety Analysis Set

IRT- Region Subject is Enrolling In: Non-Asia

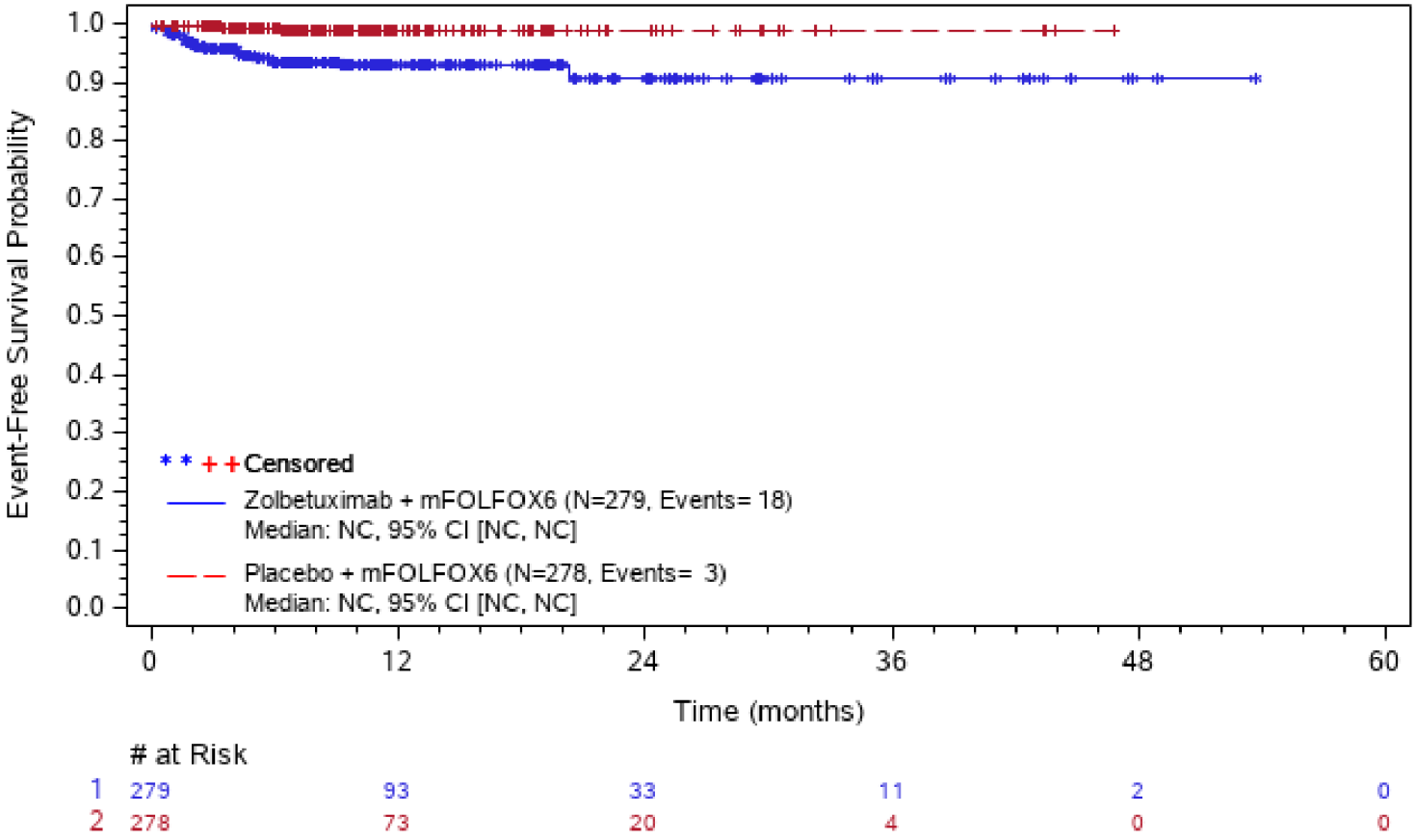


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.249: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Nausea (AESI) - Safety Analysis Set

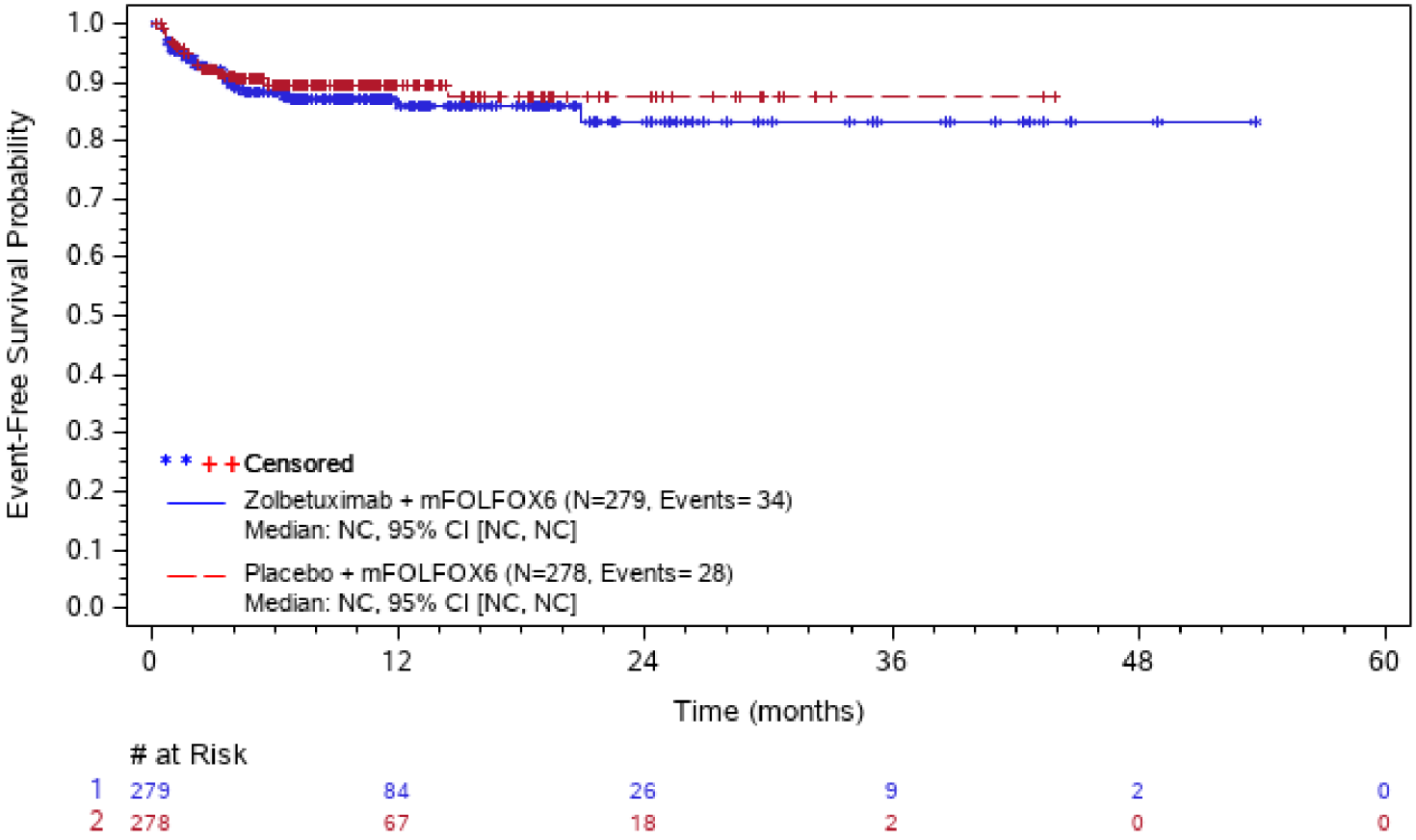


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.250: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Neutropenia (AESI) - Safety Analysis Set

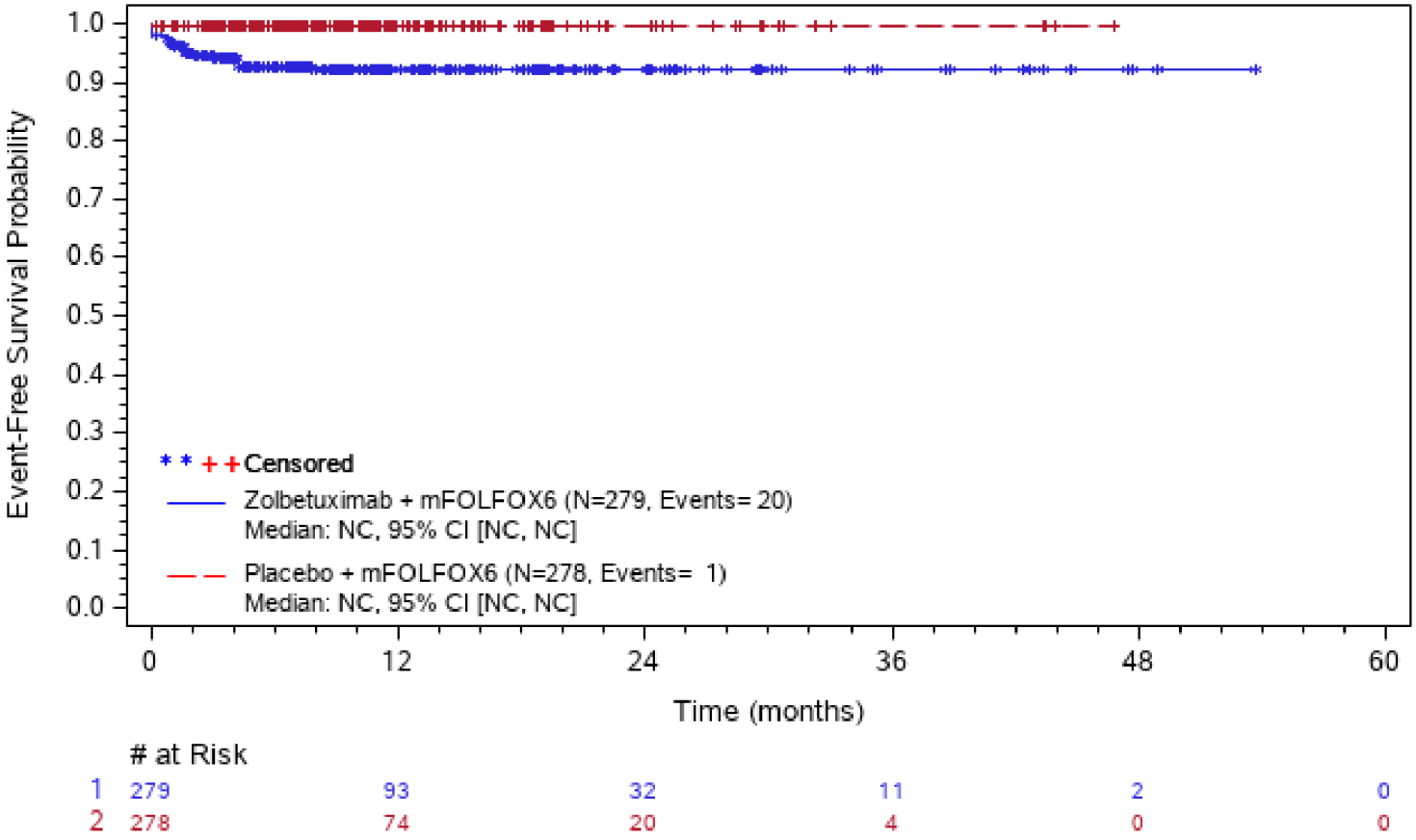


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.251: Kaplan-Meier Plot of Time to first TEAE leading to Permanent Treatment Discontinuation - Vomiting (AESI) - Safety Analysis Set

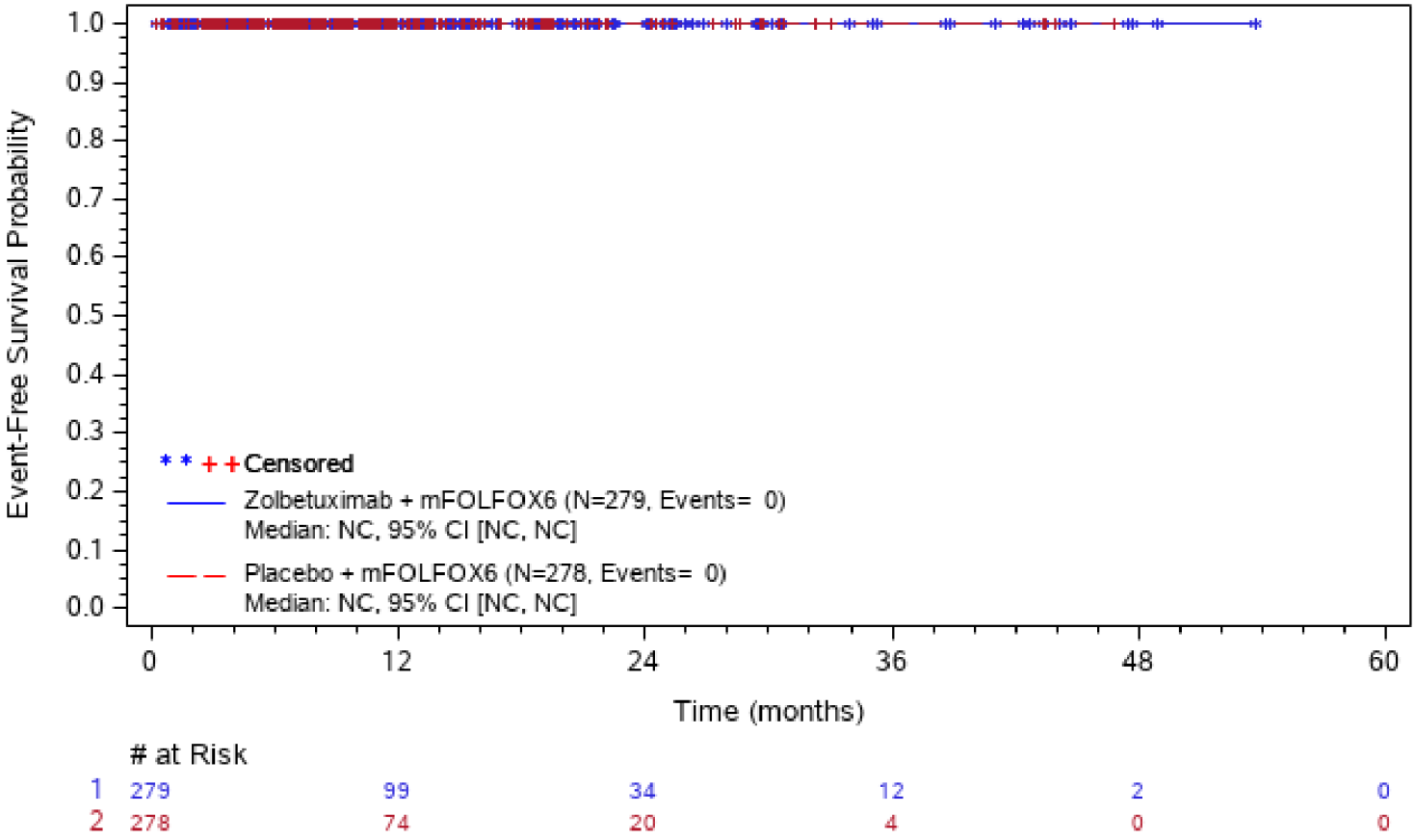


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.273: Kaplan-Meier Plot of Time to first TEAE leading to Death - Abdominal Pain (AESI) - Safety Analysis Set

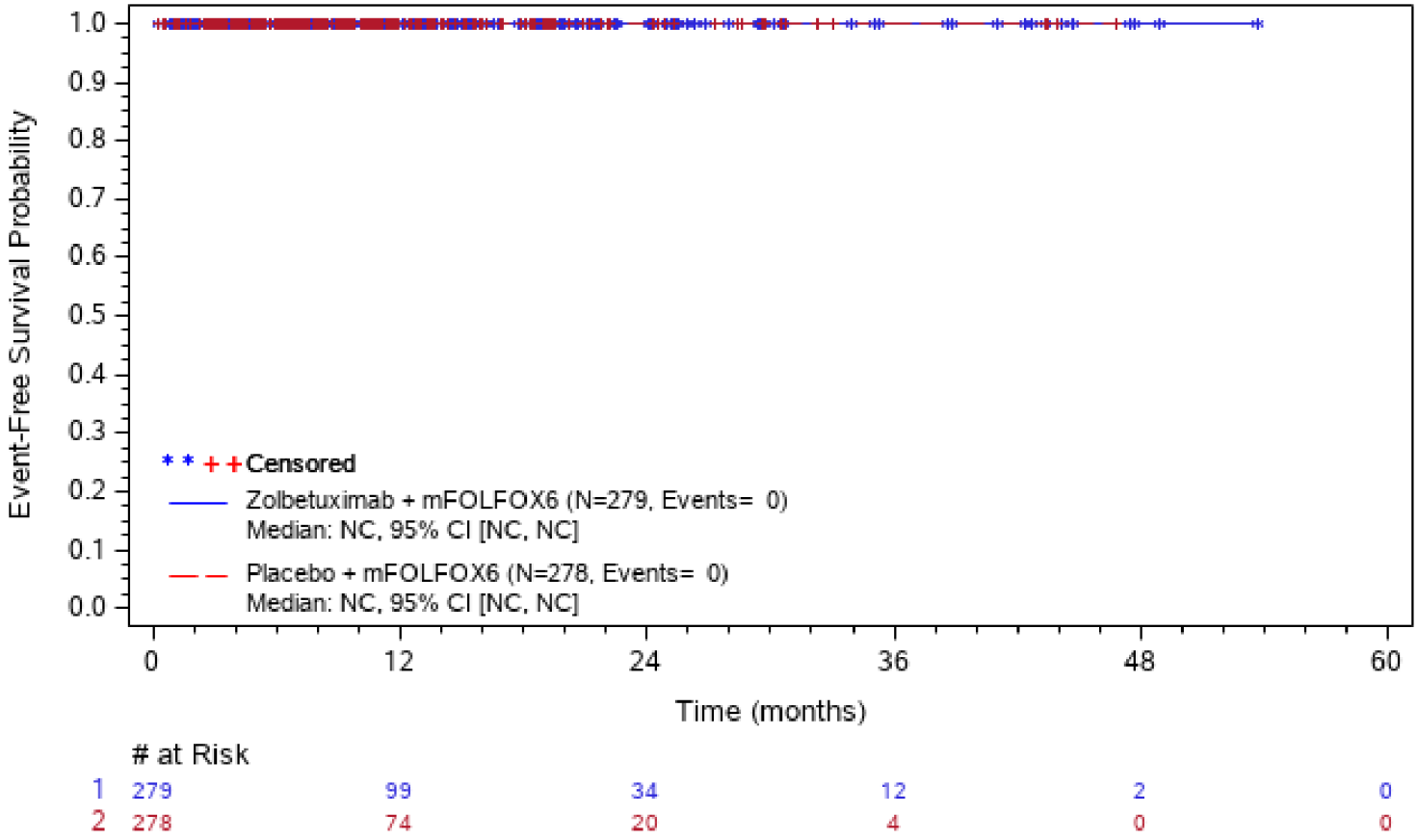


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.274: Kaplan-Meier Plot of Time to first TEAE leading to Death - Anemia (AESI) - Safety Analysis Set

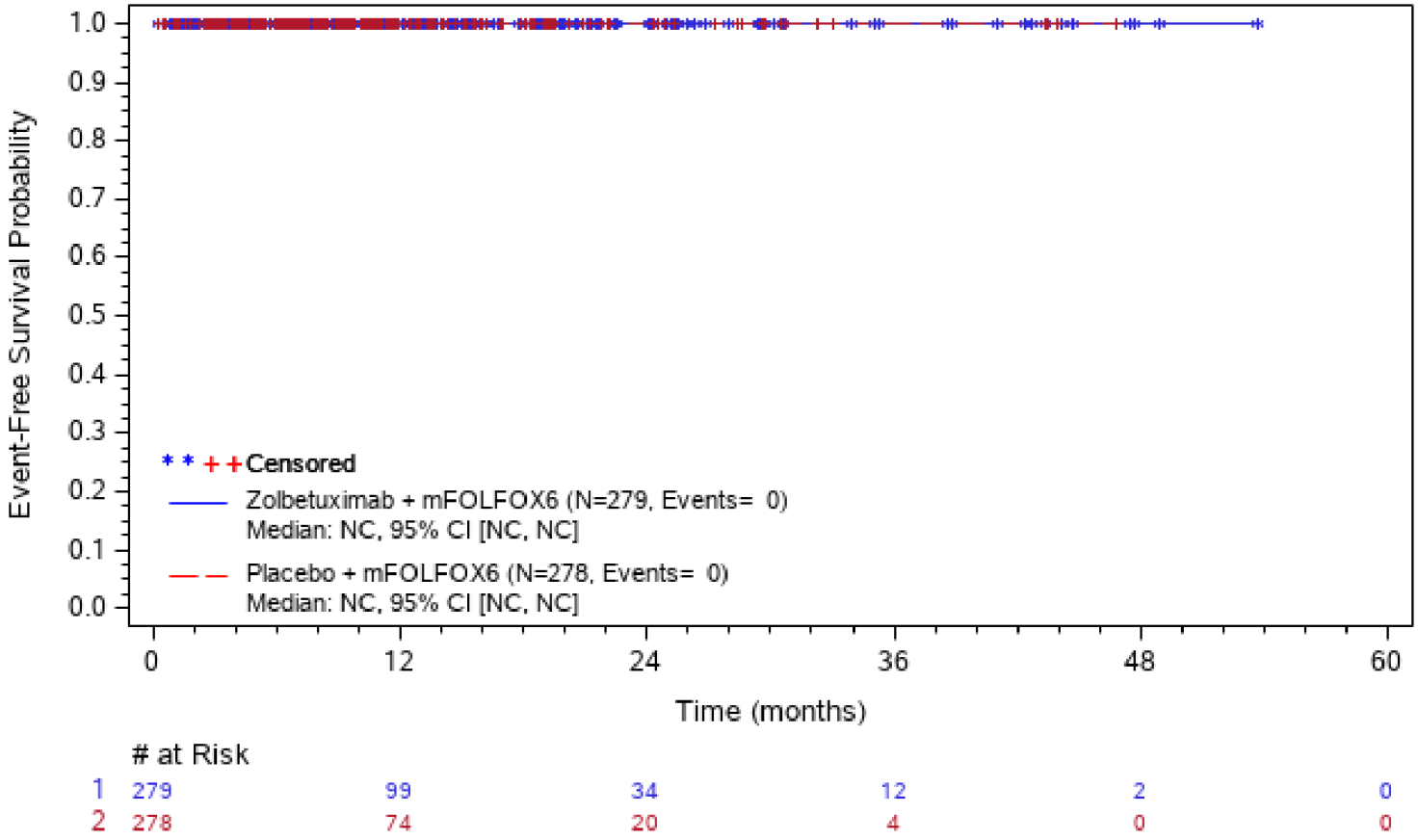


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.275: Kaplan-Meier Plot of Time to first TEAE leading to Death - Hypersensitivity Reactions (AESI) - Safety Analysis Set

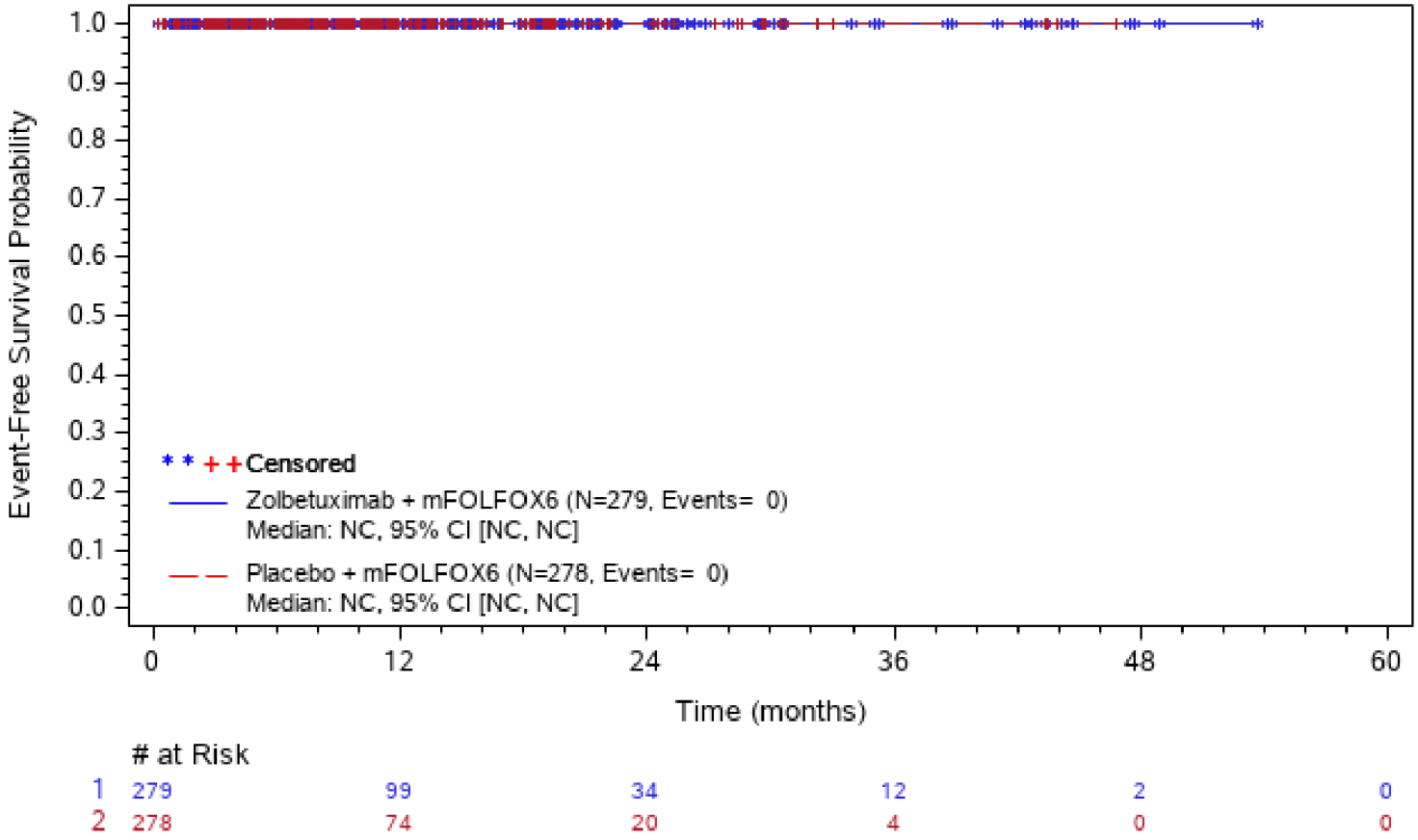


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.276: Kaplan-Meier Plot of Time to first TEAE leading to Death - Infusion Related Reaction (AESI) - Safety Analysis Set

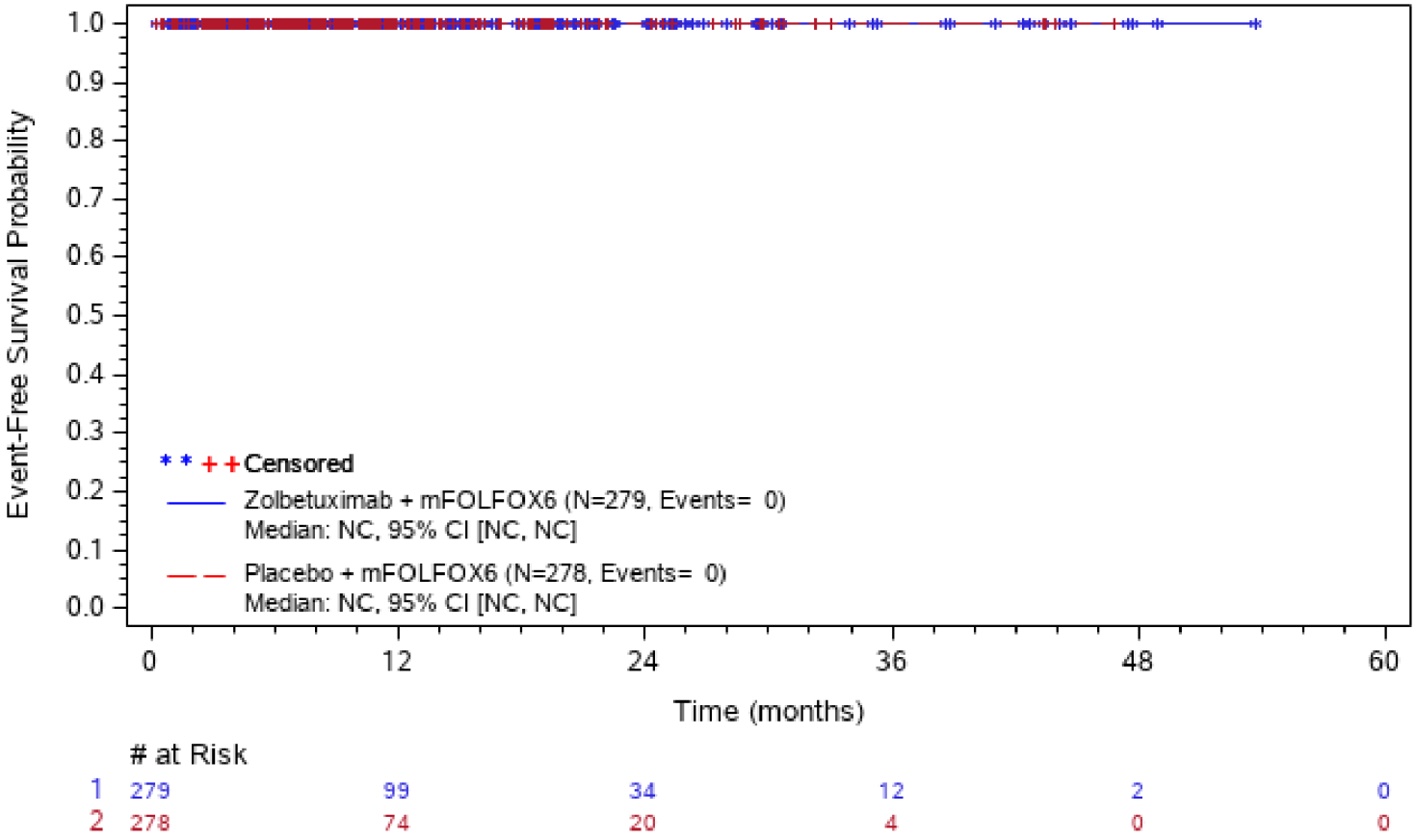


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.277: Kaplan-Meier Plot of Time to first TEAE leading to Death - Nausea (AESI) - Safety Analysis Set

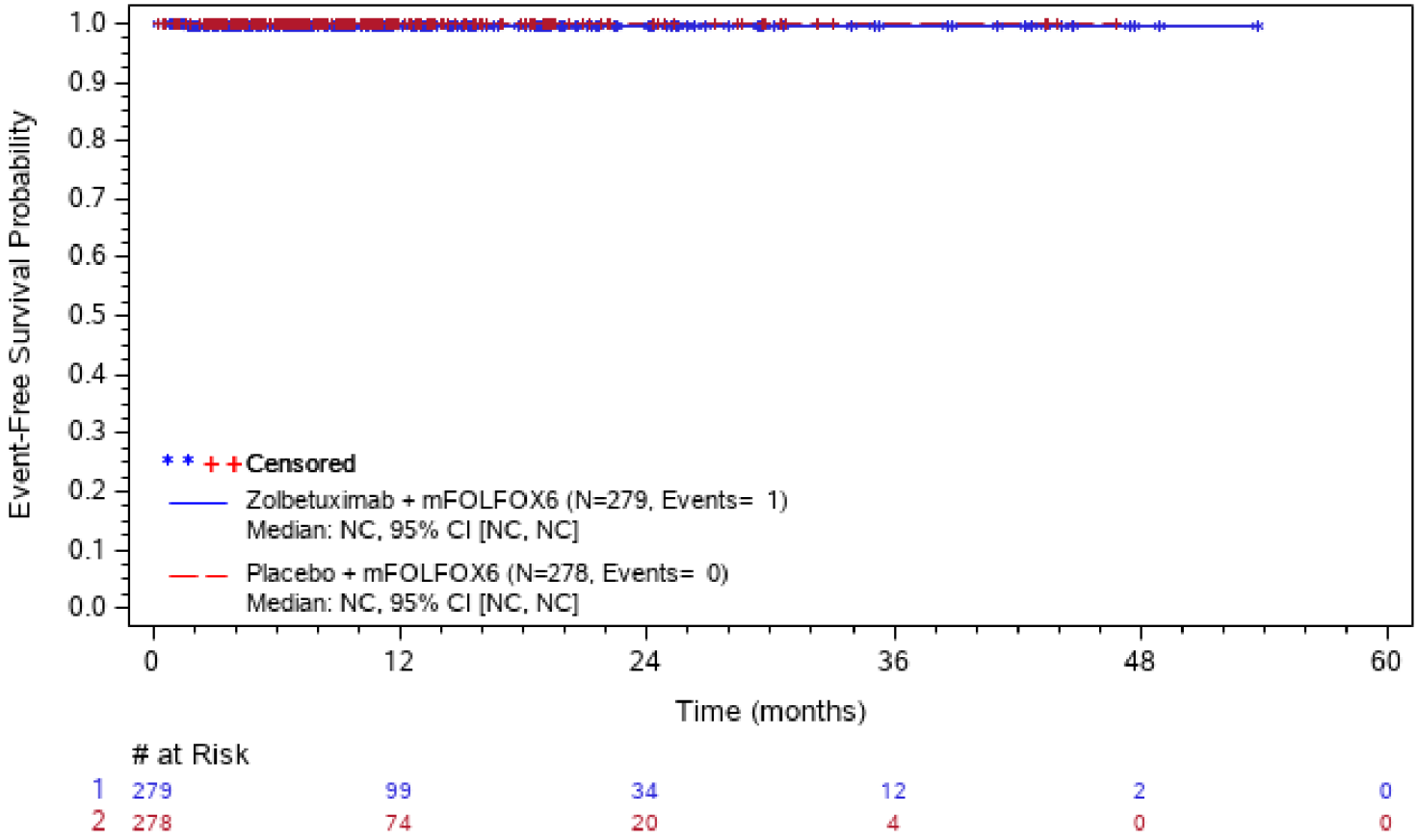


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.278: Kaplan-Meier Plot of Time to first TEAE leading to Death - Neutropenia (AESI) - Safety Analysis Set

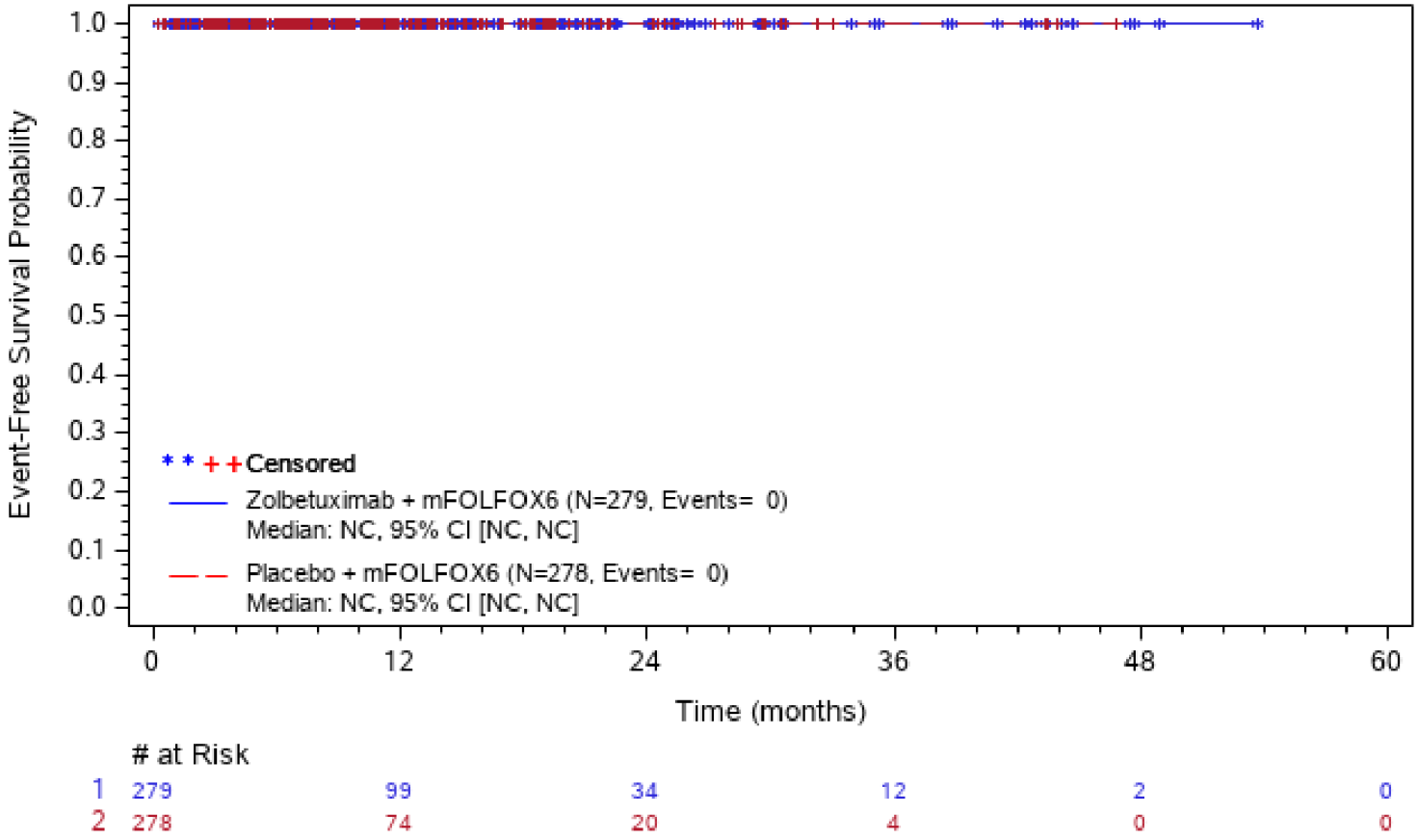


Abbreviations: # at Risk=number of patients at risk; AESI=adverse event of special interest; CI=confidence interval; N=number of patients; NC=not calculated; TE(S)AE=treatment-emergent (serious) adverse event.

ASTELLAS Data Cutoff Date: 08SEP23

The SAS System

Figure 301.3.2001.279: 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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023

Anhang 4-G4 Weitere Analysen

Anhang 4-G4 Beobachtungsdauern

Table 301.3.1001.2.1: Summary of Duration of Observation Time of Overall Survival - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	17.8 (12.31)	16.0 (10.62)
Median	16.5	14.3
Q1-Q3	7.7 - 25.3	7.8 - 22.0
Range	0 - 53	0 - 49

Abbreviations: 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: 08SEP23

Table 301.3.1001.2.2: Summary of Duration of Observation Time of Progression-Free Survival (IRC) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	11.0 (9.80)	9.3 (7.62)
Median	8.3	7.6
Q1-Q3	4.2 - 15.1	4.2 - 12.5
Range	0 - 51	0 - 45

Abbreviations: IRC=independent review committee; 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: 08SEP23

Table 301.3.1001.2.3: Summary of Duration of Observation Time of Progression-Free Survival (INV) - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	283	282
Mean (SD)	11.1 (9.94)	9.3 (7.65)
Median	8.2	7.8
Q1-Q3	4.2 - 15.1	4.2 - 12.2
Range	0 - 51	0 - 45

Abbreviations: INV=investigator; 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: 08SEP23

Table 301.3.3000.1: EORTC QLQ-C30 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	11.4 (10.07)	10.0 (7.99)
Median	8.6	8.2
Q1-Q3	4.6 - 15.9	4.7 - 12.9
Range	0 - 53	0 - 46

Abbreviations: EORTC QLQ-C30=european organisation for research and treatment of cancer quality of life questionnaire-core 30; 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: 08SEP23

Table 301.3.3000.2: EORTC QLQ-OG25 - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	11.4 (10.07)	10.0 (7.99)
Median	8.6	8.2
Q1-Q3	4.6 - 15.9	4.7 - 12.9
Range	0 - 53	0 - 46

Abbreviations: EORTC QLQ-OG25=european organisation for research and treatment of cancer oesophago-gastric module 25; 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-OG25 questionnaire includes the time from randomisation until the last date data were collected for EORTC QLQ-OG25 questionnaire.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3000.3: EQ-5D-5L Visual Analog Scale - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	11.4 (10.07)	10.0 (7.99)
Median	8.6	8.3
Q1-Q3	4.6 - 15.9	4.7 - 12.9
Range	0 - 53	0 - 46

Abbreviations: EQ-5D-5L=european quality of life 5 dimensions 5 level; N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for EQ-5D VAS includes the time from randomisation until the last date data were collected for EQ-5D VAS.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.3000.4: Global Pain - Summary of Duration of Observation Time - Full Analysis Set

	Zolbetuximab + mFOLFOX6 (N=283)	**Placebo + mFOLFOX6 (N=282)**
Duration of observation period (months)		
n	273	271
Mean (SD)	11.4 (10.05)	10.0 (7.99)
Median	8.6	8.2
Q1-Q3	4.6 - 15.9	4.7 - 12.9
Range	0 - 53	0 - 46

Abbreviations: N=number of patients; n=number of patients with non-missing values; Q1=first quartile; Q3=third quartile; SD=standard deviation.
Observation period for Global Pain questionnaire includes the time from randomisation until the last date data were collected for Global Pain questionnaire.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.2000.6.1: Summary of Duration of Observation Time for Safety Endpoints - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of observation period (months)		
n	279	278
Mean (SD)	13.0 (9.82)	11.7 (7.68)
Median	10.2	9.9
Q1-Q3	5.4 - 17.6	6.6 - 15.1
Range	0 - 53	0 - 46

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: 08SEP23

Table 301.3.2000.6.2: Summary of Duration of Observation Time for any TEAE - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of observation period (months)		
n	279	278
Mean (SD)	11.6 (10.02)	10.4 (7.71)
Median	8.5	8.5
Q1-Q3	4.5 - 15.8	5.2 - 13.2
Range	0 - 53	0 - 46

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: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Begleitmedikationen

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
Overall	278 (98.2%)	277 (98.2%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	53 (18.7%)	63 (22.3%)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	1 (0.4%)
ALL OTHER THERAPEUTIC PRODUCTS	24 (8.5%)	12 (4.3%)
ANALGESICS	182 (64.3%)	193 (68.4%)
ANESTHETICS	27 (9.5%)	25 (8.9%)
ANTHELMINTICS	1 (0.4%)	1 (0.4%)
ANTI-ACNE PREPARATIONS	3 (1.1%)	5 (1.8%)
ANTI-PARKINSON DRUGS	1 (0.4%)	1 (0.4%)
ANTIANEMIC PREPARATIONS	68 (24.0%)	73 (25.9%)
ANTIBACTERIALS FOR SYSTEMIC USE	106 (37.5%)	93 (33.0%)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	11 (3.9%)	9 (3.2%)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	76 (26.9%)	76 (27.0%)
ANTIEMETICS AND ANTINAUSEANTS	197 (69.6%)	180 (63.8%)
ANTIEPILEPTICS	9 (3.2%)	8 (2.8%)
ANTIFUNGALS FOR DERMATOLOGICAL USE	5 (1.8%)	6 (2.1%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
ANTIGOUT PREPARATIONS	8 (2.8%)	8 (2.8%)
ANTIHEMORRHAGICS	14 (4.9%)	17 (6.0%)
ANTIHISTAMINES FOR SYSTEMIC USE	113 (39.9%)	85 (30.1%)
ANTIHYPERTENSIVES	4 (1.4%)	6 (2.1%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	68 (24.0%)	49 (17.4%)
ANTIMYCOTICS FOR SYSTEMIC USE	7 (2.5%)	5 (1.8%)
ANTINEOPLASTIC AGENTS	1 (0.4%)	2 (0.7%)
ANTIPROTOZOALS	9 (3.2%)	5 (1.8%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	23 (8.1%)	17 (6.0%)
ANTIPSORIATICS	1 (0.4%)	1 (0.4%)
ANTISEPTICS AND DISINFECTANTS	7 (2.5%)	4 (1.4%)
ANTITHROMBOTIC AGENTS	102 (36.0%)	85 (30.1%)
ANTIVIRALS FOR SYSTEMIC USE	6 (2.1%)	5 (1.8%)
APPETITE STIMULANTS	15 (5.3%)	6 (2.1%)
BETA BLOCKING AGENTS	26 (9.2%)	32 (11.3%)
BILE AND LIVER THERAPY	24 (8.5%)	22 (7.8%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	103 (36.4%)	79 (28.0%)
CALCIUM CHANNEL BLOCKERS	45 (15.9%)	41 (14.5%)
CALCIUM HOMEOSTASIS	0	1 (0.4%)
CARDIAC THERAPY	11 (3.9%)	20 (7.1%)
CONTRAST MEDIA	4 (1.4%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE	119 (42.0%)	91 (32.3%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	33 (11.7%)	20 (7.1%)
COUGH AND COLD PREPARATIONS	35 (12.4%)	35 (12.4%)
DERMATOLOGICALS	1 (0.4%)	4 (1.4%)
DIAGNOSTIC AGENTS	0	3 (1.1%)
DIGESTIVES, INCL. ENZYMES	12 (4.2%)	7 (2.5%)
DIURETICS	52 (18.4%)	34 (12.1%)
DRUGS FOR ACID RELATED DISORDERS	229 (80.9%)	202 (71.6%)
DRUGS FOR CONSTIPATION	107 (37.8%)	118 (41.8%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	205 (72.4%)	165 (58.5%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	22 (7.8%)	21 (7.4%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
DRUGS FOR TREATMENT OF BONE DISEASES	21 (7.4%)	10 (3.5%)
DRUGS USED IN DIABETES	37 (13.1%)	44 (15.6%)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS	2 (0.7%)	1 (0.4%)
EMOLLIENTS AND PROTECTIVES	23 (8.1%)	27 (9.6%)
ENDOCRINE THERAPY	21 (7.4%)	17 (6.0%)
GENERAL NUTRIENTS	51 (18.0%)	42 (14.9%)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	3 (1.1%)	0
HOMEOPATHIC PREPARATION	15 (5.3%)	3 (1.1%)
IMMUNOSTIMULANTS	93 (32.9%)	93 (33.0%)
IMMUNOSUPPRESSANTS	1 (0.4%)	0
LIPID MODIFYING AGENTS	36 (12.7%)	51 (18.1%)
MEDICATED DRESSINGS	5 (1.8%)	2 (0.7%)
MINERAL SUPPLEMENTS	75 (26.5%)	57 (20.2%)
MUSCLE RELAXANTS	13 (4.6%)	8 (2.8%)
NASAL PREPARATIONS	13 (4.6%)	8 (2.8%)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	19 (6.7%)	30 (10.6%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
OPHTHALMOLOGICALS	106 (37.5%)	92 (32.6%)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	20 (7.1%)	18 (6.4%)
OTHER DERMATOLOGICAL PREPARATIONS	15 (5.3%)	4 (1.4%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0.4%)	1 (0.4%)
OTHER HEMATOLOGICAL AGENTS	2 (0.7%)	1 (0.4%)
OTHER NERVOUS SYSTEM DRUGS	16 (5.7%)	8 (2.8%)
OTHER RESPIRATORY SYSTEM PRODUCTS	2 (0.7%)	0
OTOLOGICALS	36 (12.7%)	23 (8.2%)
PANCREATIC HORMONES	1 (0.4%)	2 (0.7%)
PERIPHERAL VASODILATORS	3 (1.1%)	3 (1.1%)
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	3 (1.1%)	1 (0.4%)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	4 (1.4%)	3 (1.1%)
PSYCHOANALEPTICS	38 (13.4%)	37 (13.1%)
PSYCHOLEPTICS	177 (62.5%)	148 (52.5%)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	3 (1.1%)	6 (2.1%)
STOMATOLOGICAL PREPARATIONS	64 (22.6%)	55 (19.5%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.5: Summary of Concomitant Therapies - Full Analysis Set

Therapeutic Subgroup	Zolbetuximab + mFOLFOX6 (N=283)	Placebo + mFOLFOX6 (N=282)
THROAT PREPARATIONS	9 (3.2%)	9 (3.2%)
THYROID THERAPY	25 (8.8%)	18 (6.4%)
TONICS	1 (0.4%)	2 (0.7%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	12 (4.2%)	11 (3.9%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	20 (7.1%)	19 (6.7%)
UROLOGICALS	49 (17.3%)	38 (13.5%)
VACCINES	56 (19.8%)	55 (19.5%)
VASOPROTECTIVES	15 (5.3%)	5 (1.8%)
VITAMINS	71 (25.1%)	67 (23.8%)

Abbreviations: ATC=anatomical therapeutic chemical; N=number of patients.
Sorting order: alphabetical order by Therapeutic Subgroup (ATC 2nd level).
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Studienmedikation - Exposition

Table 301.3.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of Zolbetuximab/Placebo (days)		
n	279	278
Mean (SD)	306.5 (310.7)	270.9 (239.3)
Median	213.0	212.5
Range	1 - 1603	1 - 1395
Duration of Oxaliplatin (days)		
n	274	278
Mean (SD)	131.4 (56.66)	130.1 (51.79)
Median	150.0	148.0
Range	1 - 267	1 - 253
Duration of Leucovorin (days)		
n	178	187
Mean (SD)	271.7 (281.6)	232.0 (228.7)
Median	189.0	170.0
Range	1 - 1373	1 - 1388
Duration of Levo-Folinic Acid (days)		
n	127	112
Mean (SD)	286.8 (281.5)	245.7 (225.0)
Median	183.0	179.5
Range	1 - 1268	1 - 1290
Duration of Fluorouracil Bolus (days)		
n	272	277
Mean (SD)	239.3 (263.4)	207.3 (205.6)
Median	160.0	151.0
Range	1 - 1330	1 - 1305

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.
Zolbetuximab + mFOLFOX6 components: Zolbetuximab, Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
Placebo + mFOLFOX6 components: Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.6: Summary of Study Drug Exposure - Safety Analysis Set

	Zolbetuximab + mFOLFOX6 (N=279)	**Placebo + mFOLFOX6 (N=278)**
Duration of Fluorouracil (days)		
n	273	278
Mean (SD)	310.8 (285.0)	255.1 (229.5)
Median	208.0	181.5
Range	2 - 1375	3 - 1390

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.
Zolbetuximab + mFOLFOX6 components: Zolbetuximab, Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
Placebo + mFOLFOX6 components: Oxaliplatin, Leucovorin (Folinic acid) / Levofolinate, Fluorouracil Bolus and Fluorouracil.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Patientenfluss

Table 301.3.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + mFOLFOX6	Placebo + mFOLFOX6	Total
Number of Subjects with Informed Consent			2735
Discontinued Before Randomization to Treatment			2170 (79.3%)
Randomized to Treatment			565 (20.7%)
Number of Randomized Patients	283	282	565
Safety Analysis Set	279 (98.6%)	278 (98.6%)	557 (98.6%)
Full Analysis Set	283 (100.0%)	282 (100.0%)	565 (100.0%)
Pharmacokinetics Analysis Set	275 (97.2%)	0	275 (48.7%)
Overall Treatment Discontinuation [1]			
Yes	245 (86.6%)	257 (91.1%)	502 (88.8%)
No	38 (13.4%)	25 (8.9%)	63 (11.2%)
Reason for Overall Treatment Discontinuation [2]			
Adverse Event	27 (9.5%)	13 (4.6%)	40 (7.1%)
Death	15 (5.3%)	18 (6.4%)	33 (5.8%)
Lost to Follow-Up	1 (0.4%)	0	1 (0.2%)
Other	23 (8.1%)	18 (6.4%)	41 (7.3%)
Pregnancy	0	0	0
Progressive Disease	151 (53.4%)	196 (69.5%)	347 (61.4%)
Protocol Deviation	1 (0.4%)	0	1 (0.2%)
Withdrawal by Subject	31 (11.0%)	19 (6.7%)	50 (8.8%)
Post-Treatment Follow-Up Discontinuation			
Yes	251 (88.7%)	259 (91.8%)	510 (90.3%)
No	32 (11.3%)	23 (8.2%)	55 (9.7%)
Primary Post-Treatment Follow-Up Status			
Adverse Event	5 (1.8%)	2 (0.7%)	7 (1.2%)
Death	87 (30.7%)	99 (35.1%)	186 (32.9%)
Lost to Follow-Up	1 (0.4%)	2 (0.7%)	3 (0.5%)

[1]: Of both treatments.
[2]: Reason for overall treatment discontinuation is summarized using the reason of the latest discontinued compound.
If the subject discontinued from both treatments on the same day, all different reasons of discontinuation are summarized.
ASTELLAS Data Cutoff Date: 08SEP23

Table 301.3.1001.7: Summary of Disposition of Subjects

	Zolbetuximab + mFOLFOX6	Placebo + mFOLFOX6	Total
Other	52 (18.4%)	53 (18.8%)	105 (18.6%)
Pregnancy	0	0	0
Progressive Disease	76 (26.9%)	76 (27.0%)	152 (26.9%)
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	30 (10.6%)	27 (9.6%)	57 (10.1%)
Survival Follow-Up Discontinuation			
Yes	225 (79.5%)	235 (83.3%)	460 (81.4%)
No	58 (20.5%)	47 (16.7%)	105 (18.6%)
Primary Survival Follow-Up Status			
Death	197 (69.6%)	216 (76.6%)	413 (73.1%)
Lost to Follow-Up	1 (0.4%)	3 (1.1%)	4 (0.7%)
Other	2 (0.7%)	0	2 (0.4%)
Study Terminated by Sponsor	0	0	0
Withdrawal by Subject	25 (8.8%)	16 (5.7%)	41 (7.3%)

[1]: Of both treatments.
[2]: Reason for overall treatment discontinuation is summarized using the reason of the latest discontinued compound.
If the subject discontinued from both treatments on the same day, all different reasons of discontinuation are summarized.
ASTELLAS Data Cutoff Date: 08SEP23

Anhang 4-G4 *Post hoc* Analysen für die Studie SPOTLIGHT, finaler Datenschnitt 08.09.2023
Anhang 4-G4 Weitere Analysen
Anhang 4-G4 Folgetherapien

Program: /sas/projects/8951/8951-cl-0301-f/progs/prod/tables/cm05t.sas [Output: cm05ta.lst] Final OS update (Cut-off date - 08SEP2023)
Study: 8951-cl-0301 Table 9.2.2.6.1 Source: ADCM
New Anti-Cancer Therapies
Full Analysis Set

Therapeutic Subgroup (ATC 2nd level) Chemical Subgroup (ATC 4th level) Preferred WHO Name (Ingredients)	Arm A (N=283)	Arm B (N=282)	Overall (N=565)
Overall	152 (53.7%)	165 (58.5%)	317 (56.1%)
ALL OTHER THERAPEUTIC PRODUCTS	18 (6.4%)	14 (5.0%)	32 (5.7%)
ALL OTHER THERAPEUTIC PRODUCTS	9 (3.2%)	7 (2.5%)	16 (2.8%)
ALL OTHER THERAPEUTIC PRODUCTS	9 (3.2%)	7 (2.5%)	16 (2.8%)
DETOXIFYING AGENTS FOR ANTINEOPLASTIC TREATMENT	8 (2.8%)	7 (2.5%)	15 (2.7%)
CALCIUM FOLINATE	3 (1.1%)	2 (0.7%)	5 (0.9%)
CALCIUM LEVOFOLINATE	1 (0.4%)	0	1 (0.2%)
CALCIUM LEVOFOLINATE PENTAHYDRATE	1 (0.4%)	0	1 (0.2%)
FOLINIC ACID	1 (0.4%)	4 (1.4%)	5 (0.9%)
LEVOFOLINATE SODIUM	1 (0.4%)	1 (0.4%)	2 (0.4%)
SODIUM FOLINATE	1 (0.4%)	0	1 (0.2%)
OTHER THERAPEUTIC PRODUCTS	1 (0.4%)	1 (0.4%)	2 (0.4%)
TIPIRACIL	1 (0.4%)	1 (0.4%)	2 (0.4%)
ANTIANEMIC PREPARATIONS	1 (0.4%)	1 (0.4%)	2 (0.4%)
FOLIC ACID AND DERIVATIVES	1 (0.4%)	1 (0.4%)	2 (0.4%)
CALCIUM FOLINATE	1 (0.4%)	1 (0.4%)	2 (0.4%)
ANTINEOPLASTIC AGENTS	150 (53.0%)	156 (55.3%)	306 (54.2%)
ANTHRACYCLINES AND RELATED SUBSTANCES	1 (0.4%)	0	1 (0.2%)
EPIRUBICIN	1 (0.4%)	0	1 (0.2%)
ANTINEOPLASTIC AGENTS	7 (2.5%)	6 (2.1%)	13 (2.3%)
ANTINEOPLASTIC AGENTS	3 (1.1%)	1 (0.4%)	4 (0.7%)
INVESTIGATIONAL ANTINEOPLASTIC DRUGS	4 (1.4%)	5 (1.8%)	9 (1.6%)
COMBINATIONS OF ANTINEOPLASTIC AGENTS	65 (23.0%)	64 (22.7%)	129 (22.8%)
ATEZOLIZUMAB;BEVACIZUMAB	0	1 (0.4%)	1 (0.2%)

Number of subjects and percentage of subjects (%) are shown.
Sorting order: alphabetical order by Therapeutic Subgroup and Chemical Subgroup and Preferred WHO Name (Ingredients). Ingredients are the list of active ingredients for combination drugs.
Arm A = Zolbetuximab + mFOLFOX6, Arm B = Placebo + mFOLFOX6.
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Study: 8951-cl-0301 Table 9.2.2.6.1 Source: ADCM
New Anti-Cancer Therapies
Full Analysis Set

Therapeutic Subgroup (ATC 2nd level) Chemical Subgroup (ATC 4th level) Preferred WHO Name (Ingredients)	Arm A (N=283)	Arm B (N=282)	Overall (N=565)
CALCIUM FOLINATE;FLUOROURACIL;IRINOTECAN	1 (0.4%)	0	1 (0.2%)
CALCIUM FOLINATE;FLUOROURACIL;IRINOTECAN HYDROCHLORIDE	25 (8.8%)	26 (9.2%)	51 (9.0%)
CAPECITABINE;IRINOTECAN	0	1 (0.4%)	1 (0.2%)
CAPECITABINE;OXALIPLATIN	1 (0.4%)	0	1 (0.2%)
CISPLATIN;DOCETAXEL;FLUOROURACIL	1 (0.4%)	0	1 (0.2%)
CISPLATIN;FLUOROURACIL	1 (0.4%)	1 (0.4%)	2 (0.4%)
COMBINATIONS OF ANTINEOPLASTIC AGENTS	10 (3.5%)	7 (2.5%)	17 (3.0%)
FLUOROURACIL;FOLINIC ACID;IRINOTECAN	1 (0.4%)	1 (0.4%)	2 (0.4%)
FLUOROURACIL;FOLINIC ACID;OXALIPLATIN	14 (4.9%)	11 (3.9%)	25 (4.4%)
FLUOROURACIL;IRINOTECAN;OXALIPLATIN	0	1 (0.4%)	1 (0.2%)
PACLITAXEL;RAMUCIRUMAB	29 (10.2%)	28 (9.9%)	57 (10.1%)
FOLIC ACID ANALOGUES	3 (1.1%)	0	3 (0.5%)
METHOTREXATE	1 (0.4%)	0	1 (0.2%)
RALTITREXED	2 (0.7%)	0	2 (0.4%)
HERBAL ANTICANCER REMEDIES	1 (0.4%)	0	1 (0.2%)
ASTRAGALUS MONGHOLICUS ROOT;ISATIS TINCTORIA LEAF;PANAX NOTOGINSENG ROOT;PARIS POLYPHYLLA VAR. CHINENSIS RHIZOME;PEARL	1 (0.4%)	0	1 (0.2%)
MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES	0	1 (0.4%)	1 (0.2%)
ANTINEOPLASTIC MONOCLONAL ANTIBODIES	0	1 (0.4%)	1 (0.2%)
OTHER ANTINEOPLASTIC AGENTS	1 (0.4%)	2 (0.7%)	3 (0.5%)
ALPN 202	0	1 (0.4%)	1 (0.2%)
BI 836880	0	1 (0.4%)	1 (0.2%)
INCB 086550	1 (0.4%)	0	1 (0.2%)
OTHER CYTOTOXIC ANTIBIOTICS	1 (0.4%)	1 (0.4%)	2 (0.4%)
MITOMYCIN	1 (0.4%)	1 (0.4%)	2 (0.4%)

Number of subjects and percentage of subjects (%) are shown.
Sorting order: alphabetical order by Therapeutic Subgroup and Chemical Subgroup and Preferred WHO Name (Ingredients). Ingredients are the list of active ingredients for combination drugs.
Arm A = Zolbetuximab + mFOLFOX6, Arm B = Placebo + mFOLFOX6.
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Study: 8951-cl-0301 Table 9.2.2.6.1 Source: ADCM
New Anti-Cancer Therapies
Full Analysis Set

Therapeutic Subgroup (ATC 2nd level) Chemical Subgroup (ATC 4th level) Preferred WHO Name (Ingredients)	Arm A (N=283)	Arm B (N=282)	Overall (N=565)
OTHER MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES	2 (0.7%)	2 (0.7%)	4 (0.7%)
AMIVANTAMAB	1 (0.4%)	0	1 (0.2%)
BEMARITUZUMAB	0	1 (0.4%)	1 (0.2%)
DATOPOTAMAB DERUXTECAN	1 (0.4%)	0	1 (0.2%)
GEMTUZUMAB	0	1 (0.4%)	1 (0.2%)
OTHER PROTEIN KINASE INHIBITORS	2 (0.7%)	3 (1.1%)	5 (0.9%)
CATEQUENTINIB HYDROCHLORIDE	1 (0.4%)	1 (0.4%)	2 (0.4%)
REGORAFENIB	1 (0.4%)	2 (0.7%)	3 (0.5%)
PD-1/PDL-1 (PROGRAMMED CELL DEATH PROTEIN 1/DEATH LIGAND 1) INHIBITORS	38 (13.4%)	33 (11.7%)	71 (12.6%)
CAMRELIZUMAB	1 (0.4%)	0	1 (0.2%)
DURVALUMAB	1 (0.4%)	0	1 (0.2%)
EZABENLIMAB	0	1 (0.4%)	1 (0.2%)
NIVOLUMAB	23 (8.1%)	24 (8.5%)	47 (8.3%)
PEMBROLIZUMAB	10 (3.5%)	7 (2.5%)	17 (3.0%)
SINTILIMAB	0	2 (0.7%)	2 (0.4%)
SPARTALIZUMAB	1 (0.4%)	0	1 (0.2%)
TISLELIZUMAB	1 (0.4%)	0	1 (0.2%)
TORIPALIMAB	1 (0.4%)	0	1 (0.2%)
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS	1 (0.4%)	0	1 (0.2%)
BRUCEA JAVANICA OIL	1 (0.4%)	0	1 (0.2%)
PLATINUM COMPOUNDS	11 (3.9%)	12 (4.3%)	23 (4.1%)
CARBOPLATIN	1 (0.4%)	2 (0.7%)	3 (0.5%)
CISPLATIN	1 (0.4%)	2 (0.7%)	3 (0.5%)
OXALIPLATIN	10 (3.5%)	8 (2.8%)	18 (3.2%)
POLY (ADP-RIBOSE) POLYMERASE (PARP) INHIBITORS	1 (0.4%)	0	1 (0.2%)
OLAPARIB	1 (0.4%)	0	1 (0.2%)

Number of subjects and percentage of subjects (%) are shown.
Sorting order: alphabetical order by Therapeutic Subgroup and Chemical Subgroup and Preferred WHO Name (Ingredients). Ingredients are the list of active ingredients for combination drugs.
Arm A = Zolbetuximab + mFOLFOX6, Arm B = Placebo + mFOLFOX6.
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Study: 8951-cl-0301 Table 9.2.2.6.1 Source: ADCM
New Anti-Cancer Therapies
Full Analysis Set

Therapeutic Subgroup (ATC 2nd level) Chemical Subgroup (ATC 4th level) Preferred WHO Name (Ingredients)	Arm A (N=283)	Arm B (N=282)	Overall (N=565)
PYRIMIDINE ANALOGUES	33 (11.7%)	32 (11.3%)	65 (11.5%)
CALCIUM FOLINATE;FLUOROURACIL	0	1 (0.4%)	1 (0.2%)
CAPECITABINE	6 (2.1%)	5 (1.8%)	11 (1.9%)
FLUOROURACIL	13 (4.6%)	15 (5.3%)	28 (5.0%)
FLUOROURACIL;FOLINIC ACID	2 (0.7%)	1 (0.4%)	3 (0.5%)
GIMERACIL;OTERACIL POTASSIUM;TEGAFUR	7 (2.5%)	4 (1.4%)	11 (1.9%)
TEGAFUR;URACIL	1 (0.4%)	0	1 (0.2%)
TIPIRACIL HYDROCHLORIDE;TRIFLURIDINE	3 (1.1%)	7 (2.5%)	10 (1.8%)
TIPIRACIL;TRIFLURIDINE	3 (1.1%)	1 (0.4%)	4 (0.7%)
TRIFLURIDINE	1 (0.4%)	1 (0.4%)	2 (0.4%)
TAXANES	70 (24.7%)	74 (26.2%)	144 (25.5%)
DOCETAXEL	7 (2.5%)	9 (3.2%)	16 (2.8%)
PACLITAXEL	54 (19.1%)	60 (21.3%)	114 (20.2%)
PACLITAXEL NANOPARTICLE ALBUMIN-BOUND	11 (3.9%)	6 (2.1%)	17 (3.0%)
TAXANES	0	1 (0.4%)	1 (0.2%)
TOPOISOMERASE 1 (TOP1) INHIBITORS	12 (4.2%)	22 (7.8%)	34 (6.0%)
IRINOTECAN	11 (3.9%)	19 (6.7%)	30 (5.3%)
IRINOTECAN HYDROCHLORIDE	1 (0.4%)	2 (0.7%)	3 (0.5%)
IRINOTECAN HYDROCHLORIDE TRIHYDRATE	0	1 (0.4%)	1 (0.2%)
VASCULAR ENDOTHELIAL GROWTH FACTOR RECEPTOR (VEGFR) TYROSINE KINASE INHIBITORS	3 (1.1%)	3 (1.1%)	6 (1.1%)
RIVOCERANIB	0	1 (0.4%)	1 (0.2%)
RIVOCERANIB MESYLATE	3 (1.1%)	2 (0.7%)	5 (0.9%)
VEGF/VEGFR (VASCULAR ENDOTHELIAL GROWTH FACTOR) INHIBITORS	40 (14.1%)	39 (13.8%)	79 (14.0%)
RAMUCIRUMAB	40 (14.1%)	39 (13.8%)	79 (14.0%)
CARDIAC THERAPY	1 (0.4%)	0	1 (0.2%)

Number of subjects and percentage of subjects (%) are shown.
Sorting order: alphabetical order by Therapeutic Subgroup and Chemical Subgroup and Preferred WHO Name (Ingredients). Ingredients are the list of active ingredients for combination drugs.
Arm A = Zolbetuximab + mFOLFOX6, Arm B = Placebo + mFOLFOX6.
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Study: 8951-cl-0301 Table 9.2.2.6.1 Source: ADCM
New Anti-Cancer Therapies
Full Analysis Set

Therapeutic Subgroup (ATC 2nd level) Chemical Subgroup (ATC 4th level) Preferred WHO Name (Ingredients)	Arm A (N=283)	Arm B (N=282)	Overall (N=565)
OTHER CARDIAC PREPARATIONS	1 (0.4%)	0	1 (0.2%)
PACLITAXEL	1 (0.4%)	0	1 (0.2%)
CONTRAST MEDIA	1 (0.4%)	0	1 (0.2%)
ULTRASOUND CONTRAST MEDIA	1 (0.4%)	0	1 (0.2%)
ULTRASOUND CONTRAST MEDIA	1 (0.4%)	0	1 (0.2%)
DRUGS FOR TREATMENT OF BONE DISEASES	0	1 (0.4%)	1 (0.2%)
BISPHOSPHONATES	0	1 (0.4%)	1 (0.2%)
ZOLEDRONIC ACID	0	1 (0.4%)	1 (0.2%)
IMMUNOSTIMULANTS	1 (0.4%)	0	1 (0.2%)
INTERLEUKINS	1 (0.4%)	0	1 (0.2%)
THOR 707	1 (0.4%)	0	1 (0.2%)
IMMUNOSUPPRESSANTS	2 (0.7%)	1 (0.4%)	3 (0.5%)
IMMUNOSUPPRESSANTS	2 (0.7%)	0	2 (0.4%)
IMMUNOTHERAPY	2 (0.7%)	0	2 (0.4%)
OTHER IMMUNOSUPPRESSANTS	0	1 (0.4%)	1 (0.2%)
METHOTREXATE	0	1 (0.4%)	1 (0.2%)
OPHTHALMOLOGICALS	1 (0.4%)	0	1 (0.2%)
ANTIVIRALS	1 (0.4%)	0	1 (0.2%)
TRIFLURIDINE	1 (0.4%)	0	1 (0.2%)
VARIOUS	4 (1.4%)	17 (6.0%)	21 (3.7%)
VARIOUS	4 (1.4%)	17 (6.0%)	21 (3.7%)
RADIOTHERAPY	4 (1.4%)	17 (6.0%)	21 (3.7%)

Number of subjects and percentage of subjects (%) are shown.
Sorting order: alphabetical order by Therapeutic Subgroup and Chemical Subgroup and Preferred WHO Name (Ingredients). Ingredients are the list of active ingredients for combination drugs.
Arm A = Zolbetuximab + mFOLFOX6, Arm B = Placebo + mFOLFOX6.
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